

**WHO Prequalification of In Vitro Diagnostics  
PUBLIC REPORT  
Product: Aquios CL flow cytometer  
WHO Reference Number: PQDx 0156-053-00**

**Aquios CL flow cytometer** with the product codes B23536, B23538, B23533 and B23534 manufactured by **Beckman Coulter Life Sciences, CE marked regulatory version**, was accepted for the WHO list of prequalified in vitro diagnostics, and was listed on 3 November 2015.

**Summary of prequalification status for AQUIOS CL flow cytometer**

	Date	Outcome
<b>Prequalification listing</b>	6-Nov-2015	listed
<b>Dossier assessment</b>	29-May-2015	MR
<b>Site inspection(s) of quality management system</b>	25-Mar-2015	MR
<b>Product performance evaluation</b>	29-Sep-2015	MR

MR: Meets Requirements

**Report amendments and/or product changes**

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of amendment	Date of report amendment
2.0	Software update to address possible positioning errors that could lead to a potential risk of probe bending),	9-Nov-2015
3.0	Upgrade the Operating System of the AQUIOS CL workstation from Microsoft Windows 7 to Microsoft Windows 10 and add cybersecurity components. 2. Adding Optional Signal Light Information. 3. A Signal Light Information System was implemented to provide the customer with a visual indication of instrument status visible from a distance.	11-Nov-2021

	<p>4. Labelling Updates.</p> <p>5. Labelling has been updated to include information that addresses the cybersecurity features in the Windows 10 Operating System.</p> <p>6. The AQUIOS CL Instructions for Use (IFU) were updated to include wording to clarify when maintenance should be performed.</p> <p>7. An addendum was generated to address the signal light information system.</p>	
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#### **Intended use:**

According to the claim of intended use from Beckman Coulter Life Sciences, “ *the AQUIOS CL Flow Cytometer is intended for use with in vitro diagnostic flow cytometric applications using up to four fluorescent detection channels using a blue (488 nm) laser, two light scatter detection channels and electronic volume (EV). AQUIOS Flow Cytometry Software may be run on an independent computer workstation for off-line analysis of results generated by the AQUIOS CL Flow Cytometer with its monoclonal antibody reagents. The off-line analysis must be performed in accordance with the product labeling.*

*This product is intended for laboratory professional use.”*

#### **Assay principle:**

According to the claim of assay description from Beckman Coulter Life Sciences, “*the Aquios system can be operated using up to 40 samples at start-up with the ability to add 5-tube cassettes as testing proceeds. The tube(s) are loaded into the instrument cassette which is further loaded on the system including the Tetra-1 Panel. Whole blood is incubated with AQUIOS Tetra-1 Panel monoclonal antibody reagents which contains a combination of four murine monoclonal antibodies, (CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5). Each monoclonal antibody is conjugated to a specific fluorochrome and specific for different cell surface antigens. Red blood cells are lysed with the AQUIOS Lysing Reagent Kit. The remaining white blood cells are analyzed by flow cytometry using lymphocyte gates. The AQUIOS System Software with AQUIOS Tetra-1 Panel monoclonal antibody reagents provides automated analysis of lymphocyte subpopulations including total CD3+, CD3+CD4+, CD3+CD8+, CD3+CD4+/CD3+CD8+ (ratio only) lymphocyte percentages and absolute counts. In addition, CD45+ absolute count CD45+ Low SS (lymphocytes) percentage and absolute count.”*



**Test kit contents**

Component name	Product code	Quantity	Description
AQUIOS Sodium Hypochlorite Solution	B23536	4 X 50ml	A cleaning agent that is used during cleaning cycles to counteract protein build-up that occurs in tubing and the flow cell.
AQUIOS Lysing Reagent Kit	B23538	1 x 38ml 1 x 15ml (100 tests)	A cyanide-free lytic reagent that lyses red blood cells to allow enumeration of white blood cells.
AQUIOS Tetra-1 Panel	B23533	1 x 0.9ml (50 tests)	Reagent panel that employs monoclonal antibodies: CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5.
<i>AQUIOS Tetra-2+ Panel</i>	<i>B23534</i>	<i>1 x 0.9ml (50 tests)</i>	<i>Reagent panel that employs monoclonal antibodies: CD45-FITC/CD56-RD1+CD16-RD1/CD19-ECD/CD3-PC5. Note: this reagent was not reviewed as part of this prequalification assessment</i>

**Materials required but not provided:****The system instrument:**

Product name	Product code	Description
AQUIOS CL flow cytometer	B30166	Flow cytometry instrument
AQUIOS CL with UPS for 110v, AQUIOS Workstation and Software, Supply Cart	B39101	(1) flow cytometry instrument; (2) uninterruptible power supply for 110v (B37943); (3) all-in-one computer with touch-screen monitor, wireless mouse, wireless keyboard; (4) vacuum pump module, vacuum trap bottle, sheath filter and sheath pump, and holds the AQUIOS Sheath Solution

		Cubitainer, and waste container
AQUIOS CL with UPS for 220v, AQUIOS Workstation and software, Supply Cart	B39102	(1) flow cytometry instrument; (2) uninterruptible power supply for 220v (B37954), cable assembly (6009252), interconnect cables (B43588) (3) all-in-one computer with touch-screen monitor, wireless mouse, wireless keyboard; (4) vacuum pump module, vacuum trap bottle, sheath filter and sheath pump, and holds the AQUIOS Sheath Solution Cubitainer, and waste container

### The system consumables:

Product name	Product code	Quantity	Description
AQUIOS Sheath Solution	B25697	1 x 10L	A non-fluorescent, azide-free balanced electrolyte solution for use on AQUIOS CL flow cytometer with light scatter and fluorescent applications.
AQUIOS Cleaning Agent	B25698	1 x 500ml	This azide-free, formaldehyde-free, biodegradable cleaner contains a proteolytic enzyme that aids in the removal of protein build-up in the fluidics system and flow cell of a flow cytometer.
AQUIOS IMMUNO-TROL Cells	B23535	2 X 3mL	An integrated control that enables monitoring of system performance for all directly measured and calculated parameters.
AQUIOS IMMUNO-TROL LOW Cells	B25700	2 X 3mL	An integrated control that enables monitoring of system performance for all directly measured and calculated parameters.
AQUIOS Deep Well Plates	B23502	50 plates/box	Reservoirs for specimen preparation.

**Accessories used as part of the system:**

Accessories part	Product code	Quantity	Provided/not provided with the instrument
Type 1 Cassette (13 x 75mm)	B25218	2	Provided (additional available for order)
Type 2 Cassette (13 x 100mm)	B25219	1	Provided (additional available for order)
Type 3 Cassette (16 x 100mm)	B25220	1	Provided (additional available for order)
Type 4 Cassette (10.25 x 50mm)	B25221	2	Provided (additional available for order)
Type 5 Cassette (Immuno-Trol)	B25318	2	Provided (additional available for order)
Type 6 Cassette (Sarstedt 13 x 75mm)	B25918	2	Provided (additional available for order)
Type 7 Cassette (Sarstedt 13 x 90mm)	B52994	1	Not provided
Type 8 Cassette (Sarstedt 11 x 66mm)	B53022	1	Not provided
Type 9 Cassette (Sarstedt 15 x 92mm)	B53031	1	Not provided
Type 10 Cassette (Sarstedt 13 x 65mm)	B53808	1	Not provided
Color Laser Printer	B31892	1	Not provided
4mL Round Bottom Test Tubes	B42830	25	Provided
Gravimetric Bottle	B42831	2	Provided
40 Test Tube Rack	178696	1	Provided

**Storage conditions:**

Product name	Product code	Temperature °C
AQUIOS CL Flow Cytometer	B30166	N/A
AQUIOS Sheath Solution	B25697	18 - 26°C
AQUIOS Cleaning Agent	B25698	18 - 26°C
AQUIOS Sodium Hypochlorite Solution	B23536	18 - 26°C
AQUIOS Lysing Reagent Kit	B23538	18 - 26°C
AQUIOS Tetra-1 Panel	B23533	2 - 8°C
AQUIOS Tetra-2+ Panel	B23534	2 - 8°C
AQUIOS IMMUNO-TROL Cells	B23535	2 - 8°C
AQUIOS IMMUNO-TROL LOW Cells	B25700	2 - 8°C
AQUIOS Deep Well Plates	B23502	N/A

**Shelf-life:**

Product name	Product code	Shelf life
AQUIOS CL Flow Cytometer	B30166	N/A
AQUIOS Sheath Solution	B25697	18 months
AQUIOS Cleaning Agent	B25698	12 months
AQUIOS Sodium Hypochlorite Solution	B23536	12 months
AQUIOS Lysing Reagent Kit	B23538	350 days
AQUIOS Tetra-1 Panel	B23533	12 months
AQUIOS Tetra-2+ Panel	B23534	12 months
AQUIOS IMMUNO-TROL Cells	B23535	270 days
AQUIOS IMMUNO-TROL LOW Cells	B25700	270 days
AQUIOS Deep Well Plates	B23502	N/A

**Limitation:**

Users may receive system notifications of “potential specimen or gating issue” that may require intervention and technical expertise to review the results before release. Notifications alert the operator that there may be a potential anomaly with the specimen result produced. Therefore it should be reviewed especially for the presentation of the cellular populations and the gating accomplished by the instrument, to verify that there are no additional changes needed, prior to releasing the result. In this prequalification assessment, the frequency of such notifications which required user intervention was up to 30% of all specimens tested at one of two sites.

**Prioritization for prequalification**

Beckman Coulter Life Sciences submitted an application for prequalification of AQUIOS CL flow cytometer. Based on the established prioritization criteria, AQUIOS CL flow cytometer was given priority for prequalification assessment.

**Dossier assessment**

Beckman Coulter Life Sciences submitted a product dossier for AQUIOS CL flow cytometer as per the Instructions for compilation of a product dossier (PQDx\_018 v1). The information submitted in the product dossier was reviewed by WHO staff and external experts (assessors) appointed by WHO in accordance with the internal report on the screening and assessment of a product dossier (PQDx\_009 v2). Based on the product

dossier screening and assessment findings, a recommendation was made to accept the product dossier for AQUIOS CL flow cytometer for prequalification.

## Manufacturing site inspection

A comprehensive inspection was performed at the site of manufacture (11800 SW 147 Ave, Miami, FL, USA (instrument site) and 740 W 83 Street, Hialeah, FL, USA (reagent site) of AQUIOS CL flow cytometer in February 2015 as per the Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics (PQDx\_014 v1). The inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality. The manufacturer's responses to the nonconformities found at the time of the inspection were accepted 25 March 2015.

## Product performance evaluation

Aquios CL together with AQUIOS Tetra-1 Panel (CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC) and Aquios Immuno-Trol and Aquios Immuno-Trol low controls were evaluated in two WHO collaborating laboratories; namely Institute of Tropical Medicine (ITM), Antwerp, Belgium and Centres for Disease Control and Prevention, Atlanta, GA, USA (CDC) between March and July 2015. The evaluation was conducted using the WHO evaluation protocol "Protocol for multicenter laboratory assessment of dedicated and point-of-care CD4+ T-lymphocytes enumeration technologies" (SOP\_PQDx\_114) which was also approved by in-country ethical review boards in Belgium and USA.

Aquios CL together with AQUIOS Tetra-1 Panel (CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC) and Aquios Immuno-Trol/Immuno-Trol low controls are a bench-top automated flow cytometric system intended for enumeration of CD3+, CD3+CD4+, CD3+CD8+, and CD3+CD4+/CD3+CD8+ (ratio only). 100 µl of well mixed venous whole blood and AQUIOS™ Tetra-1 Panel reagents are required to perform the assays and the results are obtained after 15 minutes incubation.

A total of 537 venous whole blood specimens were used study failure rate, reproducibility (intra-laboratory variation and inter-assay), carry over and agreement with the FACSCalibur as the reference method. Lastly, ease to use was assessed.

The acceptance criteria for reproducibility studies was that the assay should have the a percentage coefficient of variation (%CV) less than 15% for CD4<sup>+</sup> T counts less than or equal to 200/µL and less than 10% for CD4 counts more than 200 cells/µL, while the carry-over constant (k) should be less than 2.0%.

Consecutive routine venous whole blood specimens collected in EDTA vacutainer tubes with at least 3.0 ml of blood were used to compare Aquios CL together with AQUIOS Tetra-1 Panel against FACSCalibur as the reference method. Agreement between the dedicated and the reference method was assessed using the regression analysis, Bland Altman plots and/or Scott percentage.

The failure rate was 1.54% and 6.1% in laboratory 1 and 2 respectively. The mean intra-laboratory variability was 4.1 % for CD4 absolute count and 3.1 % for CD4% at ITM. While at CDC, it was 4.9% and 2.3% for CD4 counts and CD4% respectively. The average inter-assay variability was 4.2% and 1.6% for CD4 counts and CD4% respectively at ITM while at CDC laboratory it was 5.7% and 2.1% for CD4 counts and CD4% respectively. The mean carry-over was less than 2% in both laboratories. The observed bias was always within the optimal limits proposed by WHO and the misclassification was less than 3.8% at 350 and 500 CD4/ml levels.

Aquios CL is globally easy to use. However, the frequency of notifications of “potential specimen or gating issue” required user intervention for up to 30% of all specimens tested in this evaluation. The manufacturer was informed of this finding.

## **Labelling**

- 1. Labels**
- 2. Instructions for use**

## **1. Labels**





Manufactured for  
Beckman Coulter Ireland Inc.  
Lismeehan  
O'Callaghan's Mills  
Co. Clare, Ireland 353 (0)65 683 1100

製造販売元: ベクマン・コールター株式会社  
東京都江東区有明三丁目5番7号  
TOC有明ウエストタワー

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Made in USA

B28994-AA

HOLD AREA for  
Barcode, Lot and  
Exp. symbols  
1-1/8" x 2-1/2"

IVD / 体外診断用医薬品

REF B23538

### AQUIOS Lysing Reagent Kit

ライズ試薬キット

1 x 38 mL Reagent A  
1 x 15 mL Reagent B

Intended for preparation of leukocytes from whole blood for flow cytometry/Diseñado en la preparación de leucocitos de sangre total para citometría de flujo / Предназначено для приготовления лейкоцитов из цельной крови для проточной цитометрии/ Akış sitometrisi için tüm kandan lökosit hazırlama amacını taşır

Reactive Ingredients:

#### Reagent A

Saponin.....< 0.5 g/L  
Potassium  
pyro sulfate.....< 0.5 g/L

#### Reagent B

Sodium sulfate.....< 60 g/L  
Buffering Agent.....< 4 g/L



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Special Instructions: N/A

Description: CTN; AQUIOS GENERIC BCI BRANDING 2" X 1-3/4" X 3-3/16"  
LYSING KIT

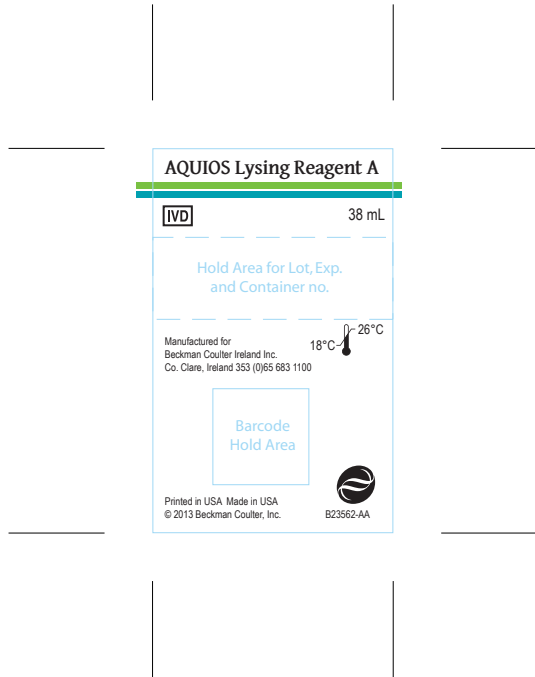
Ink Color(s): 100% Black, PMS 320C, PMS 368C

Part Number: B28994

Revision: AA

Label Size: 2" x 1-3/4" x 3-3/16"

Scale: 1 : 1



**Special Instructions:** Barcode size: 3/8" x 3/8"; Hold area size: 1/2" x 1/2"; Location: 5/16" from bottom, 3/8" from left edge.

**Description:** LBL; PRIM, AQUIOS LYSING REAGENT A

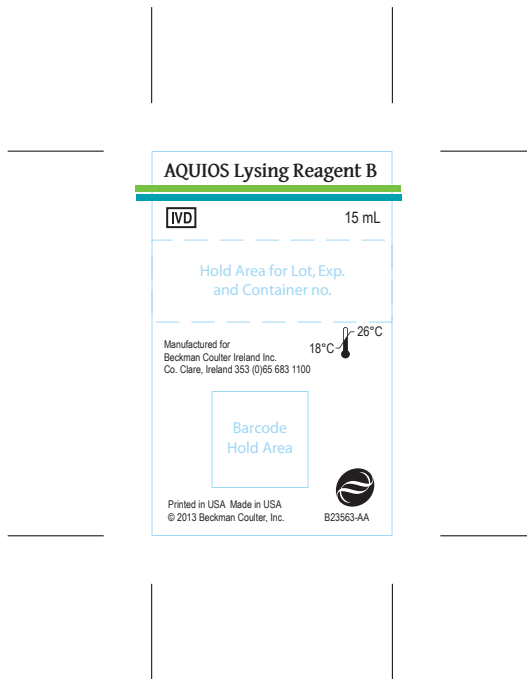
**Ink Color(s):** 100% Black, PMS 368C, PMS 320C

**Part Number:** B23562

**Revision:** AA

**Label Size:** 1-1/4" x 2"

**Scale:** 1 : 1



<b>Special Instructions: Barcode size: 3/8" x 3/8"; Hold area size: 1/2" x 1/2"; Location: 5/16" from bottom, 3/8" from left edge.</b>			
<b>Description: LBL; PRIM, AQUIOS LYSING REAGENT B</b>		<b>Ink Color(s): 100% Black, PMS 368C, PMS 320C</b>	
<b>Part Number: B23563</b>	<b>Revision: AA</b>	<b>Label Size: 2" x 1-1/4"</b>	<b>Scale: 1 : 1</b>

**LOT**



**AQUIOS IMMUNO-TROL Low Cells**

**EUH208**

**Printed in USA**

**Made in USA**

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**B23565-AB**

<b>Special Instructions: Reduce 50%, REFERENCE BASE LABEL: B29137</b>			
<b>Description: LBL; PRI TEM, AQUIOS IMMUNO-TROL LOW CELLS</b>		<b>Ink Color(s): N/A</b>	
<b>Part Number: B23565</b>	<b>Revision:AB</b>	<b>Label Size: 1-3/8" x 1-5/8"</b>	<b>Scale: 2:1</b>

**LOT**



**AQUIOS IMMUNO-TROL Cells**

**EUH208**

**Printed in USA**

**Made in USA**

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**B23566-AB**

<b>Special Instructions: Reduce 50%, REFERENCE BASE LABEL: B29137</b>			
<b>Description: LBL; PRI TEM, AQUIOS IMMUNO-TROL CELLS</b>		<b>Ink Color(s): N/A</b>	
<b>Part Number: B23566</b>	<b>Revision:AB</b>	<b>Label Size: 1-3/8" x 1-5/8"</b>	<b>Scale: 2:1</b>

**AQUIOS**

**REF** B23535

**IMMUNO-TROL Cells**

Contents: 2 x 3 mL, Package Insert/ Notice/  
Foglio illustrativo/ Gebrauchsinformation/  
Prospecto/ Folheto informativo/  
Pakkeindlæg/ Bipacksedel/ Priložená  
informace/ Ulotka w opakowaniu/  
Листок-вкладыш в упаковке/ Ambalaj  
Prospektüsü/ Pakkavedlegg/ Pakendi infoleht/  
Pakiranje je umetnuto/ Pribalový leták/  
添付文書

Neomycin Sulfate <0.1%,  
Penicillin-G, sodium salt <0.1%  
EUH208



Reactive Ingredients: Stabilized Human  
Erythrocyte and Leukocyte Preparation 2 x 3  
mL/成分：安定ヒト赤血球および  
白血球製剤 2本 各3mL

B23567-AB



<b>Special Instructions: N/A</b>			
<b>Description: LBL; SEC TEM, AQUIOS IMMUNO-TROL KIT</b>		<b>Ink Color(s): 100% Black</b>	
<b>Part Number: B23567</b>	<b>Revision: AB</b>	<b>Label Size: 2-6/8" x 2-6/8"</b>	<b>Scale: 1:1</b>

**AQUIOS Sodium Hypochlorite Solution**

**IVD**

**50 mL**

Hold Area for Lot and Exp



**DANGER**  
H314, 401

Manufactured for  
Beckman Coulter Ireland Inc.  
Co. Clare, Ireland 353 (0)65 683 1100

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B23568-AB



**Special Instructions: N/A**

**Description: LBL; PRIM, AQUIOS SODIUM HYPOCHLORITE**

**Ink Color(s): 100% Black, PMS 368C, PMS 320C, PMS 186C**

**Part Number: B23568**

**Revision: AB**

**ze: 2" x 2-3/4"**

**Scale: 1 : 1**

# AQUIOS Cleaning Agent

REF B25698 500 mL

**IVD**

**SDS**

For use as a cleaning agent for AQUIOS flow cytometer components that come in contact with blood samples / Para uso como agente limpiador de componentes del citómetro de flujo de AQUIOS que entran en contacto con las muestras de sangre / Используется в качестве очистителя компонентов AQUIOS проточного цитометра, которые пребывают в контакте с образцами крови / Kan örnekleleriyle temas eden AQUIOS akış sitometresi bileşenleri için temizleme ajanı olarak kullanılır.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

Avoid breathing vapours.

In case of inadequate ventilation, wear respiratory protection.

IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.

If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Wear protective gloves, protective clothing and eye/face protection.

Take off contaminated clothing and wash it before use.

**REACTIVE INGREDIENTS:** A solution of a proteolytic enzyme/

反応成分: 蛋白質分解酵素溶液

2D Barcode  
Hold Area  
DO NOT  
VARNISH

Beckman Coulter Ireland Inc.  
Lismeehan  
O'Callaghan's Mills  
Co. Clare, Ireland 353 (0)65 683 1100

製造販売元: ベックマン・コールター株式会社  
東京都江東区有明三丁目5番7号  
TOC有明ウエストタワー

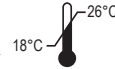
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**DANGER**

Subtilisin <1%

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) <0.05%



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B25694-AB

HOLD AREA for  
Lot, Exp, and  
Container ID.  
1-1/4" x 3"  
DO NOT VARNISH

<b>Special Instructions: Barcode size 3/8" x 3/8", location not critical</b>			
<b>Description: AQUIOS Cleaning Agent, Secondary Label</b>		<b>Ink Color(s): 100% Black, PMS 320C, PMS 368C, PMS 186C</b>	
<b>Part Number: B25694</b>	<b>Revision: AB</b>	<b>Label Size: 5-1/4" x 3"</b>	<b>Scale: 1 : 1</b>

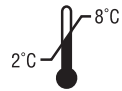


**IVD**

Intended as an assayed, lysable whole blood quality control product for immunophenotyping analysis using monoclonal antibody reagents for flow cytometry. / Para uso como control de calidad analizado a base de sangre total lisable para análisis de inmunofenotipificación utilizando reactivos de anticuerpos monoclonales para citometría de flujo. / Анализированный и лизированный контроль из цельной крови, предназначенный для определения иммунофенотипа с помощью реагентов, содержащих моноклональные антитела, для проточной цитометрии. / Akış sitometresi için monoklonal antikor reaktifler kullanan immunofenotiplendirme analizi için test edilmiş ve lizabl tam kan kalitesi kontrol ürünü olarak tasarlanmıştır.



Potential Biohazardous Material  
生物学的汚染に対する注意



**SDS**



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Co. Clare, Ireland 353 (0)65 683 1100

製造販売元: ベックマン・コールター株式会社  
東京都江東区有明三丁目5番7号  
TOC有明ウエストタワー



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B28990-AB

2-3/4" x 2-3/4"  
Sec Label Area

**Special Instructions: None**

**Description:** Carton, Preprint, AQUIOS IMMUNO-TROL Cells and AQUIOS IMMUNO-TROL Low Cells and AQUIOS IMMUNO-TROL Cells (PLG/Tetra) and AQUIOS IMMUNO-TROL Low Cells (PLG/Tetra)

**Ink Color(s):** 100% Black, PMS 320C, PMS 368C

**Part Number:** B28990

**Revision:** AB

**Label Size:** 3-15/16" x 1-9/32" x 4-9/16"

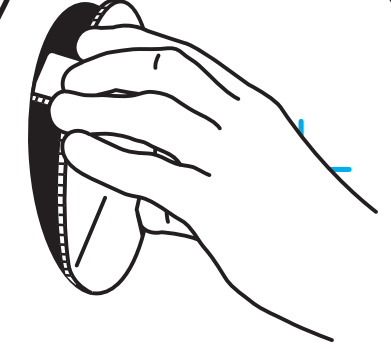
**Scale:** 1 : 1



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ベックマン・コールター株式会社



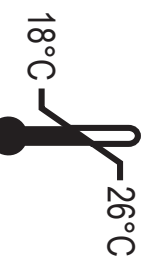
IVD / 体外診断用医薬品

10 L

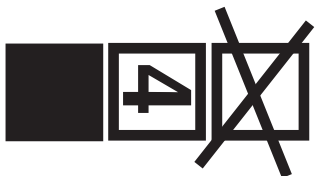
AQUIOS

Sheath Solution

シース液



Hold area for Barcode,  
Lot & Exp.  
4" X 4"



**INTENDED USE:** A non-fluorescent, balanced electrolyte solution for use on AQUIOS Flow Cytometers with light scatter and fluorescent applications. / **APLICACION:** Una solución electrolítica balanceada, no fluorescente para uso en los Citoímetros de Flujo AQUIOS con aplicaciones de dispersión de luz y fluorescentes. / **ПРЕДНАЗНАЧЕНИЕ:** Нефлуоресцирующая балансирующая раствор электролита, предназначенный для использования в проточных цитометрах типа AQUIOS с рассеиванием света и флуоресценцией. / **КОЛЛАТИМ АМАС:** İsk sergilli ve floresan uygulamalı AQUIOS Akış Sitometrelerinde kullanılmaya atılmış taşıyıcı, floresan olmayan dengeli bir elektrolit çözeltisidir.

**REACTIVE INGREDIENTS/ 成分:**  
Sodium Chloride/ 塩化ナトリウム ..... 7.93 g/L  
Disodium EDTA/ ニナトリウムEDTA ..... 0.38 g/L  
Potassium Chloride/ 塩化カリウム ..... 0.40 g/L  
Monosodium Phosphate/ ナトリウムリンリン酸塩 ..... 0.19 g/L  
Disodium Phosphate/ ニナトリウムリンリン酸塩 ..... 1.55 g/L  
Sodium Fluoride/ フッ化ナトリウム ..... 0.30 g/L

B28991-AA



製造販売元: ベックマン・コールター株式会社  
東京都江東区有明三丁目5番7号  
TCC有明ウエスタタワー

Beckman Coulter Ireland Inc.  
Lismeehan  
O'Callaghan's Mills  
Co. Clare, Ireland 353 (0)65 683 1100

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Hold area for Barcode,  
Lot & Exp.  
4" X 4"

AQUIOS  
Sheath Solution  
シース液

REF B25697

AQUIOS Sheath Solution  
シース液

REF B25697

THIS BOX IS FOR TECH COMM INFORMATIONAL USE ONLY. Refer to "4print.zip" file for all printing specifications.

Special Instructions: Overlay of colors resulting in new colors is acceptable.

Description: AQUIOS SHEATH SOLUTION

Ink Color(s): GCMI #90, GCMI #387, GCMI #2081

Page 19 of 40  
Part Number: B28991

Revision: AA

Label Size: N/A

Scale: 1 : 1



**IVD / 体外診断用医薬品**

For Use In Flow Cytometric Analysis/Para uso en análisis por citometría de flujo/Для использования в проточном цитометрическом анализе/Akış Sitometrisi Analizinde Kullanmak İçindir

Reactive Ingredient: Murine Monoclonal Antibody 0.9 mL  
成分：マウスモノクローナル抗体 0.9 mL

SDS



製造販売元: ベックマン・コールター株式会社  
東京都江東区有明三丁目5番7号  
TOC有明ウエストタワー



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Co. Clare, Ireland 353 (0)65 683 1100

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B28992-AB

HOLD AREA FOR LABEL  
3" x 2-1/2"

Special Instructions: N/A

Description: CTN; AQUIOS GENERIC BRANDING 2" X 1-1/4" X 2-3/4"

Ink Color(s): 100% Black, PMS 320C, PMS 368C

Part Number: B28992

Revision: AB

Label Size: 2" x 1-1/4" x 2-3/4"

Scale: 1 : 1



Manufactured for  
Beckman Coulter Ireland Inc.  
Lismeehan  
O'Callaghan's Mills  
Co. Clare, Ireland 353 (0)65 683 1100

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東京都江東区有明三丁目5番7号  
TOC有明ウエストタワー

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B28993-AB

Printed in USA  
Made in USA

HOLD AREA for  
Barcode, Lot and  
Exp.

IVD / 体外診断用医薬品

REF B23536

**AQUIOS Sodium Hypochlorite Solution**

4 x 50 mL

次亜塩素酸ナトリウム溶液

AQUIOS Sodium Hypochlorite Solution is a cleaning agent used with AQUIOS flow cytometers. The solution maintains instruments in optimal condition. / La solución de hipoclorito de sodio AQUIOS es un agente de limpieza utilizado con los citómetros de flujo AQUIOS. La solución mantiene el instrumento en óptimo estado. / Раствор гипохлорита натрия AQUIOS является очищающим средством, которое используется для проточных цитометров AQUIOS. Раствор поддерживает работоспособность приборов в оптимальных условиях. / AQUIOS Sodyum Hipoklorit Solüsyonu AQUIOS akış sitometreleriyle kullanılan bir temizlik ajanıdır. Solüsyon aletleri optimum durumda tutar.

Reactive Ingredients:  
Sodium Hypochlorite 5.25%  
Surfactant

SDS

成分: 次亜塩素酸ナトリウム 5.25%  
界面活性剤









**DANGER**  
H314, 401  
Sodium Hypochlorite 1-10%








www.beckmancoulter.com/ifu

Special Instructions: N/A			
Description: CTN; AQUIOS GENERIC BRANDING 4-3/16" x 2-3/16" x 4-3/8" SODIUM HYPOCHLORITE		Ink Color(s): 100% Black, PMS 320C, PMS 368C, PMS 186C	
Part Number: B28993	Revision: AB	Label Size: 4-3/16" x 2-3/16" x 4-3/8"	Scale: 1 : 1


	<b>AQUIOS Tetra-1 Panel</b>  B23533	
		<b>50 Tests</b>
CD45-FITC CD4-RD1 CD8-ECD CD3-PC5		
Content: 1 x 0.9 mL, cap/ bouchon/ cappuccio/ Deckel/ tapón/ tampa/ hætte/ lock/ krytka/ zatyczka/ крышка/ kapak/ hette/ キャップ/ krytka/ kapica/ kaas.		
	Printed in USA Made in USA © 2014 Beckman Coulter, Inc. B28995-AB	
		
		Iodoacetamide <0.1%
		

<b>Special Instructions: N/A</b>			
<b>Description:</b> LBL; SEC TEM, AQUIOS TETRA-1 KIT		<b>Ink Color(s): 100% Black</b>	
<b>Part Number:</b> B28995	<b>Revision:</b> AB	<b>Label Size:</b> 2-3/8" x 2-7/8"	<b>Scale:</b> 1:1



	<b>AQUIOS Tetra-2+ Panel</b> <span style="border: 1px solid black; padding: 0 2px;">REF</span> B23534
	<b>50 Tests</b>
CD45-FITC (CD56+CD16)-RD1 CD19-ECD CD3-PC5	
Content: 1 x 0.9 mL, cap/ bouchon/ cappuccio/ Deckel/ tapón/ tampa/ hætte/ lock/ krytka/ zatyczka/ крышка/ kapak/ hette/ キャップ/ krytka/ kapica/ kaas.	
	Printed in USA Made in USA © 2014 Beckman Coulter, Inc. B29060-AB
	
EUH208 Iodoacetamide <0.1%	
	

<b>Special Instructions: N/A</b>			
<b>Description:</b> LBL; SEC TEM, AQUIOS TETRA-2+ KIT		<b>Ink Color(s):</b> 100% Black	
<b>Part Number:</b> B29060	<b>Revision:</b> AB	<b>Label Size:</b> 2-3/8" x 2-7/8"	<b>Scale:</b> 1:1

LOT	
	



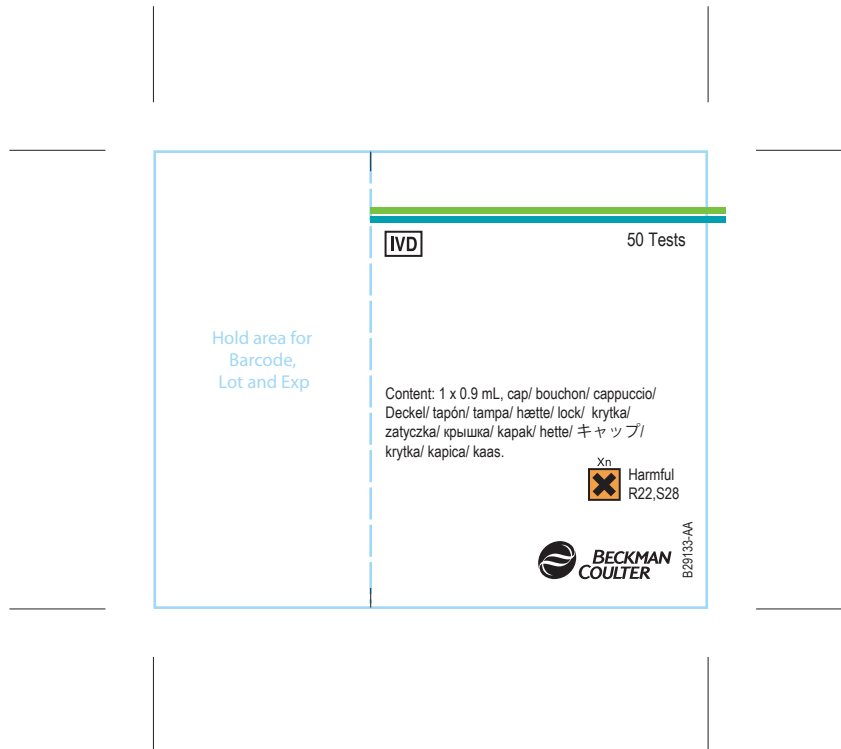
**IMPORTANT:** The Expiration date is displayed above as YYYY-MM-DD. If entering the Lot and Expiration information manually, the expiration date must be entered in the software in the following format: MM/DD/YYYY.

**Assay Values\***

Phenotype Result	Min	Max	Mean	Separation	Range (MIN - MAX)
CD3+/CD4+ Percent Lymphs				CD3	
CD3+/CD4+ Count/μL				CD4	
CD3+/CD8+ Percent Lymphs				CD8	
CD3+/CD8+ Count/μL				CD56/16	
CD3+ Percent Lymphs				CD19	
CD3+ Count/μL				CD45 Lymph/High SS Cells	
CD3-/CD56+CD16+ Percent Lymphs				SS Lymph/High SS Cells	
CD3-/CD56+CD16+ Count/μL				FS Lymph/High SS Cells	
CD3-/CD19+ Percent Lymphs					
CD3-/CD19+ Count/μL					
CD45+ Low SS Percent					
CD45+ Low SS Count/μL					
CD45+ Count/μL					

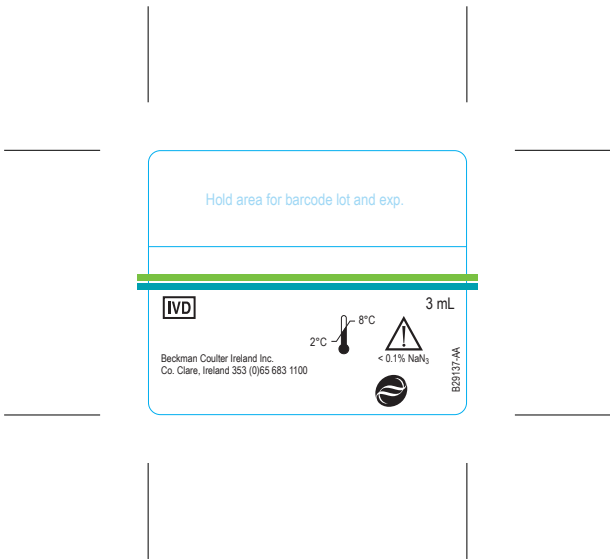
\*Do not use beyond expiration date.  
 Note: In case of manual entry values must be entered as shown.

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<b>Special Instructions:</b> Barcode size 2-3/8 x 1-1/8; Hold area location: Left edge; Label folds at barcode hold area.			
<b>Description:</b> LBL; SEC, AQUIOS Tetra KIT Base Label		<b>Ink Color(s):</b> 100% Black, PMS 368C, PMS 320C, PMS 150C	
<b>Part Number:</b> B29133	<b>Revision:</b> AA	<b>Label Size:</b> 2-3/8" x 2-7/8"	<b>Scale:</b> 1 : 1





<b>Special Instructions:</b>			
<b>Description:</b> AQUIOS IMMUNO-TROL Primary Base Label		<b>Ink Color(s):</b> 100% Black, PMS 368C, PMS 320C	
<b>Part Number:</b> B29137	<b>Revision:</b> AA	<b>Label Size:</b> 1-21/32" x 1-3/8"	<b>Scale:</b> 1 : 1

**AQUIOS** REF B25700  
**IMMUNO-TROL Low Cells**

Contents: 2 x 3 mL, Package Insert/ Notice/  
Foglietto illustrativo/ Gebrauchsinformation/  
Prospecto/ Folhetos informativos/  
Pakkeindlæg/ Bipačksedēl/ Příloženē  
informace/ Ulotka w opakowaniu/  
Листок-вкладыш в упаковке/ Ambalaj  
Prospektüsü/ Pakkevedlegg/ Pakendi infoleht/  
Pakiranje je umolnuto/ Pribalový leták/  
添付文書

Neomycin Sulfate <0.1%,  
Penicillin-G, sodium salt <0.1%  
EUH208

Reactive Ingredients: Stabilized Human  
Erythrocyte and Leukocyte Preparation 2 x 3  
mL/成分：安定ヒト赤血球および  
白血球製剤 2本 各3mL



B29140-AB



<b>Special Instructions: N/A</b>			
<b>Description: LBL; SEC TEM, AQUIOS IMMUNO-TROL LOW KIT</b>		<b>Ink Color(s): 100% Black</b>	
<b>Part Number: B29140</b>	<b>Revision: AB</b>	<b>Label Size: 2-6/8" x 2-6/8"</b>	<b>Scale: 1:1</b>

<b>LOT</b>	
	



**IMPORTANT:** The Expiration date is displayed above as YYYY-MM-DD. If entering the Lot and Expiration information manually, the expiration date must be entered in the software in the following format: MM/DD/YYYY.

**Assay Values\***

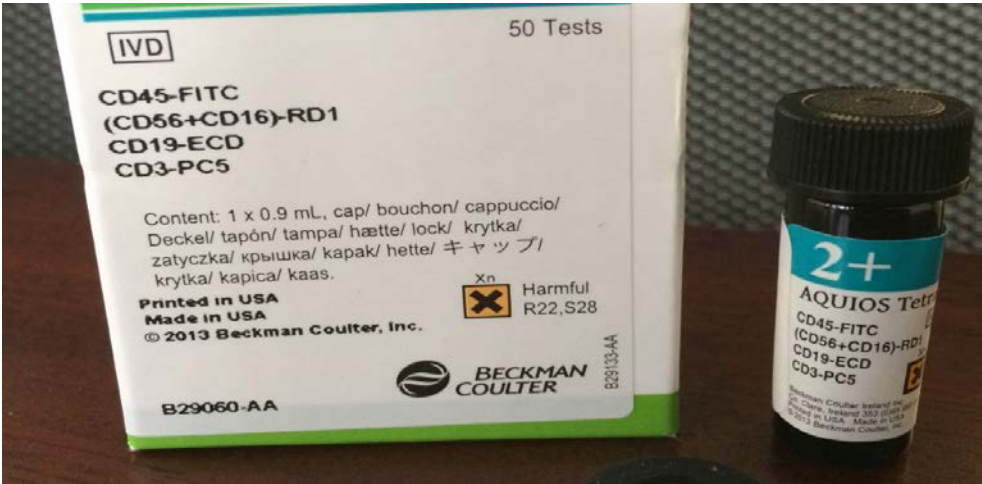
Phenotype Result	Min	Max	Mean	Separation	Range (MIN - MAX)
CD3+/CD4+ Percent Lymphs				CD3	
CD3+/CD4+ Count/μL				CD4	
CD3+/CD8+ Percent Lymphs				CD8	
CD3+/CD8+ Count/μL				CD56/16	
CD3+ Percent Lymphs				CD19	
CD3+ Count/μL				CD45 Lymph/High SS Cells	
CD3-/CD56+CD16+ Percent Lymphs				SS Lymph/High SS Cells	
CD3-/CD56+CD16+ Count/μL				FS Lymph/High SS Cells	
CD3-/CD19+ Percent Lymphs					
CD3-/CD19+ Count/μL					
CD45+ Low SS Percent					
CD45+ Low SS Count/μL					
CD45+ Count/μL					

\*Do not use beyond expiration date.

Note: In case of manual entry values must be entered as shown.

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AQUIOS Tetra-2+ Panel



# AQUIOS Tetra-1 Panel



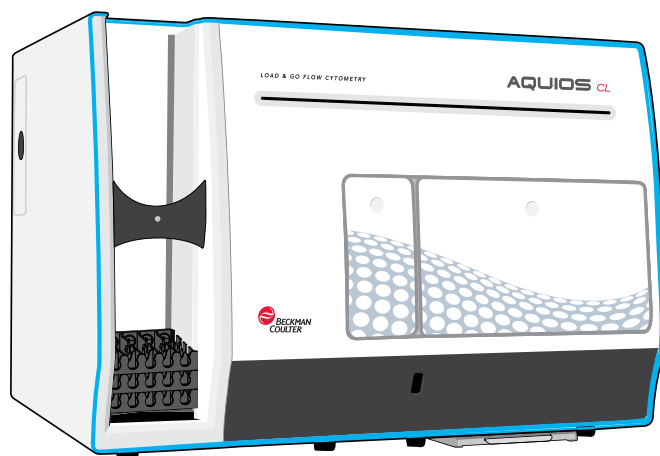
## 2. Instructions for use<sup>1</sup>

---

<sup>1</sup> English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

# Instructions For Use

## **AQUIOS CL Flow Cytometer** **Rx Only in the U.S.A.**



PN B21896AH  
July 2020



Beckman Coulter Ireland Inc.  
Lismeehan  
O'Callaghan's Mills  
Co. Clare, Ireland 353-65-683-1100



## **AQUIOS CL Flow Cytometer**

PN B21896AH (July 2020)

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### **Contact Us**

If you have any questions, contact our Customer Support Center.

- Worldwide, find us via our website at [www.beckman.com/support/technical](http://www.beckman.com/support/technical).
- In the USA and Canada, call us at 1-800-369-0333.
- Outside of the USA and Canada, contact your local Beckman Coulter Representative.

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

The summary of safety and performance is located at [beckman.com/techdocs](http://beckman.com/techdocs).

Glossary of Symbols is available at [beckman.com/techdocs](http://beckman.com/techdocs) (PN C24689).

*May be covered by one or more pat. - see [www.beckman.com/patents](http://www.beckman.com/patents)*

Original Instructions



# Revision History

**Initial Issue, May 2014**

Software version 1.0

**Issue AB, April 2015**

Software version 2.0

Complete revision.

**Issue AC, November 2015**

Software version 2.0

Updates were made to the following sections: Safety Symbols.

**Issue AD, March 2016**

Software version 2.0

Minor formatting changes.

**Issue AE, April 2017**

Software version 2.0.1

Updates were made to the following sections:

**Safety and Notices****CHAPTER 4, Quality Control**

- Instrument Drift Tab

**CHAPTER 9, Troubleshooting**

- System Error Messages

**APPENDIX B, Installation**

- Location

**Issue AF, December 2017**

Software version 2.1.1

Updates were made to the following sections:

Safety Notice

**CHAPTER 4, Quality Control**

- Run QC Samples

**CHAPTER 9, Troubleshooting**

- System Error Messages

*This document applies to the latest software listed and higher versions. When a subsequent software version affects the information in this document, a new issue will be released to the Beckman Coulter Web site. For labeling updates, go to [www.beckman.com/techdocs](http://www.beckman.com/techdocs) and download the latest version of the manual or system help for your instrument.*

**Issue AG, September 2018**

Software version 2.1.1

Updates were made to the following sections:

**Introduction**

- Safety Symbols

**CHAPTER 1, System Overview**

- System Components
- Supply Cart

**CHAPTER 6, Data Review**

- Select Review Option for a Sample
- Load Regions and/or Patient Information
- Edit Regions and/or Patient Information

**CHAPTER 7, Shutdown**

- Shutdown

**CHAPTER 9, Troubleshooting**

- Caution/Warning Label and Locations
- Biohazard Label and Locations
- Power Up the System
- Power Down the System

**CHAPTER 11, Replacement Procedures**

- Replacing the Inline Waste Filter

**APPENDIX B, Installation**

- Power and Signal Cable Connections
- Fluidic and Pneumatic Tubing

**Issue AH, July 2020**

Software version 2.2

Updates were made to the following sections:

**Safety Notice**

- Alerts for Warning, Caution, Important, and Note

**Introduction**

- How to Use Your Manuals
- Safety Symbols

**CHAPTER 1, System Overview**

- Intended User
- System Components
- Workstation
- Consumables and Supplies
- Physical Specifications

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**CHAPTER 3, Daily Startup**

- Startup

**CHAPTER 5, Sample Processing**

- Add Test Request for a Patient Sample
- Running Samples Using the Autoloader
- Running a Sample Using the Single-tube Loader

**CHAPTER 8, Setup**

- Setup Screens
- System Setup Screen
- Test Settings
- LIS Setup Screen
- RMS (Windows 7 Only)
- Maintenance Screen

**CHAPTER 9, Troubleshooting**

- System Error Messages

**APPENDIX A, Software Screens**

- Main Screen

**APPENDIX B, Installation**

- Delivery Inspection
- Special Requirements
- System Connections

**APPENDIX F, Security Features****APPENDIX G, Software Observations**

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# Safety Notice

Read all product manuals and consult with Beckman Coulter-trained personnel before attempting to operate instrument. Do not attempt to perform any procedure before carefully reading all instructions. Always follow product labeling and manufacturer's recommendations. If in doubt as to how to proceed in any situation, contact your Beckman Coulter Representative.

Beckman Coulter, Inc. urges its customers and employees to comply with all national health and safety standards such as the use of barrier protection. This may include, but is not limited to, protective eyewear, gloves, and suitable laboratory attire when operating or maintaining this or any other automated laboratory analyzer.

## Alerts for Warning, Caution, Important, and Note

---

### **WARNING**

**WARNING** indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis.

### **CAUTION**

**CAUTION** indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis.

**IMPORTANT** IMPORTANT is used for comments that add value to the step or procedure being performed. Following the advice in the IMPORTANT adds benefit to the performance of a piece of equipment or to a process.

**NOTE** NOTE is used to call attention to notable information that should be followed during installation, use or maintenance of this equipment.

 **WARNING**

Risk of operator injury if:

- All doors, covers, and panels are not closed and secured in place prior to and during instrument operation.
- The integrity of safety interlocks and sensors is compromised.
- Instrument alarms and error messages are not acknowledged and acted upon.
- You contact moving parts.
- You mishandle broken parts.
- Doors, covers, and panels are not opened, closed, removed, and/or replaced with care.
- Improper tools are used for troubleshooting.

To avoid injury:

- Keep doors, covers, and panels closed and secured in place while the instrument is in use.
- Take full advantage of the safety features of the instrument. Do not defeat safety interlocks and sensors.
- Acknowledge and act upon instrument alarms and error messages.
- Keep away from moving parts.
- Report any broken parts to your Beckman Coulter Representative.
- Open/remove and close/replace doors, covers, and panels with care.
- Use the proper tools when troubleshooting.

 **CAUTION**

System integrity could be compromised and operational failures could occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
- You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.
- You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.
- You connect external devices such as thumb drives, external hard drives, and CD/DVDs. Ensure that all external devices are free from viruses before connecting.

 CAUTION

If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, contact your Beckman Coulter Representative.

 CAUTION

Risk of personal injury. Safety protection can be impaired if used in a manner not specified by the manufacturer. To avoid personal injury, use the instrument according to the manufacturer's instructions only.

WINDOWS 10

 CAUTION

The instrument workstation is vulnerable to malware, viruses, data corruption, and unauthorized instrument setting changes, or privacy breaches if unauthorized access is gained by malicious personnel. To reduce the risk of such events, only allow authorized laboratory personnel access to the instrument Workstation, and implement all security features outlined in [APPENDIX F, Security Features](#) on the workstation. Contact your institutional security department for assistance.

WINDOWS 7

 CAUTION

The instrument workstation is vulnerable to malware, viruses, and unauthorized access if connected to a network without using the PROService RMS hardware available from Beckman Coulter. To reduce the risk of data corruption, unauthorized instrument setting changes, or privacy breaches, only connect the instrument Workstation to a network via the PROService RMS hardware. [Contact us](#) to obtain PROService.

**Safety Notice**

Alerts for Warning, Caution, Important, and Note



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## Overview

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This introduction contains the following information:

- [How to Use Your Manuals](#)
- [About This Manual](#)
- [Conventions](#)
- [Safety Symbols](#)
- [Graphics](#)

## How to Use Your Manuals

---

**IMPORTANT** If you use this flow cytometer in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired. If you have not already done so, read the Warnings and Cautions listed in [Alerts for Warning, Caution, Important, and Note](#) in the [Safety Notice](#) section in the front of this manual.

Your AQUIOS flow cytometry system includes the manuals listed below:

- Use this **Instructions for Use (IFU)** manual for information on the day-to-day operation of your AQUIOS CL flow cytometer. You can find detailed step-by-step procedures for Daily Startup and Quality Control, configuring settings, running samples, printing reports, and performing Startup and Shutdown. This manual also contains physical and system specifications, safety and troubleshooting information, error messages, as well as information about what your AQUIOS CL does and the methods it uses. It also contains procedures for cleaning and replacement. The Appendices contain software and report information as well as installation, a tube list, barcode label specifications, and customer replaceable parts.
- The **AQUIOS System Guide** provides reference information and instructions for the specific application.
- The **AQUIOS Host Transmission** manual provides the information needed to program the transmission interface between the AQUIOS CL Flow Cytometer and your laboratory information system (LIS) or LIS middleware.

Carefully read the information and instructions in this manual before attempting to use your AQUIOS CL Flow Cytometer and specific application System Guide.

To quickly determine which manual to read for the information you need, see [Related Documents](#) on the back cover.

## About This Manual

---

The information in your Instructions for Use (IFU) manual is organized as follows:

### [CHAPTER 1, System Overview](#)

Provides the intended use of the AQUIOS CL system, its controls and indicators, and information on using the system's software.

### [CHAPTER 2, Operation Principles](#)

Contains a description of the AQUIOS CL system's capabilities, functionality, and operating principles.

### [CHAPTER 3, Daily Startup](#)

Provides information on powering up the AQUIOS CL followed by the checks that are required each day.

### [CHAPTER 4, Quality Control](#)

Provides information on how to run quality control material to verify instrument setup and performance. Information on how to collect or send IQAP data is also included.

### [CHAPTER 5, Sample Processing](#)

Provides information on specimen collection, specimen storage, and how to run samples using the autoloader or Single-tube Loader.

### [CHAPTER 6, Data Review](#)

Provides information on reviewing sample results, including flagged results.

### [CHAPTER 7, Shutdown](#)

Provides information on correctly shutting down the AQUIOS CL and the proper way to perform an extended shutdown when needed.

### [CHAPTER 8, Setup](#)

Provides information on customizing the software.

### [CHAPTER 9, Troubleshooting](#)

Describes safety precautions, operational hazards, general troubleshooting techniques, system messages, and troubleshooting guidelines.

### [CHAPTER 10, Cleaning Procedures](#)

Describes when, why, and how to perform cleaning procedures.

### [CHAPTER 11, Replacement Procedures](#)

Describes when, why, and how to perform replacement procedures.

Additionally, this manual includes several appendices that cover a range of topics including the AQUIOS software screens, installation, tube list, barcode label specifications, and a list of orderable reagents and accessories.


This manual also includes a list of References, a list of Abbreviations (including acronyms), Glossary, and the Beckman Coulter, Inc. Customer End User License Agreement.



## Conventions

---


This manual applies the following conventions:

- **Bold** font indicates a screen icon or menu item on the Workstation screen.
- *Italics* font indicates screen text displayed by the Workstation.
- [Blue](#) text indicates that you can click on the text to access related information.
- The term 'select' is used to indicate either one or both of the following actions:
  - to tap or touch your finger on the touch screen
  - to click with a mouse
- Instrument may be used when referring to the entire AQUIOS CL flow cytometry system (Cytometer, Supply Cart, and Workstation).
- Tabs in the software are blue when not selected and inactive. Tabs in the software turn green when selected and active.
- Sections that contain entirely new content are flagged with a New Section icon  at the end of the section title or chapter.

## Safety Symbols

---

Safety symbols alert you to potentially dangerous conditions. The symbol applies to specific procedures and appears as needed throughout this manual.

Symbol	Warning Condition	Action
	Consider all materials (specimens, controls, monoclonal antibodies, and so forth) as being potentially infectious.	Wear standard laboratory attire and follow safe laboratory procedures when handling any material in the laboratory.

## Graphics

---

All graphics, including screens and printouts, are for illustration purposes only and must not be used for any other purpose. For example, software screens that show the AQUIOS system in the background may not depict the latest production version of the system.



## Overview

---

The AQUIOS CL Flow Cytometer system is an automated analyzer for hands-off processing of whole-blood samples from sample introduction to results reporting. The system efficiently performs a range of diagnostic immune monitoring applications that use a no-wash sample preparation process.

This chapter contains information about:

- [Intended Use](#)
- [Intended User](#)
- [System Components](#)
- [Cytometer](#)
- [Workstation](#)
- [Supply Cart](#)
- [Uninterruptible Power Manager](#)
- [Options](#)
- [System Connections](#)
- [Software](#)
- [Consumables and Supplies](#)
- [Physical Specifications](#)
- [System Specifications](#)
- [Limitations](#)

## Intended Use

---

The AQUIOS CL Flow Cytometer is intended for use with in vitro diagnostic flow cytometric applications using up to four fluorescent detection channels using a blue (488 nm) laser, two light scatter detection channels and electronic volume (EV).

AQUIOS Flow Cytometry Software may be run on an independent computer workstation for off-line analysis of results generated by the AQUIOS CL Flow Cytometer with its monoclonal antibody reagents. The off-line analysis must be performed in accordance with the product labeling.

**NOTE** An off-line analysis workstation cannot be used for acquisition.

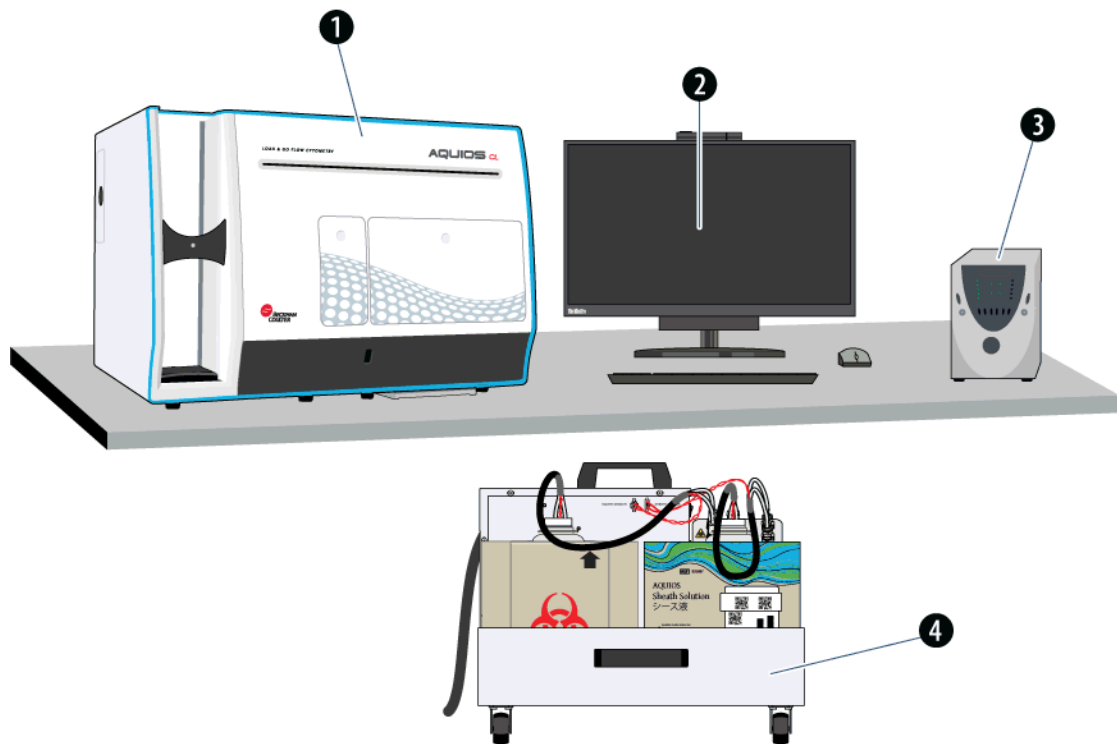
## Intended User

This product is intended for laboratory professional use.

## System Components

The main components are shown in Figure 1.1.

Figure 1.1 AQUIOS CL Main Components



1. Cytometer
2. Workstation

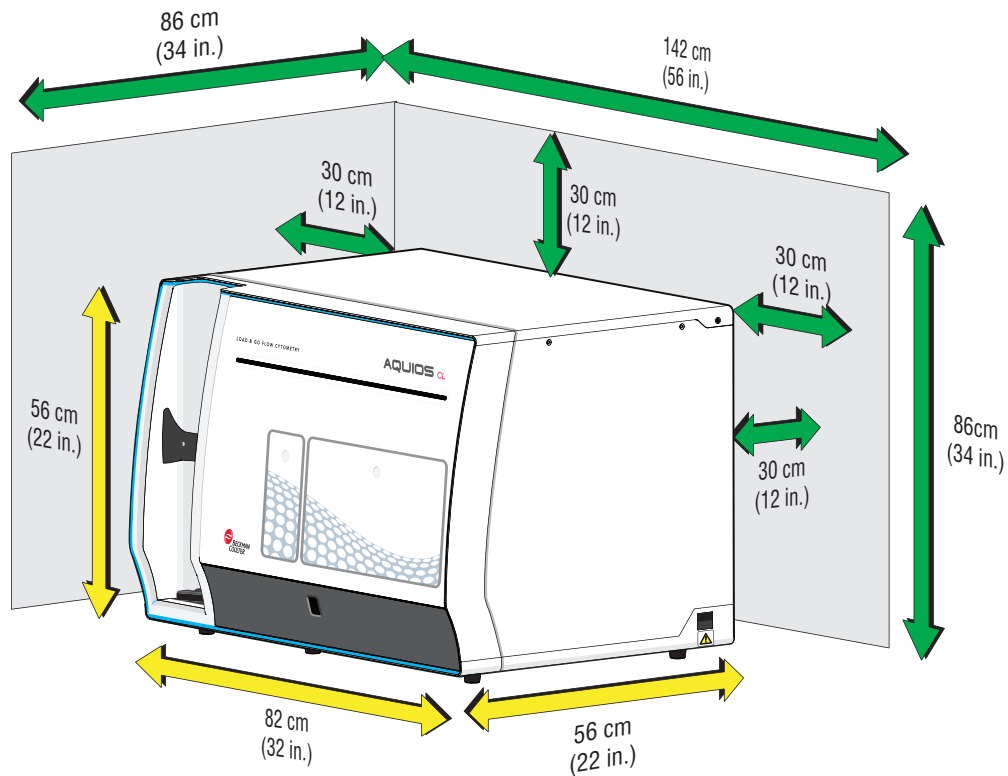
3. Uninterruptible Power Manager
4. Supply Cart

## Cytometer

### Space Requirements

Dimensions for the AQUIOS CL Cytometer are shown in [Figure 1.2](#). In addition to space for the instrument itself, allow a 30 cm (12 in.) clearance on each side of the instrument including the left side, right side, back side, and top side of the instrument for accessibility.

**Figure 1.2** Space and Accessibility Requirements for Cytometer



## Function

The Cytometer prepares and analyzes whole-blood samples. Sample introduction is routinely accomplished by placing specimen tubes in a cassette and then loading the cassette in the autoloader.

A single tube may be presented for analysis using the single-tube loader. See [Figure 1.3](#)

**Figure 1.3** AQUIOS CL Cytometer - Autoloader and Single-tube Loader Locations

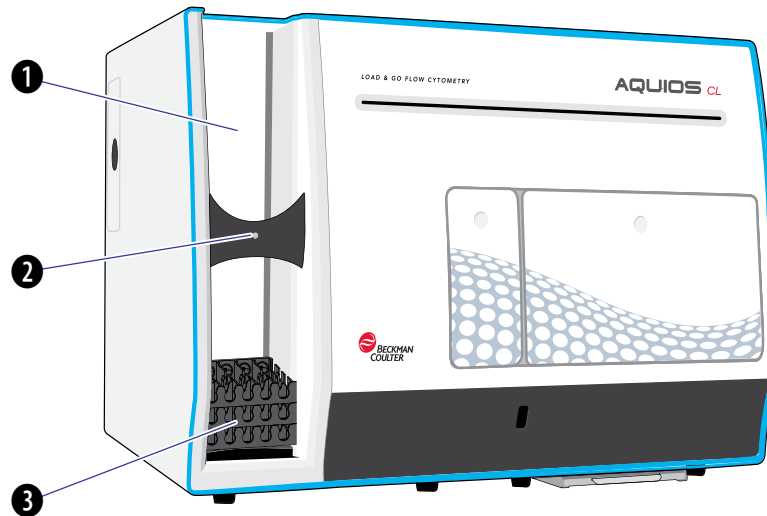


1. Autoloader
2. Single-tube Loader

## Autoloader

The autoloader is a sample loader capable of loading up to 40 specimens at a time (up to eight cassettes with a maximum of five specimens per cassette). See [Figure 1.4](#) and [Figure 1.5](#).

**Figure 1.4** Autoloader Main Components



1. Cassette Loading (upper area)
2. Indicator Light
3. Cassette Unloading (lower area)  
(After all sample aspirations are complete.)

## Autoloader Indicator Light

**Figure 1.5** Autoloader Indicator Light

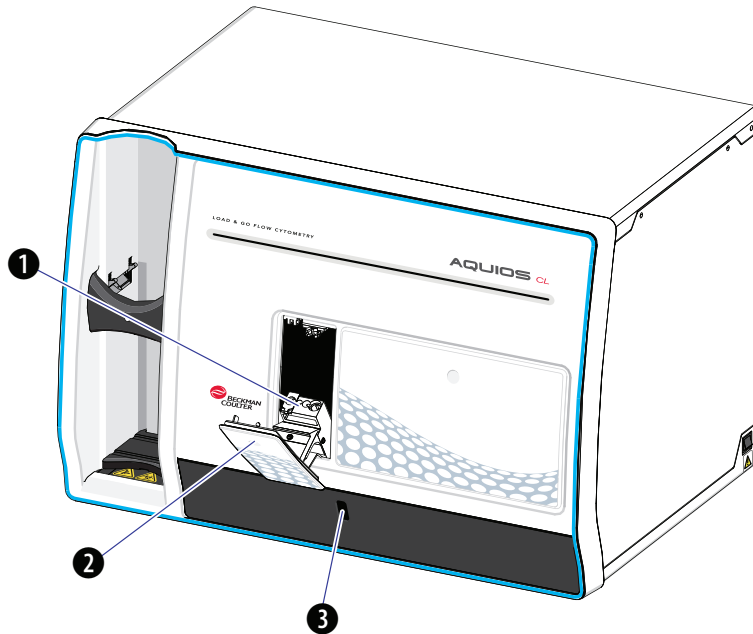


- **Green** - the Autoloader is available for loading new samples.
- **Orange** - the Autoloader has at least one cassette to be processed.
- **Red** - the system is unavailable to process samples. See the displayed error message.

## Single-tube Loader

The Single-tube loader is a sample loader for one-at-a-time specimen sampling (Figure 1.6).

Figure 1.6 Single-tube Loader Main Components



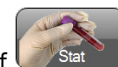
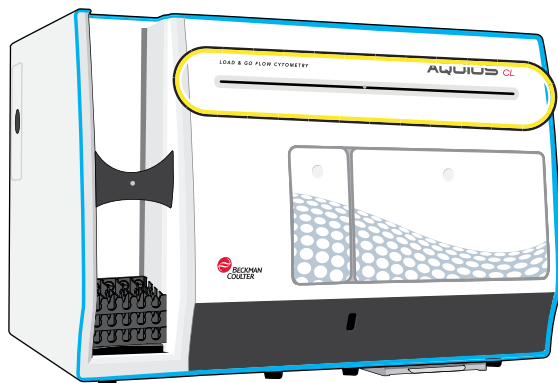
1. Single-tube loading area
2. Single-tube loader door
3. Barcode reader




## Sample Prep Probe Indicator Light

The Sample Prep Probe indicator light displays the status of the Sample Prep Probe. See [Figure 1.7](#).

**Figure 1.7** Sample Prep Probe Indicator Light



- **Green** - the Single-tube Loader is available to process a new sample. If  is selected, the system notifies you by showing the following statement: *Please press on the Single-tube door.*
- **Blue** - the system is currently busy processing samples. If the Single-tube Loader door is prompted to open, the light becomes orange.
- **Orange** - the system is busy processing samples and there is a pending request to open the Single-tube or reagent door.  
Alternatively, if Startup is in progress, the light remains orange. After Startup, the light becomes green.
- **Red** - a system error has occurred and the system is unavailable to process samples. See the displayed error message.

**NOTE** The sample prep probe indicator light is not stationary; it travels back and forth according to the location of the sample prep probe.

## Reagent Compartment

Figure 1.8 Reagent Compartment Access



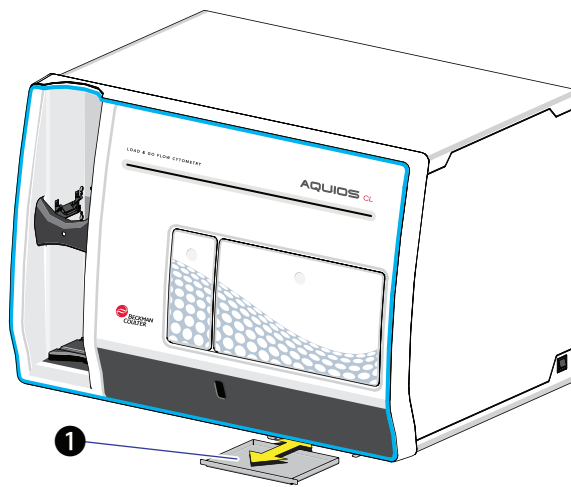
1. Reagent door
2. Reagent compartment

## Wash Station Overflow Tray



**Risk of biohazard spill. Check the wash station overflow tray (Figure 1.9) for spills during routine maintenance and after a wash station overflow and clean if necessary, to prevent any biohazardous contamination.**

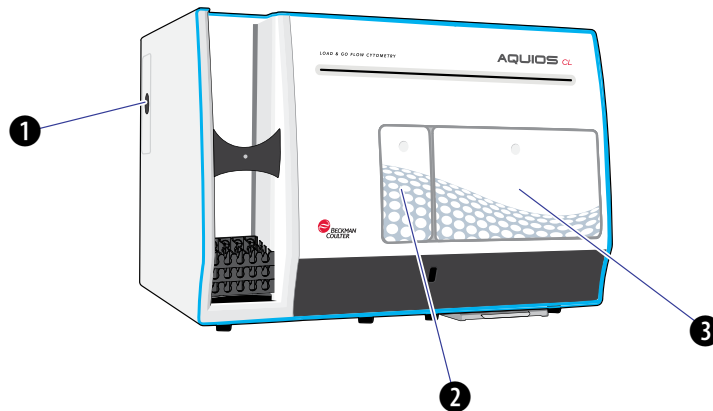
Figure 1.9 Wash station overflow tray



1. Wash station overflow tray

## Doors

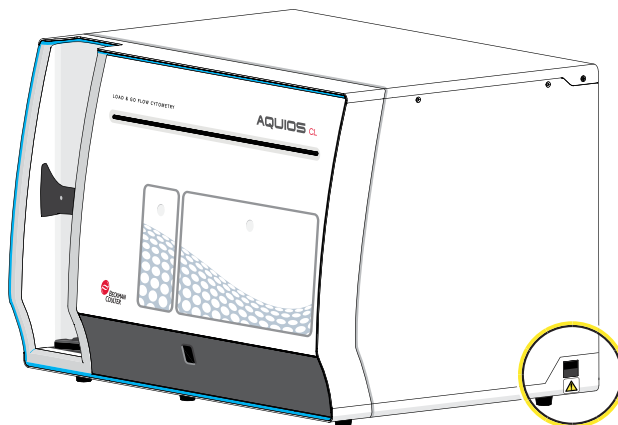
Figure 1.10 Cytometer Doors



1. **Cleaning reagent door:** Used to access the onboard cleaning reagent container.
2. **Single-tube Loader door on the front cover (smaller of the two doors):** Used to load a single specimen tube in the Single-tube Loader. May be used for initiating analysis of a Stat specimen.
3. **Reagent door on the front cover (larger of the two doors):** Used to access the Deep Well Plate, onboard AQUIOS monoclonal antibodies, application specific lytic and associated reagents, or test tube with AQUIOS Sodium Hypochlorite Solution.

## Cytometer Power ON/OFF Switch

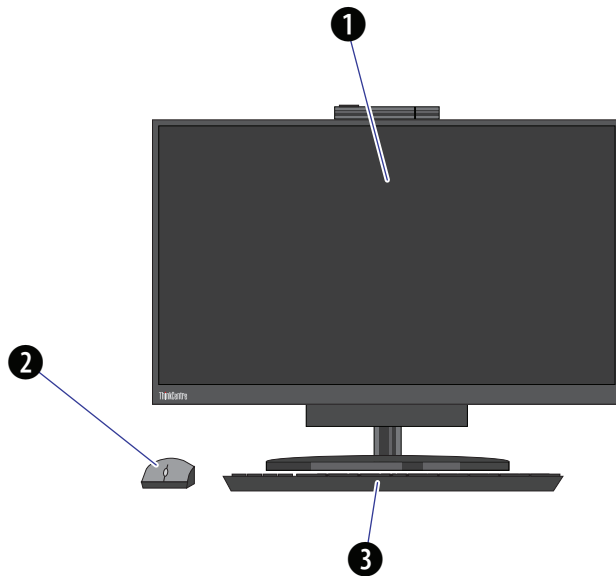
Figure 1.11 Power Switch Location on the Cytometer



## Workstation

The Workstation (Figure 1.12) runs the software that controls the Cytometer and monitors the electronic, fluidic and pneumatic signals from the Supply Cart. It displays sample results and other information.

Figure 1.12 Workstation Main Components



1. All-in-One computer with touch-screen monitor for selecting options and displaying data
2. Wireless mouse
3. Wireless keyboard

 **CAUTION**

**Risk of inaccurate time and date stamp on results if you enable daylight savings time. Daylight savings time has been disabled to ensure that time changes do not affect the time and date stamp of results. It is recommended that you keep daylight savings time disabled.**

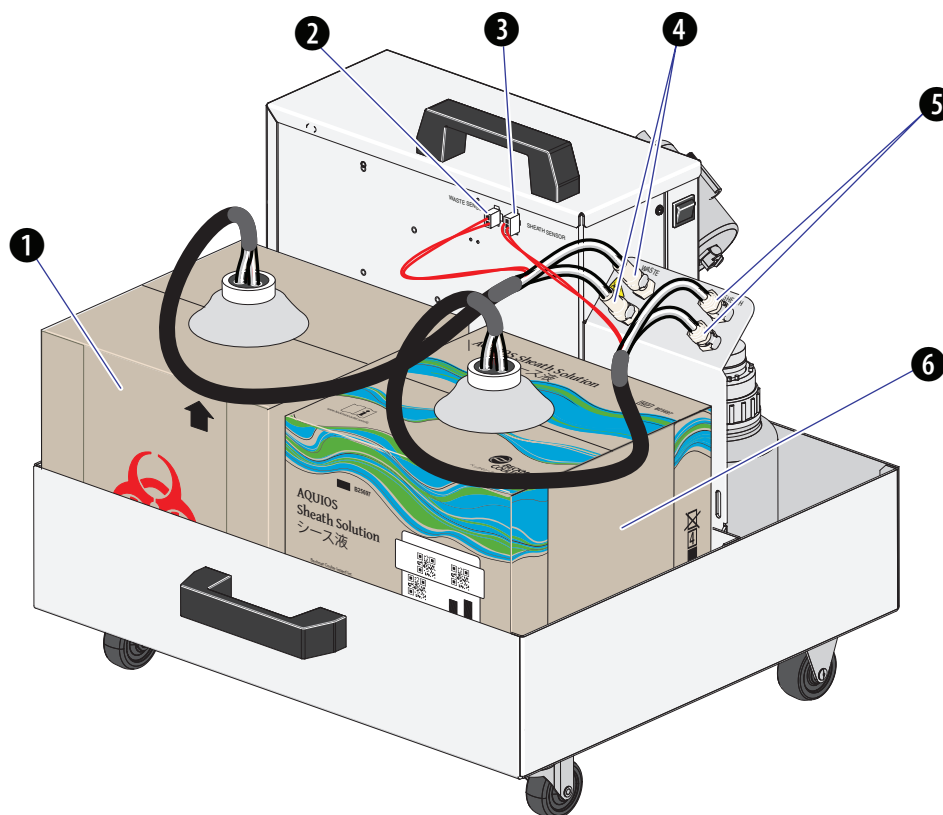
**CAUTION**

Risk of viruses or malware if you enable Windows Autorun. The Windows Autorun feature on USB ports and CD-ROMs and DVD-ROMs has been disabled as a security precaution. It is recommended that you keep it disabled to minimize the risk of viruses or malware.

## Supply Cart

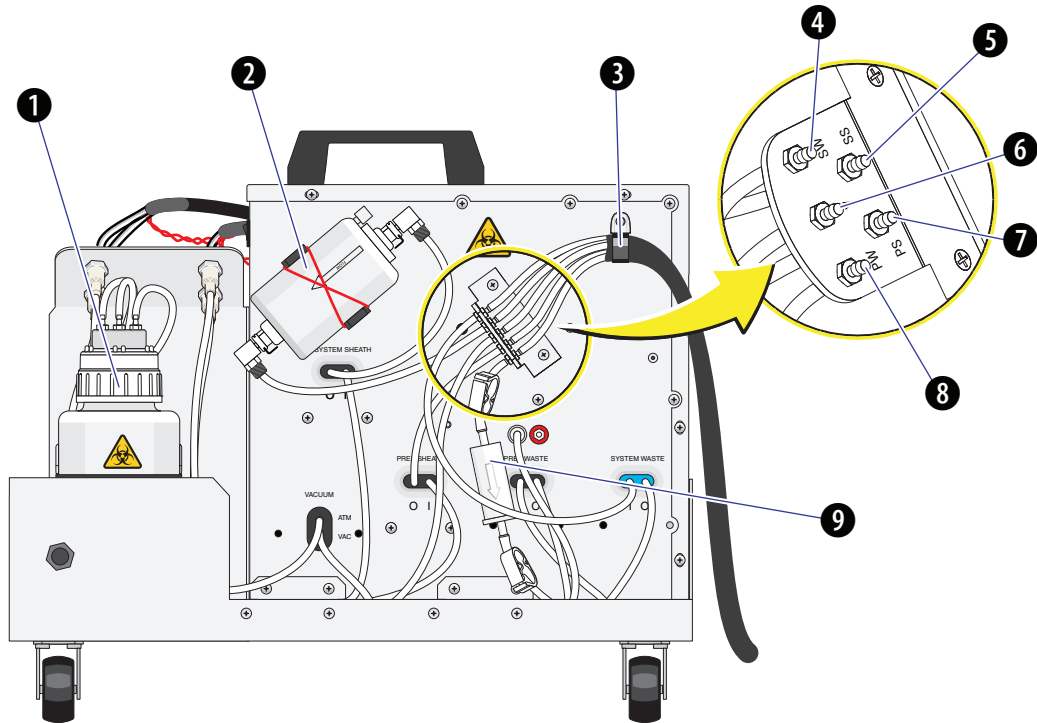
The Supply Cart provides vacuum to the Cytometer. It contains the vacuum pump module, vacuum trap bottle, sheath filter and sheath pump, and holds the AQUIOS Sheath Solution Cubitainer, and waste container. See [Figure 1.13](#).

**Figure 1.13** Supply Cart Main Components (front view)



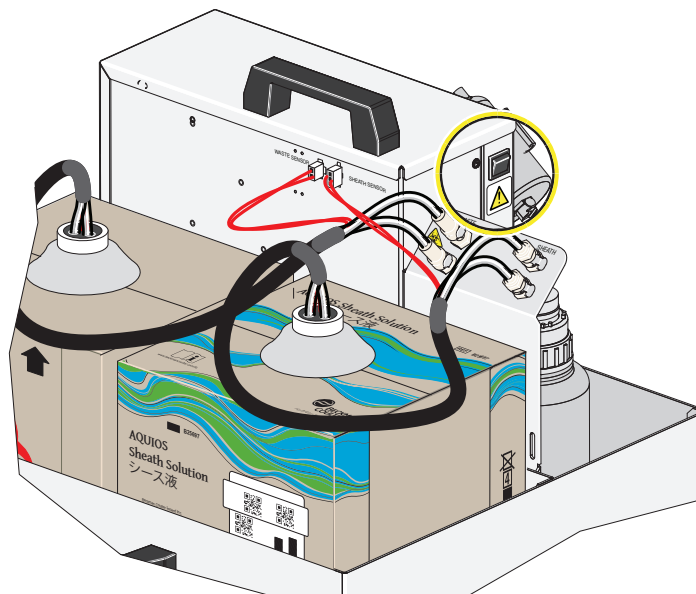
1. Waste Container (10 L): Located in the supply cart, the waste container accumulates the waste generated by the cytometer.
2. Waste sensor
3. Sheath sensor
4. Waste Connector
5. Sheath Connector
6. AQUIOS Sheath Solution Cubitainer (10 L): Located in the supply cart, this container supplies the sheath fluid needed to operate the cytometer.

Figure 1.14 Supply Cart Main Components (back view)



- |  |  |
|--|--|
| 1. Vacuum reservoir                          | 6. Vacuum connection (connects to Cytometer)     |
| 2. Sheath filter                             | 7. Prep Wash Station IN (connects to Cytometer)  |
| 3. 5-tube bundle                             | 8. Prep Wash Station OUT (connects to Cytometer) |
| 4. Waste connection (connects to Cytometer)  | 9. Inline Waste Filter                           |
| 5. Sheath connection (connects to Cytometer) |  |

Figure 1.15 Power Switch Location on the Supply Cart (View of Right Side)



## Uninterruptible Power Manager

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The Uninterruptible Power Manager (UPM) incorporates a low impedance isolation transformer which delivers clean, fully conditioned power which is free from noise, voltage spikes and common-mode disturbances. It includes a battery backup in case of power outage.

**IMPORTANT** When a power failure occurs, remove all cassettes from the Autoloader and perform a Shutdown. The instrument finishes the samples that are in process and shuts down automatically when sample processing is complete. If you leave specimens in the Autoloader after a power failure, the samples may be partially processed, you may lose samples, leave the instrument in an unknown state or have samples stuck in instrument.

**Table 1.1** Uninterruptible Power Manager Specifications

Locale and Model No.	Load Current (Amps)	Load Power (VA)	Input Voltage (VAC)	Output Voltage (VAC)	Frequency (Hz)	Ship Weight (lb)
<b>North America</b>						
ABCE800-11	7.9	800	96-151	120	50/60	47
<b>International</b>						
ABCE800-22	3.9	800	181-290	230	50/60	21.5

The UPM case for both the North America and International model is 8.0 in. x 5.8 in. x 17.5 in. (20.3 cm x 14.7 cm x 44.5 cm).

## Options

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### Printer

Provides a printout of sample results and other information. The printers available for the system are subject to change, contact your Beckman Coulter Representative for an up-to-date list of available printers.

## System Connections

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For more information on System Connections, please see [System Connections](#) in [APPENDIX B, Installation](#).

## Software

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**IMPORTANT** For the software to properly load, operating system format and locale settings must remain as their defaults of English and United States. Do not change the operating system format and locale settings.

The AQUIOS CL Flow Cytometry System contains the Acquisition software that is used when running the Cytometer.

## Consumables and Supplies

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**Risk of erroneous results.** The AQUIOS CL Flow Cytometer system tracks all onboard reagents (except AQUIOS Sodium Hypochlorite Solution) for remaining tests and expiration dates. However, the AQUIOS Cleaning Agent and AQUIOS Sheath Solution are tracked for percentage remaining. If your laboratory has more than one AQUIOS CL Flow Cytometer and the systems are networked (up to a maximum of five instruments), the networked databases will share information. For example, reagents can be moved from system-to-system without error.

If the systems are not networked, do not load the reagents from one system onto another, as the systems will not be able to accurately track the reagent. Use the reagents only on one instrument.

For example, if a monoclonal antibody vial has 10 tests remaining and is moved to another system (that is not networked and sharing databases), the system will think the vial is full (50 tests remaining in the vial) and continue to aspirate from that vial even though it is empty. Therefore, Beckman Coulter strongly recommends that multiple systems in a laboratory always be networked and sharing the same database.

**NOTE** The AQUIOS CL Flow Cytometer system tracks the remaining tests of the AQUIOS Cleaning Agent.

**NOTE** The AQUIOS CL Flow Cytometer system does not track the AQUIOS Sodium Hypochlorite Solution. You must track the expiration date of the AQUIOS Sodium Hypochlorite Solution upon use.



## Reagents

**⚠ CAUTION**

It is recommended that all reagents loaded in the reagent carousel remain in the carousel during storage and refrigeration for optimum reagent tracking and management.

**⚠ CAUTION**

Risk of misreading the barcode if using a photocopied, damaged, poor quality, or modified barcode label. If a reagent label is damaged upon receipt or cannot be read, please contact your Beckman Coulter Representative.

**⚠ CAUTION**

Risk of erroneous results. Use only reagents and deep well plates provided by Beckman Coulter for use with the AQUIOS CL Flow Cytometer.

Your AQUIOS CL Flow Cytometer is optimized to operate with AQUIOS reagents. The stated analytical characteristics and specifications cited in this manual can only be guaranteed by using the AQUIOS reagents.

Additionally, AQUIOS reagents are labeled with barcodes for smart-track monitoring and to minimize data entry errors.

Contact your Beckman Coulter Representative if a product is damaged upon receipt. For more information about AQUIOS reagents, visit the Beckman Coulter Web site at [www.beckman.com](http://www.beckman.com) or contact your Beckman Coulter Representative.

### AQUIOS Sheath Solution

AQUIOS Sheath Solution is a non-fluorescent, azide-free balanced electrolyte solution for use on AQUIOS CL Flow Cytometers with light scatter and fluorescent applications. It is used to rinse components between sample analyses, and provide a sheath stream to transport the sample cells in single file through the flow cell.

AQUIOS Sheath Solution has the following characteristics:

- 0.2 µm filtered
- Transparent and nonfluorescent to 488 nm laser light
- Low background
- Balanced electrolyte solution
- Compatible with the characteristics of the sample being measured (such as pH, osmolality, and conductivity).

**NOTE** When the AQUIOS Sheath Solution cubitainer is replaced, scan the barcode to ensure that the correct reagent is being loaded and tracked. For more information, see [Replacing the AQUIOS Sheath Solution Cubitainer](#) in CHAPTER 11, [Replacement Procedures](#).

The 10 L AQUIOS Sheath Solution cubitainer is stored on the Supply Cart. The contents of the AQUIOS Sheath Solution cubitainer are supplied to the Cytometer via the tubing attached to a connector labeled **SHEATH**.

### **AQUIOS Lysing Reagents**

For details concerning the AQUIOS Lysing Reagents, see your application specific AQUIOS System Guide.

### **AQUIOS Cleaning Agent**

AQUIOS Cleaning Agent is a biodegradable formulation that flushes the sample tubing and helps to reduce protein buildup and particles in the Cytometer. It is used during Shutdown and performing a flush cycle as a preventative measure for optimal system operation.

**NOTE** When the AQUIOS Cleaning Agent bottle is replaced, the system looks for a specific barcode to ensure that the correct reagent is being loaded and tracked. For more information, see [Replacing the AQUIOS Cleaning Agent Bottle](#) in [CHAPTER 11, Replacement Procedures](#).

The 500 mL bottle is housed inside a compartment that is accessible via a door on the left-hand side of the cytometer.

### **AQUIOS Sodium Hypochlorite Solution**

AQUIOS Sodium Hypochlorite Solution is a cleaning agent that is used during cleaning and bleaching cycles to counteract protein buildup that occurs in tubing and the flow cell. For more information, see [Replacing the AQUIOS Sodium Hypochlorite Solution Tube](#) in [CHAPTER 11, Replacement Procedures](#).

**NOTE** AQUIOS Sodium Hypochlorite Solution is a cleaner, and not to be used as a disinfectant.

## **Quality Control Materials**

For details concerning the Quality Control Materials, see your application specific AQUIOS System Guide.

## Material Safety Data Sheets (SDS/MSDS)

To obtain an SDS or MSDS for Beckman Coulter reagents used on the AQUIOS system:

- On the Internet, go to [www.beckman.com](http://www.beckman.com):
  1. Select **Safety Data Sheets (SDS/MSDS)** from the Support menu.
  2. Follow the instructions on the screen.
  3. [Contact us](#) if you have difficulty locating the information.
- If you do not have Internet access, [contact us](#).

## Cassettes

The AQUIOS CL Flow Cytometer uses a five-position cassette to load specimen tubes onto the autoloader. Specimen cassettes can hold up to five specimen tubes of the same size and the autoloader can process up to eight different cassettes (40 specimens) at one time. The control cassette holds up to 3 control tubes. Each cassette is uniquely identified to track specimen tubes and recover samples from a given cassette.



### WARNING

**Risk of injury, biohazardous contamination, and instrument damage. The use of incorrect tubes can result in tubes being forced inside the instrument and possible tube breakage. Follow all tube recommendations to prevent tube breakage.**

## Cassette Types

Ten types of cassettes are available for use:

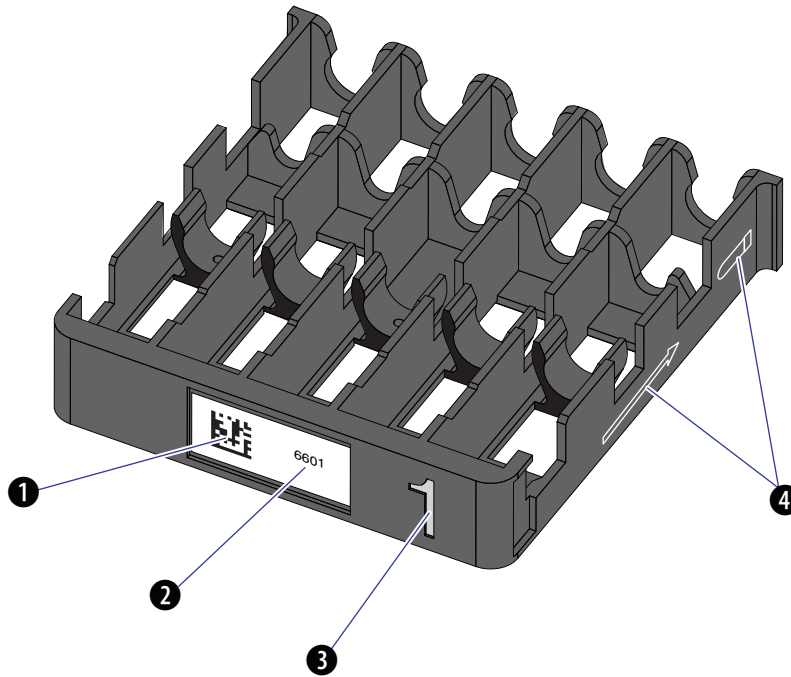
- Type 1 holds up to five specimen tubes with an outside diameter of 13 mm with a length of 75 mm.
- Type 2 holds up to five specimen tubes with an outside diameter of 13 mm with a length of 100 mm.
- Type 3 holds up to five specimen tubes with an outside diameter of 16 mm with a length of 100 mm.
- Type 4 holds up to five specimen tubes with an outside diameter of 10.25 mm with a length of 50 mm.
- Type 5 holds up to three AQUIOS whole blood control tubes. Like the other cassettes, this cassette has five positions but the two outside positions do not allow tube insertion.
- Type 6 holds up to five Sarstedt tubes (tube must have an outside diameter of 13 mm with a length of 75 mm).
- Type 7 holds up to five Sarstedt tubes (tube must have an outside diameter of 13 mm with a length of 90 mm).
- Type 8 holds up to five Sarstedt tubes (tube must have an outside diameter of 11 mm with a length of 66 mm).
- Type 9 holds up to five Sarstedt tubes (tube must have an outside diameter of 15 mm with a length of 92 mm).

- Type 10 holds up to five Sarstedt tubes (tube must have an outside diameter of 13 mm with a length of 65 mm).

**NOTE** For a complete tube list, see [Tube List for both the Autoloader and the Single-tube Loader](#) in [APPENDIX C, Tube List](#).

### Cassette Labels

Each cassette has an identifying label that contains three elements as shown below.



1. 2D barcode symbol that can be read by the Cytometer barcode reader
2. Visually-readable number
3. Numeral identifying the cassette type (1 through 10)
4. Orientation markers - indicates the direction that the tube should be loaded.

### Plates and Racks

Sample preparation requires a 96-deep well plate with a conical-shaped, deep well capable of holding up to 600  $\mu$ L. Each plate has a unique barcode label identifier, which enables the system to keep track of the plate usage and sample location.

The Gravimetrics Procedure uses a 40 tube rack, this rack is used for holding the tubes, for more information see [Syringe Gravimetrics](#) in [CHAPTER 8, Setup](#).

## Waste Container

Cytometer waste is collected in a 10 L waste container that is stored on the Supply Cart. Waste travels from the Cytometer to the waste container via tubing attached to a container labeled **WASTE**.



### WARNING

**Risk of chemical injury from bleach. To avoid contact with the bleach, use barrier protection, including protective eyewear, gloves, and suitable laboratory attire. Refer to the Safety Data Sheet for details about chemical exposure before using the chemical.**

Before placing the waste container on the Supply Cart, add 1L of high-quality, fragrance-free, gel-free bleach (5 to 6% solution of sodium hypochlorite - available chlorine) to the empty 10L waste container. Check with local regulations and acceptable laboratory procedures. The waste container is used until it is full. The waste container is monitored by the system and warns you when the waste is full. For more information, see [Replacing the Waste Container](#) in [CHAPTER 11, Replacement Procedures](#).

## Physical Specifications




### CAUTION

**Risk of instrument damage. This device is intended for indoor use only. To avoid damage, do not install the instrument outdoors.**

**Table 1.2** Physical Specifications

Specification	Description
Power Requirements	An Uninterruptible Power Manager (UPM) is used with the AQUIOS System and requires a dedicated line. All system components must be plugged into the Uninterruptible Power Manager. See <a href="#">Supply Cart</a> for system connection information. For specific details, see the <a href="#">Electrical Input</a> in <a href="#">APPENDIX B, Installation</a> .
Installation Category	Category II (per IEC 61010-1 standard)
Pollution Degree	Pollution degree 2
Acoustic Noise Level	≤65 dBa

**Table 1.2** Physical Specifications (*Continued*)

Specification	Description
Ambient Temperature and Stability Recommendations	<p>Keep the room temperature between 18°C and 26°C (64.4°F and 78.8°F). Temperature fluctuations within the ambient temperature range can affect performance. For optimal performance, Beckman Coulter recommends the room temperature not fluctuate more than <math>\pm 2.8^\circ\text{C}</math> (<math>\pm 5^\circ\text{F}</math>) during Cytometer use. Refer to the application specific System Guide for the recommended room temperature required for each application assay.</p> <p><b>NOTE</b> Room temperature fluctuation requirements can be verified by recording the room temperature on a log sheet form prior to running the equipment and then a second time after completing the tests.</p>
Humidity	35-85%, without condensation
Operational Altitude	Operate at altitudes 700-1060 mbar (-1253 to +9878 feet above sea level)
Heat Dissipation	Total heat dissipation into the room is approximately 250 W (853 btu/hour). Provide sufficient air conditioning (refer to <a href="#">Ambient Temperature and Stability Recommendations</a> shown above).
Drainage	<div style="border: 1px solid black; background-color: #ffcc00; padding: 5px; display: inline-block;"> <b>WARNING</b></div> <p><b>Risk of biohazardous contamination if you have skin contact with the waste container, its contents, and its associated tubing. The waste container and its associated tubing might contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the contents of the waste container in accordance with your local regulations and acceptable laboratory procedures.</b></p> <p>The waste line from the Cytometer is connected to a 10L waste container. Dispose of the waste in accordance with your local regulations and acceptable laboratory procedures. For more information, see <a href="#">Replacing the Waste Container</a> in <a href="#">CHAPTER 11, Replacement Procedures</a>.</p>

## System Specifications

The System Specifications are shown in [Table 1.3](#). For AQUIOS Performance Characteristics, refer to the application specific System Guide.

**Table 1.3** System Specifications

Description	Specification
Carryover	$\leq 0.3\%$
Acquisition rate	Acquisition rate is flagged at 4250 events/second
Excitation	488 nm laser
Fluorescence Detectors	Up to four photomultiplier tubes
Electronic Volume	The relative measurement which uses the Coulter Principle of impedance to measure relative cell volume.

**Table 1.3** System Specifications (*Continued*)

Description	Specification
Scatter Detectors	Forward Scatter and Side Scatter diodes
Flow Cell	Patented triangular flow cell 180 x 125 $\mu\text{m}$
Valves	Computer-controlled fluidics system
Delivery System	Vacuum pump
Sample Prep Probe	Used for the preparation of the sample, monoclonal antibodies, and lytic reagents. Washed internally and externally by wash station
Analysis Probe	Used to aspirate the prepared specimen and deliver it to the flow cell for analysis. Washed internally and externally by wash station block

## Limitations

- Accurate and reproducible results will be obtained as long as the procedures used are in accordance with the AQUIOS CL Flow Cytometer Instructions for Use, specific application instructions (see your application specific System Guide), and good laboratory practices.
- Reports/Data must be reviewed by a laboratory professional before results are reported to ensure analysis was performed correctly.
- When modifying the regions and compensation, it is the user's responsibility to make the proper adjustments.
- In certain disease states, such as severe renal failure or some hemoglobinopathies, lysis of RBCs may be slow, incomplete, or even impossible. Some conditions that may cause red blood cells to not lyse: presence of nucleated red blood cells, abnormal protein concentration, or some hemoglobinopathies. This may cause falsely decreased percentages due to unlysed RBCs being counted as leukocytes.
- Abnormal states of health are not always represented by abnormal percentages of certain leukocyte populations. An individual in an abnormal state of health may show the same leukocyte percentages as a healthy person. Use test results in conjunction with clinical and other diagnostic data.
- Certain patients may present special problems due to altered or very low numbers of certain cellular populations.
- Results obtained with flow cytometry may be erroneous if the laser is misaligned or the gates are improperly set. Perform Daily QC to ensure optical, fluidics and electronic stability within the system are operating within the instrument specifications.





## Overview

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This chapter contains information about:

- [General](#)
- [Function](#)
- [Principles of Operation](#)

## General

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Using a 488 nm solid-state laser, up to four fluorescence channels, forward-scatter (FS) detection, side-scatter (SS) detection, and electronic-volume (EV) measurements, the flow cytometer can perform correlated multiparameter analyses of individual cells.

This “closed” system only runs tests preconfigured by Beckman Coulter and does not allow user-designed protocols or panels.

## Function

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The AQUIOS CL system is capable of the following parameters: Forward-Scatter (FS), Side-Scatter (SS), Electronic Volume (EV) and up to four fluorescence detectors.

The AQUIOS Load & Go technology provides:

**Integrated Cellular Analysis** — A system that combines sample preparation and fluorescence-based cellular analysis into one compact system.

**High Throughput** — Refer to the application specific System Guide.

**Random Access** — Samples can be loaded in random order and the system prepares each sample independently based on the test request.

**Automated Laboratory Information System (LIS) Requests** — If the LIS connection is enabled, the system automatically retrieves the test requests from the LIS. If your laboratory does not have a LIS system or an automated LIS, simply add a request or use a default test.

**Automated Sample Mixing** — If using the autoloader, the cassette with the samples is rocked prior to cap-piercing each of the tubes. Simply load the cassettes with the samples in the autoloader. Samples for the Single-tube Loader must be mixed by the user prior to loading the sample.

**Automated Sample Preparation** — Samples are aliquotted, stained, incubated and lysed onboard. A software scheduler ensures that all samples are prepared and analyzed within the required time.

**Automated Gating and Analysis** — The AQUIOS software uses advanced algorithms to repeatedly trace and gate the cell subsets of interest. Results are automatically generated for the specific test based on the gated regions. Users with reviewer/editor rights or administrator can edit these algorithm-defined regions.

**Automatic QC Checks** — The instrument performs daily quality checks to ensure the validity of the generated data. The system utilizes the whole blood controls to check for optical, fluidic, and electronic stability within the system before running unknown samples.

**Sample Auto-Verification** — The software routinely reviews the acquired results for flags and notifications. See [Flags And Notifications](#) in [CHAPTER 6](#), for details. The flagged samples are automatically held for review and are available for re-request from the Review Option window.

**Smart-Track Monitoring** — The AQUIOS reagents use a unique barcode identity for tracking the expiration date, on board expiration, lot and container numbers. The reagent consumption and plate usage are monitored by the system as the samples are processed. Updates of new reagents, plate usage, reagent availability and reagent location are displayed after opening and closing the reagent door.

**NOTE** The AQUIOS CL Flow Cytometer system tracks the remaining tests of the AQUIOS Cleaning Agent.

**NOTE** The AQUIOS CL Flow Cytometer system does not track the AQUIOS Sodium Hypochlorite Solution. You must track the expiration date of the AQUIOS Sodium Hypochlorite Solution upon use.

**Positive Sample Monitoring** — The system uses an internal barcode scanner for positive sample tracking of autoloader samples. The sample ID is matched to the request and the patient information is readily accessible throughout the sample process.

**Specimen Tube Flexibility** — The AQUIOS CL Flow Cytometer can handle a variety of specimen introduction methods, such as: a variety of tube sizes, cap-piercing, open-vials, no-barcode vials or bar-coded samples.

**Automated Result Submission** — If the LIS connection is enabled, results without flags or notifications can be automatically transmitted to the LIS. If your laboratory does not have an LIS system, the reports can be printed or exported as a spreadsheet or a PDF file.

**Dual-probe Design** — The unique design increases efficiency by enabling multiple specimen samples to be processed at the same time. One sample can be analyzed while a subsequent specimen sample is being prepared.

**AQUIOS Reagents** — The system offers a reagent product line that has been validated for optimal assay performance.

**Remote Review Capability** — The test menu and results can be accessed from alternate computers. Peripheral computers can be setup for remote result review and release.

## Principles of Operation

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The AQUIOS CL Flow Cytometer is a benchtop instrument capable of combining automated sample preparation and cellular analysis in a compact system. A 488 nm Solid State Diode Laser provides the light source for scatter and fluorescence measurements. The parameters that can be measured are Forward-Scatter (FS) and Electronic Volume (EV) for sizing, Side-Scatter (SS) for granularity measurements, and up to four independent fluorescence parameters.

A sample is aspirated from an open tube or obtained by cap-piercing from a closed tube, then dispensed into one or more wells of a Deep Well Plate. Fluorochrome-labeled antibodies are added that bind to molecules on the cells that express specific antigens. After an incubation period, lysing reagents are added to remove red blood cells (RBCs). The prepared sample is aspirated from the plate and transported to the flow cell.

The system uses a triangular flow cell capable of collecting optical and electronic volume measurements. Its design allows hydrodynamic focusing and stable fluorescence values. The flow cell dimensions are 180 x 125  $\mu\text{m}$  with a Numerical Aperture of 1.0 NA.

The electronic volume (EV) detector measures electrical impedance of the cell.

The flow cell is filled with conductive sheath fluid and two electrodes that create a slight current through the flow cell aperture. As a cell is drawn into the flow cell channel, the volume of the cell displaces an equivalent amount of electrolyte solution. This volume is measured in the form of voltage pulses and it is known as Electronic Volume. The Electronic Volume measurements are based on the Coulter Principle<sup>2</sup>.

The 488 nm light source excites fluorescent dyes bound to cells passing through the beam. This dye emission is directed to a set of optical filters. The different wavelengths of dye emission are then collected by up to four independent photomultiplier tubes, which convert the fluorescence intensities into proportional voltage pulses.

The forward scatter (FS) detector collects the laser light that bounces off the cell at an angle of less than 10 degrees for relative cell size measurements.

The side scatter (SS) detector collects laser light that bounces off the cell at an angle of 90 degrees for relative granularity measurements.

A syringe mechanism is capable of being used to obtain absolute counts. The syringe pump regulates the flow cell aspiration volume and the sample metered delivery for accurate cell counting.

The parameters, triggers, discriminators, and collected measurements vary according to the assay.

## Light Source Configuration

A 488 nm Solid State Diode Laser provides the light source for scatter and fluorescence measurements. Please refer to the application specific System Guide for more information.



## Overview

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This chapter contains information about how to prepare your system to run controls and patient samples, and:

- [Startup](#)

## Startup

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 **WARNING**

**Risk of personal injury or contamination:**

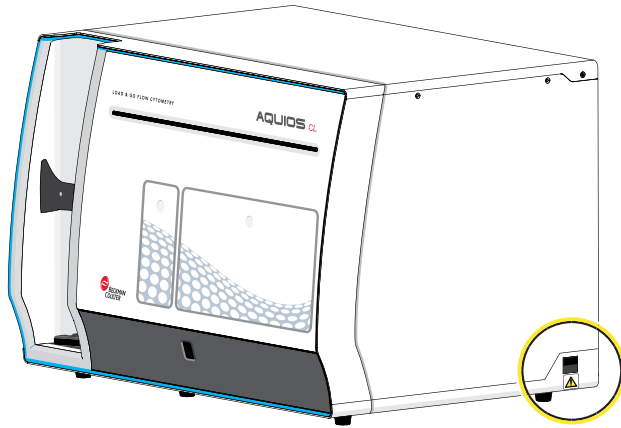
- To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection.
- Operating the instrument while the waste level sensor is disconnected can cause biological contamination. Do not operate the instrument while the waste level sensor is disconnected.

 **CAUTION**

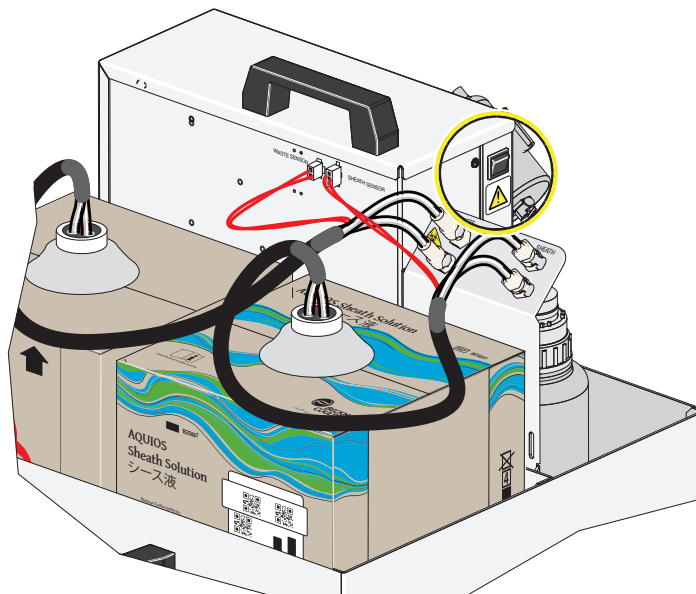
**Each time the system is turned on, remove the reagent carousel from the refrigerator and load onto the AQUIOS System. Ensure the reagents are at room temperature before use.**

After your system is set up and configured at installation, follow the procedures below to prepare the Cytometer for sample analysis.

- 1 Turn on the Cytometer.



- 2 Turn on the Supply Cart.



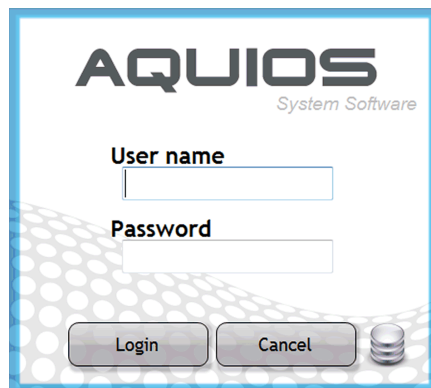
- 3 Turn on the Workstation.



- 4 The first screen you see is the Windows login screen. Login as either AqAdmin or AqUser or the customized window login created by your administrator.

- 5 Double-click the AQUIOS icon from the desktop, the Login screen appears.

**NOTE** As the software boots, it verifies the operating system format is **English** and the locale setting is **United States**. If these default settings differ, the software displays an error message and exits automatically.



- 6 Enter Username and Password and select . The Main Screen ([Figure A.1](#)) appears.

- 7 Open the reagent door by pressing at the top, middle part of the door in one single, solid motion.



**CAUTION**

Risk of instrument damage. Immediately prior to placing a new antibody vial in the carousel to put on board the system, replace the solid, non-pierceable, monoclonal antibody shipping caps with the pierceable caps provided in the reagent packaging. The pierceable caps should be handled with care to avoid contamination.

**CAUTION**

In order for the software to accurately track the open vial stability date and time, process reagents immediately after replacing the non-pierceable shipping caps with the septa caps.

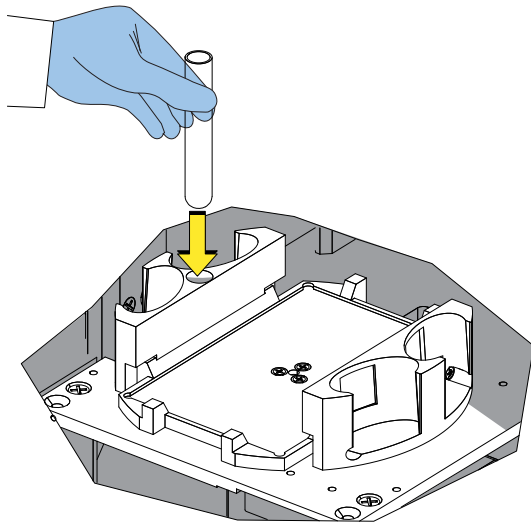
**WARNING**

Risk of personal injury from moving parts. Operating the instrument with doors or covers open can cause personal injury. Ensure that all covers and doors are closed.

- 8 Place the AQUIOS monoclonal antibody reagents that are appropriate for the application being used into the carousel and onboard the cytometer. For detailed instructions, see [Replacing Reagents and Consumables](#) in CHAPTER 11.

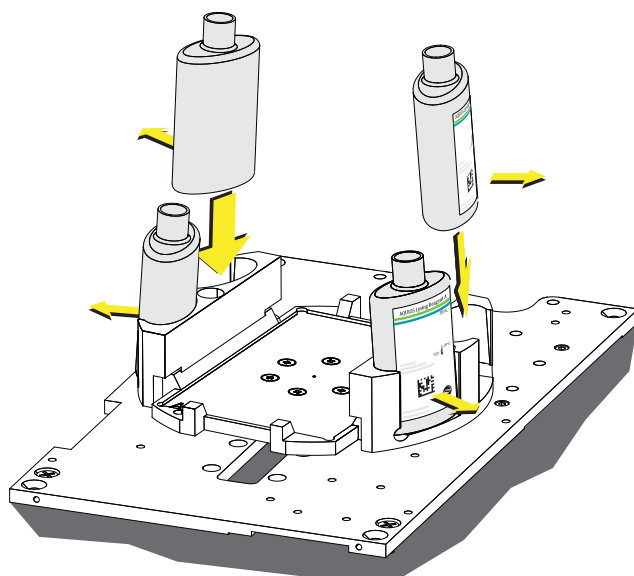


- 9 Add 2 mL of AQUIOS Sodium Hypochlorite Solution to a clean 12 x 75 mm tube and place in the designated position of the plate holder.



**NOTE** The Bleach Cycle can be run throughout the day, should it be needed, which is why the AQUIOS Sodium Hypochlorite reagent needs to be present while the system is running.

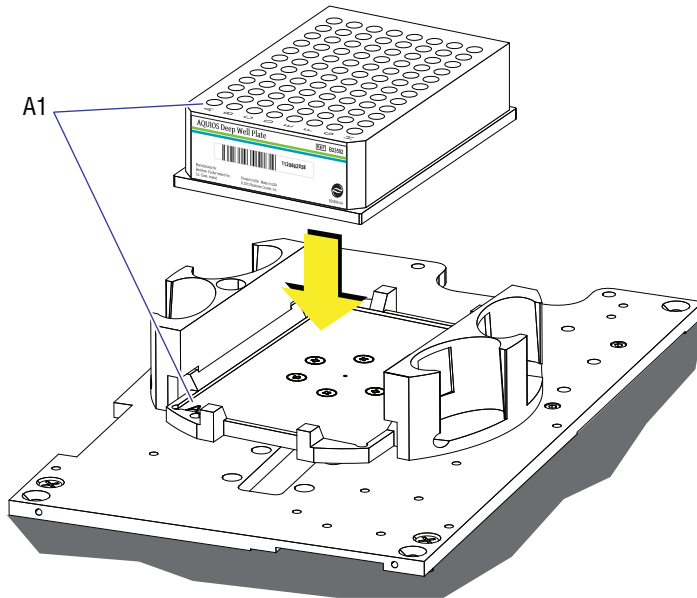
- 10 Remove the caps and insert the application specific reagents with labels facing outward. Refer to application specific System Guide for application specific reagents.



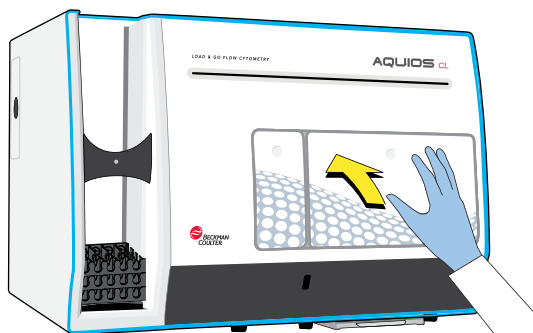
**⚠ CAUTION**


**Risk of probe damage if plate is mis-positioned in the plate platform. Make sure that plate is locked in by the edges of the plate platform.**

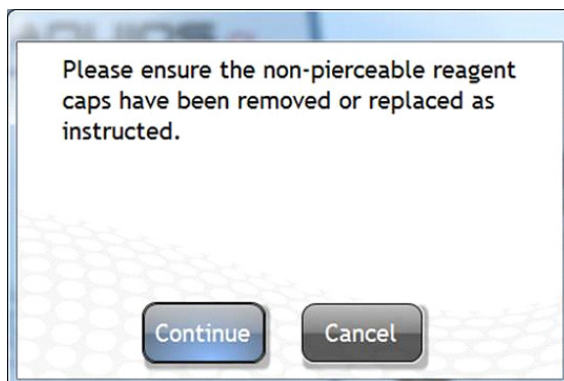
- 11** Insert the 96-deep-well plate. Ensure well A1 of the plate is next to the A1 on the plate holder and the bar code label is facing the front.



- 12** Close the reagent door, ensuring to press the top center firmly so that the latch engages.




- 
- 13 Select  from the Status bar and the following Warning appears.



**NOTE** If it has been <24 hours since the instrument was started, selecting  initiates a quick Startup rather than a full Startup. This quick Startup primes and prepares the system for operation. This only occurs if the system was previously on, and the software had been exited, but the system was not shut down.

**NOTE** When Start is selected, if any cassettes are in the Autoloader, they are ejected and will not be run.

**NOTE** The connection to the LIS is made available upon startup. Connection status is controlled with the LIS button.

- 
- 14 Select . The START cycle runs. When it is complete, the reagents and plate are scanned and the Reagents Levels dialog is displayed.

- 
- 15 Verify the levels of the onboard reagents and, if necessary, supply new reagents. If you need detailed instructions, see [Replacing Reagents and Consumables](#) in [CHAPTER 11, Replacement Procedures](#).

- 
- 16 Close the Reagent Levels dialog; the Main screen ([Figure A.1](#)) appears.
-



## Overview

---

Perform the following quality control checks using application specific controls to ensure that your system is working accurately and precisely. Run QC samples to verify the performance of the instrument before analyzing non-QC specimens. Refer to the application specific System Guide for information regarding the application specific quality control procedures and material.

This chapter contains information about:

- [Quality Control Checks](#)
- [Run QC Samples](#)
- [QC Screen](#)
- [Instrument Tab](#)
- [Instrument Drift Tab](#)

## Quality Control Checks

---

The system automatically verifies the optical, fluidic and electronic stability of the instrument. The control data is automatically populated into the Levey-Jennings charts of the QC screens: Results, Instrument Separation and Instrument Drift.

A compensation check is automatically performed while running the controls. The message “Compensation Passed” or “Compensation Failed” is then displayed under the Compensation Field of the control run.

The AQUIOS system results are displayed and flagged based on the generated values. In general, the system displays fewer digits than is that which is generated.

Results are rounded using standard rounding procedures. As a reminder, to round off decimals:

1. Find the place value you want (the 'rounding digit') and look at the digit to the immediate right of it.
2. If the digit to the right of the place value is less than 5, keep the original place value, and drop all digits to the right of the place value.
3. If the digit to the right of the place value is 5 or greater, add one to the place value, and drop all digits to the right of the place value.

For instance, 4.94 would display as 4.9, but 4.95 would display as 5.0.

For control results, if the assay range is, for example, 20-25, a result of 20 could be flagged as being out of range low, if the generated result is actually 19.9.

The same applies when comparing sample results to the normal and action ranges.

## Run QC Samples

---

**IMPORTANT** Following good clinical diagnostic practices, controls should be run in the same mode as your patient samples.

For more information on Running QC Samples, see your application specific AQUIOS System Guide.

**NOTE** If QC Results are not acceptable, refer to [CHAPTER 9, Troubleshooting](#).

## Daily QC

Daily Quality Control is a critical component of ensuring the system's performance. Refer to Daily QC Procedure.

### **WARNING**

**Risk of personal injury or contamination. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection.**

### **WARNING**

**Risk of personal injury or contamination if you have skin contact with the waste container, its contents, and its associated tubing. The waste container and its associated tubing can contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the contents of the waste container in accordance with your local regulations and acceptable laboratory procedures.**

### **CAUTION**

**Risk of misleading results if the control package insert guidelines are not followed thoroughly. Before using the controls, read and follow the package insert directions; then confirm that the assay values for the specific control lot have been registered in the instrument by going to "SetUp", then "Reagent Info". Select the reagent and lot number from the drop down menu. The assay values will be displayed.**

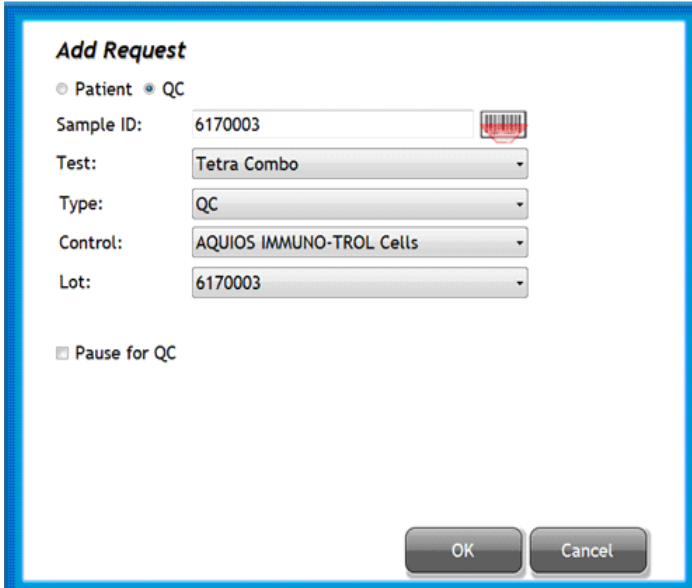
## Daily QC Procedure

---

- 1 For a new lot of controls, scan the assay sheet as described in [Starting a New Lot of Controls](#) in [CHAPTER 11, Replacement Procedures](#).

- Bring the reagents to operating temperature. Refer to the application specific reagent Instructions for Use.
- Mix the control per the reagent specific Instructions for Use. See [Running a Sample Using the Single-tube Loader](#) in [CHAPTER 5, Sample Processing](#).

- Select , then select  to create a Test Request as illustrated below.





**NOTE** Refer to [Request Screen](#) and [Add Request for a QC Sample Screen \[Tetra Application\]](#) in [APPENDIX A, Software Screens](#).

**IMPORTANT** When manually entering the Sample ID, do not use leading or trailing spaces.

- Enter the sample ID. The automatic entry method is recommended:

**Automatic Method:**

- Select  next to the Sample ID field. The barcode reader next to the Single-tube Loader activates.
- Scan barcode on the control tube. If the barcode reader deactivates, select  again. Once the barcode is scanned in, the QC field, Control type, and Lot information will be automatically populated when Test is displayed in the Test drop-down. See [Reagent Info](#) in [CHAPTER 8, Reagent Info](#).

**Manual Method:**

- a. Select and fill in the Sample ID field.
- b. Use the Test drop-down menu to select the test.
- c. Select QC from the Type drop-down menu.
- d. Use the Control drop-down menu to select the control name.
- e. Use the Lot drop-down menu to select the lot number.

**NOTE** If you select Pause for QC, once QC samples have completed analysis, the autoloader remains paused if QC fails so that the problem can be corrected before running subsequent samples. If QC passes, the autoloader continues processing additional cassettes in the autoloader.

- 
- 6 Use the Test drop-down menu to select the desired test.

- 
- 7 Select .

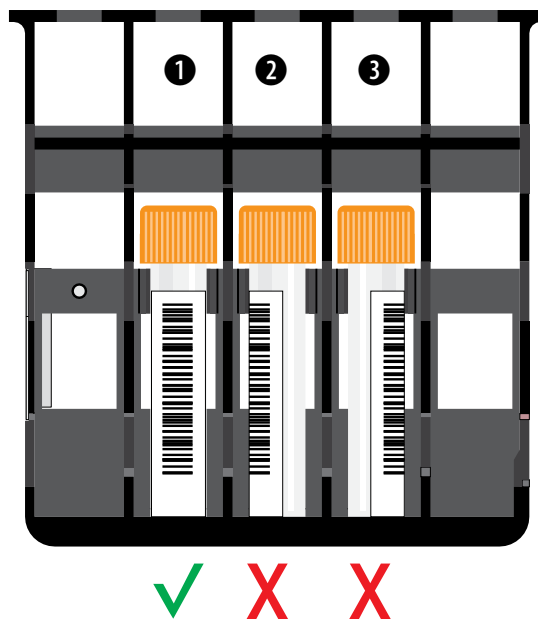
---

**IMPORTANT** Following good clinical diagnostic practices, controls should be run in the same mode as your patient samples.

- 8 Load the control.

**If controls are loaded on the autoloader:**

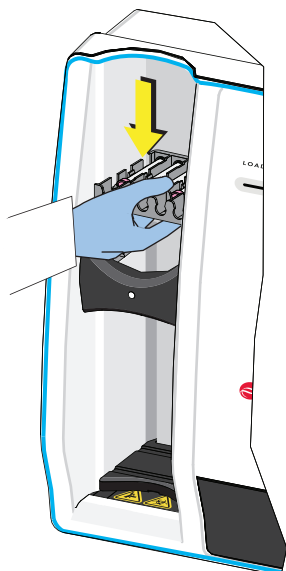
- a. Insert bar-coded control tube in the appropriate cassette size.
- b. Ensure that the control's barcode is properly positioned for the barcode reader as shown below.



**NOTE** The Autoloader stall detection prevents processing of any cassettes loaded incorrectly or loaded in the wrong orientation. Load the cassettes as instructed below.



- c. Hold the cassette from the cap-pierce side and insert it horizontally at the top portion of the autoloader with all unprocessed cassettes.

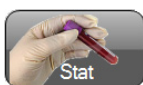


**CAUTION**

**Risk of losing onboard samples if leaving the Single-tube Loader open for an extended period of time. Always load your sample right after the Single-tube Loader opens, and close the door immediately after loading your sample.**

**If controls are loaded on the Single-tube Loader,**

- a. Gently mix the controls as instructed on the package insert.




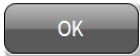
- b. At the Main Screen, select  to open the single-tube door. If the system is available, the message *Please press on the single tube door, and then wait for the system to release it* appears. Open the door by pressing the top-middle part of the door in one single, solid motion. If the system is busy, the message *The system is busy! Press on the single-tube door, and then wait for the system to release it* is displayed. Open the door by pressing the top-middle part of the door in one single, solid motion, and when the system is no longer busy, the door automatically opens. If there is a tube in the Single-tube Loader, the message *Please remove any tubes from the Single-tube loader* is displayed.
- c. Remove the tube and select . The Sample Information screen is displayed. Select **QC** radio button. See [Figure 4.1](#).

Figure 4.1 QC Sample Lookup Screen

**Sample Information** No Sample ID!

Patient  QC

Sample ID:

Test:

Type:

Control:

Lot:

Remember to Mix the Sample!

Lookup

- d. Scan the barcode, and the system automatically looks for the Sample ID. When manually entering the barcode, enter the necessary information, see [Figure 4.2](#).

Figure 4.2 Sample Information Screen - Request Found

**Sample Information** Request Found

Patient  QC

Sample ID:

Test:

Type:

Control:

Lot:

Remember to Mix the Sample!

Lookup

- e. Load the sample into the appropriate tube position per [Table 5.1](#).
  - f. Immediately after loading, close the Single-tube door. Allow the control tube to process and results to be displayed on the RESULTS screen.
- 
- 9** Verify the QC results on the Review and QC screens before running specimens. See QC Screen in [CHAPTER 4, Quality Control](#) and Review Screen in [CHAPTER 6, Data Review](#).
- 
- 10** Select **Stat** to open the Single-tube door to retrieve the control tubes.
- 
- 11** Store Controls upright in the refrigerator, refer to the reagent Instructions for Use.
-

## QC Screen

The QC screen (Figure 4.3) displays the results of the control and is divided into three tabs: Results, Instrument Separation, Instrument Drift. Each tab displays Levey-Jennings charts that can be plotted according to test, control, lot, month, and year. This data reflects performance and stability of the instrument over the specified period. There is a General Selection Bar displayed above the three QC tabs. See Figure 4.4. Refer to the application specific System Guide for further QC information.

Figure 4.3 QC Screen [Tetra Application]

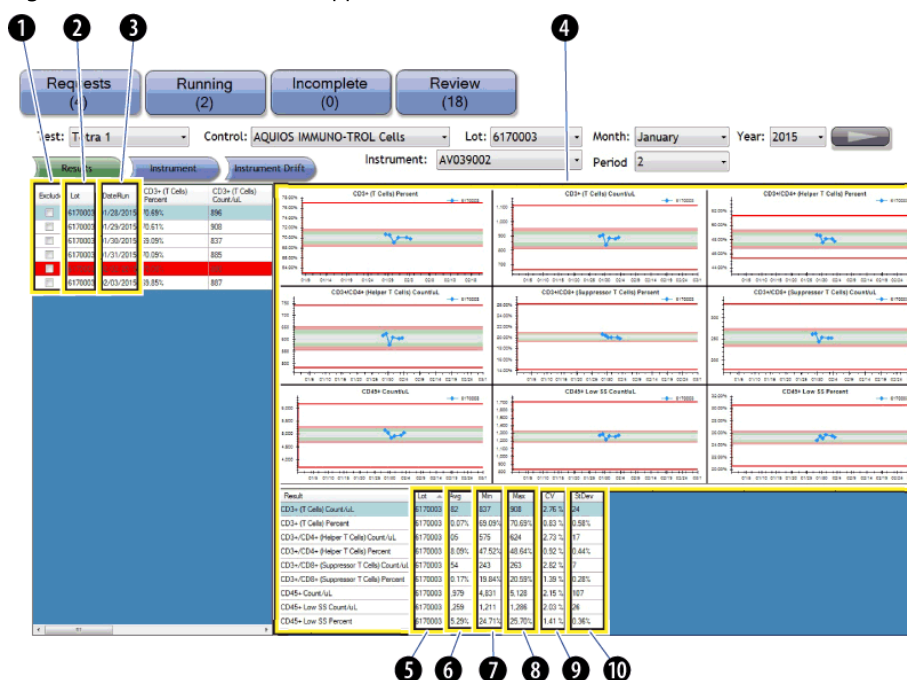



Table 4.1 General Table on QC Screens: Defined

1	<b>Exclude/Include Checkbox:</b> Use the checkbox to eliminate/include this run from the QC range calculation and select the  icon.	6	<b>Average:</b> Displays the average of all the runs listed.
2	<b>Lot:</b> Displays the control lot number used for the specified QC run.	7	<b>Min:</b> Displays the lowest value of all the runs listed.
3	<b>Date run:</b> Displays the date on which the selected QC run was performed.	8	<b>Max:</b> Displays the highest value of all the runs listed
4	<b>Display area:</b> Displays the QC results quantitatively for the selected QC run. Results displayed depend on the selected test.	9	<b>CV:</b> Displays the coefficient of variation of all the runs listed (Standard Deviation/Mean) x 100
5	<b>Lot:</b> Displays the lot number of the control reagent for all of the runs listed.	10	<b>StDev:</b> Displays the standard deviation of all the runs listed.

**NOTE** Summary statistics are listed at the bottom of the graphs. Use the vertical scroll bar to access all statistics.

**Figure 4.4** General Selection Bar [Tetra Application]




**Test:** Use the drop-down menu to select the test to display.

**Control:** Use the drop-down menu to select the type of control to display.

**Lot:** Use the drop-down menu to select the lot number to display, or select **All** to display all lots.

**Month:** Use the drop-down menu to select the starting month for data display.

**Year:** Use the drop-down menu to select the year for data display.

: Use this to refresh the displays for the selected Test, Control, Month, and Year. Also use to refresh displays after including or excluding data

**Instrument:** Use the drop-down menu to select the instrument serial number to display data for.

**Period:** Use the drop-down menu to select the period for data display. (1, 2, 3, or 4 months for Results, Instrument, and Instrument Drift)

**(Example:** Month = June, Period = 4, data is displayed for June, July, August, and September)

Table 4.2 shows the Action Toolbox.

**Table 4.2** Action Toolbox



Use to save the QC report as a PDF file for all QC tabs.



Use to print a report for all QC tabs.



Use to save the QC results to a (.csv or .crd) file for all QC tabs.

## Select Criteria for QC Screens

---

1 Select .

---

2 Use the Test drop-down menu to select the assay.

---

3 Use the Control drop-down menu to select the control.

---

4 Use the Lot drop-down menu to select the control lot number.

**NOTE** If “all lots” are selected, each lot is displayed as a separate line in a different color.

---

5 Use the Month and Year drop-down menu to select a time frame.

**NOTE** Use the drop-down menu to select the period for data display. (1,2,3, or 4 months for Results, Instrument, and Instrument Drift) [For example: Month = June, Period = 4, data is displayed for June, July, August, and September.]


---

6 Use the Instrument drop-down menu to select the instrument serial number to display data for it.

---

7 Use the Period drop-down menu to select the number of months for data display.

---

8 Select  to retrieve results. The data of interest displays on the screen.

---

9 Select the QC tab of interest , , or . Refer to the application specific System Guide for the application specific QC tabs.


---

**IMPORTANT** The **Exclude/Include** function is only available for users with the Reviewer/Editor or Administrator privileges.

10 Use the **Exclude/Include** checkbox in the data table on the left to remove or to restore a data point.

**NOTE** If a data point is excluded, it is still used by the system for flagging purposes.

---

11 Select  again to apply Exclude/Include changes.

**NOTE** All changes apply to the statistics and Levey-Jennings charts.

---

**NOTE** If the message *No Records Found* appears, then no QC data is available for the selected criteria.

## Create a QC Report PDF File

---

1 Select the criteria for the QC screen.

---

2 Select .

---

3 Select  .

---

4 Enter the file name.

---

5 Select the PDF file location.

---

6 Select  .

---

## Export QC Data

---

1 Select the criteria for the QC screen.

---

2 Select  .

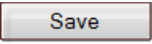
---

3 Select  .

---

4 Enter the file name and location, select file type (CSV or CRD).

---

5 Select  . The QC data shown is exported to a CSV or CRD.

---

## Print QC Report

---

1 Select the criteria for the QC screen.


---

2 Select  .

- 
- 3 Select  .
- 

## Display the Results for a QC Data Point

---

- 1 Select the criteria for the QC screen.
- 
- 2 Select  .
- 
- 3 Double-click on an entry in the data table on the left.
- 
- 4 View the results for the selected entry, see your application specific AQUIOS System Guide.
- 

## Instrument Tab

---

The Instrument Screen Levey-Jennings charts keep track of the changes over time in the Separation Quotient for application specific control material.

**NOTE** This varies depending on the test selected and the control being viewed.

The definition of the Separation Quotient Statistic is as follows:

Separation Quotient (SQ) is an indicator of relative sensitivity and resolution and can be used as an index that indicates how well separated two different populations are, such as cells versus debris, or lymphocytes versus monocytes. The larger the separation quotient, the better the separation.

The separation quotient is used as a form of quality control.

For two populations the separation between them for a given parameter is defined as:

- The difference between the 2 SD points is divided by the difference of the mean channel numbers. All calculations are done using the log of the data to take the variation between channel number and standard deviation of the function.
- The above function returns a number less than or equal to one.
- For readability the number is multiplied by 10.

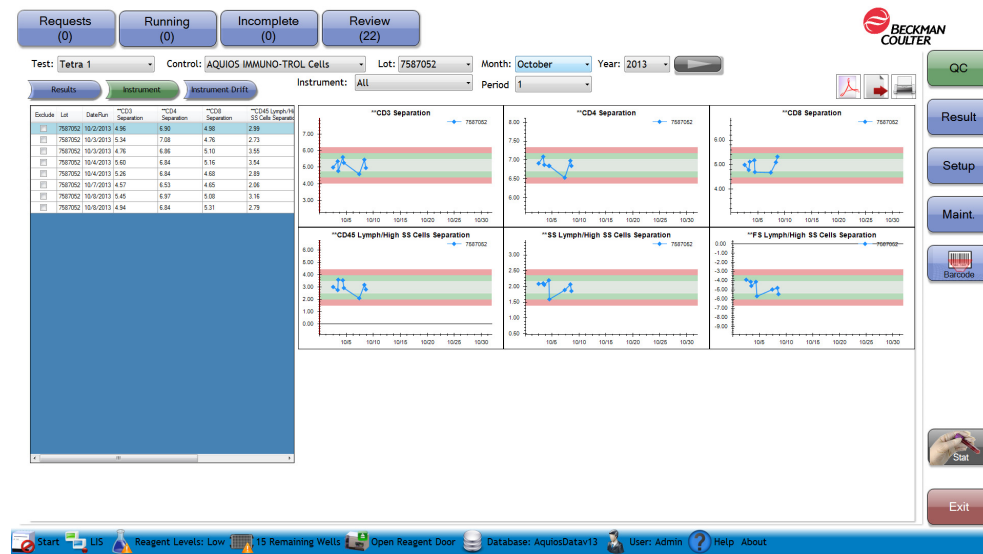
The end result is a numeric means (see [Table 4.3](#)) of qualifying separation of populations in the data plots for a test.

**Table 4.3** Separation Quotient Statistics

Numeric Range	Meaning
3 to 10	Excellent separation such that >99% of the data points in the populations are separated from each other
0 to 3	Good separation >2 SD or approximately 95% of the data points in the populations are separated from each other.
0	Point at which populations of 2 SDs touch; approximately 5% of the data points in the populations overlap.
-3 to 0	Moderate separation at which >5% of the data points in the populations overlap.
<-3	Poor separation which worsens as the numbers decrease.

**NOTE** For application specific examples, see your application specific AQUIOS System Guide.

**Figure 4.5** Instrument Tab [Tetra Application]



There is a general table listed on the left of the QC screen. See [Table 4.1](#) for details. Use the horizontal scroll bar to access all statistics.

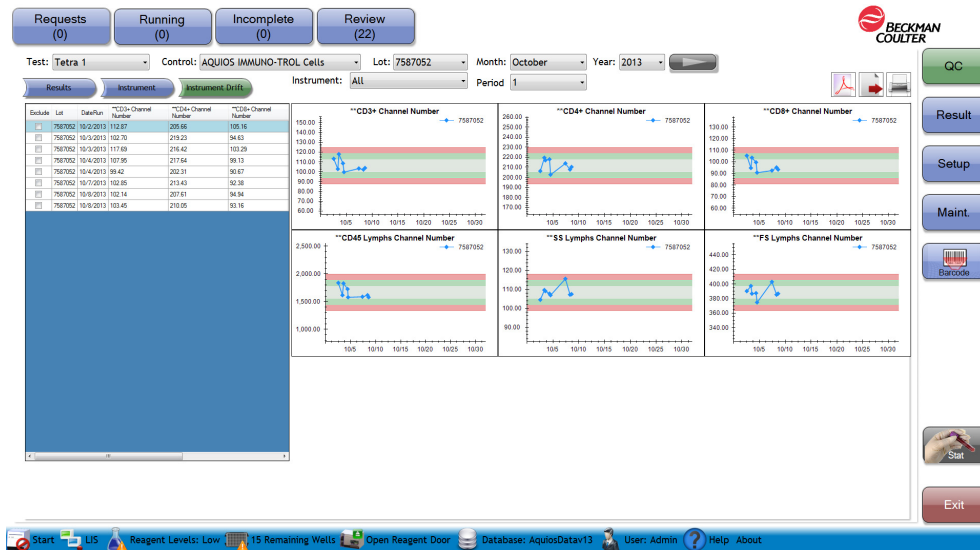
**NOTE** For application specific information regarding the Instrument Tab in [Figure 4.5](#), see your application specific System Guide.



## Instrument Drift Tab

The Instrument Drift Levey-Jennings charts display the sub-population's channel number fluctuation for application specific control material. This data reflects the changes in fluorescence intensity over the specified period. Changes in fluorescent intensity can occur with changes in standardization, or when there is a change in lots of monoclonal antibodies and/or controls.

**Figure 4.6** Instrument Drift Tab [Tetra Application]



There is a general table listed on the left of the QC screen. See [Table 4.3](#) for details. Use the horizontal scroll bar to access all statistics.

**NOTE** For application specific information regarding the Instrument Drift Tab in [Figure 4.6](#), see your application specific System Guide.



## Overview

---

This chapter contains information about:

- [Specimen Collection](#)
- [Workflow Overview](#)
- [Load-&-Go Workflow](#)
- [Options for Running Specimens](#)
- [Add Test Request for a Patient Sample](#)
- [Running Samples Using the Autoloader](#)
- [Running a Sample Using the Single-tube Loader](#)
- [Data Review](#)

## Specimen Collection

---



**Risk of misleading results and/or biohazard spills if specimen tubes are under-filled or over-filled with blood. The adequate ratio of blood to anticoagulant must be observed. A space must be left between the cap and the blood to allow for proper mixing and to prevent any blood spills while piercing the sample.**

For sample collection methods and safety procedures, refer to:

- CLSI document H3 – Procedures for the Collections of Diagnostic Blood Specimens by Venipuncture.
- CLSI document M29 – Protection of Laboratory Workers From Occupationally Acquired Infections.

For information on the minimum volume required, see your application specific AQUIOS System Guide.

## Workflow Overview

---

The AQUIOS system is designed for simplicity and minimal interaction by the user. To operate the AQUIOS CL flow cytometer, follow the workflow overview described in [Workflow Steps](#).

## Workflow Steps

1. Perform Startup. See [Startup](#) in [CHAPTER 3, Daily Startup](#).
2. Run Quality Control samples.
  - a. Create a QC request. See [Daily QC](#) in [CHAPTER 4, Quality Control](#).
  - b. Load a QC sample. See [Daily QC](#) in [CHAPTER 4, Quality Control](#).
  - c. Review a QC sample result.
    - For Auto Transmit, see [Auto Transmit](#) in [CHAPTER 8, Setup](#).
    - For generating reports, see [Setup Default Reports Option for a Specific Test](#) in [CHAPTER 8, Setup](#).

**NOTE** It is possible to setup the system to automatically transmit results to the LIS. Automatically transmitted results are sent to the Results Screen.

- d. Unload QC sample. See [Daily QC](#) in [CHAPTER 4, Quality Control](#).
  3. Run Patient Samples:
    - a. Create a request:
      - See [Add Test Request for a Patient Sample](#).
      - See [Setup Default Test \(Autoloader Only\)](#) in [CHAPTER 8, Setup](#).
    - b. Load samples.
    - c. Review samples results:
      - For Auto Transmit, see [Auto Transmit](#) in [CHAPTER 8, Setup](#).
      - For generating reports, see [Setup Default Reports Option for a Specific Test](#) in [CHAPTER 8, Setup](#).
- NOTE** Verify all sample IDs before reporting results. Review all data plots and results, including exported results prior to reporting results. See [Data Review](#) and refer to your application specific System Guide.
- d. Unload a sample.

4. Perform a shutdown. See [Shutdown](#) in [CHAPTER 7, Shutdown](#).

## Load-&-Go Workflow

---

For maximized workflow, providing minimal operator steps: set up automatic requests and automatic result transmission to the LIS.

- Create Automatic Requests:
  - See [LIS Setup Screen](#) in [CHAPTER 8, Setup](#).
  - See [Setup Default Test \(Autoloader Only\)](#) in [CHAPTER 8, Setup](#).

- Set up Auto Transmit:
  - See [Auto Transmit](#) in [CHAPTER 8, Setup](#).

## Options for Running Specimens

---

### WARNING

**Risk of personal injury and/or contamination:**

- To prevent possible injury or biohazardous exposure, you must wear proper laboratory attire, including gloves, a laboratory coat, and eye protection.
- Operating the instrument while the waste level sensor is disconnected can cause biological contamination. To prevent biological contamination, do not operate the instrument while the waste level sensor is disconnected.

### WARNING

**Risk of personal injury or contamination if you have skin contact with the waste container, its contents, and its associated tubing. The waste container and its associated tubing can contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the contents of the waste container in accordance with your local regulations and acceptable laboratory procedures.**

### WARNING

**Risk of injury from moving parts. Operating the instrument with doors or covers open can cause personal injury. Ensure that all covers and doors are closed.**

Specimen tubes can be loaded in the autoloader or the Single-tube Loader. The Single-tube Loader processes one sample at a time and also functions as a Stat loader. A higher priority is given to a specimen tube loaded into the Single-tube Loader; therefore, it is processed ahead of the specimen tubes loaded in the autoloader.

The autoloader has continuous loading capability with up to 40 samples at once. The samples are automatically processed according to the unprocessed pile cassette position (bottom to top) and sample position within a cassette (position 1 to 5, see [Figure 5.1](#)). For a cassette, place the cassette that you want to run first at the bottom of the unprocessed pile and place the specimen you want to run first in position one (1).

## Before Running Specimens



**Risk of incorrect flagging if patient reference ranges are not validated before running samples. Follow your laboratory's procedure for establishing patient reference ranges.**

Before proceeding to load specimens, verify the following:

- That Daily Startup was performed. See [Startup](#) in [CHAPTER 3, Daily Startup](#) for more information.
- That the AQUIOS reagents and reagent levels are suitable for the number of samples to be run. If you need to replace reagents, see [Replacing Reagents and Consumables](#) in [CHAPTER 11, Replacement Procedures](#). It is recommended to replace reagents before starting the workload. Replacing reagents and opening the reagent door while operating the instrument risks losing onboard samples. If you need to replace reagents while the system is running, perform the change as quickly as possible. Otherwise, the onboard samples may overlyse or over-incubate and the system will notify of these states.
- That QC was performed before loading non-QC samples. See [Quality Control](#) in [CHAPTER 4](#), for details.
- That the specimen to be loaded complies with the minimum running volume. See [Specimen Collection](#).
- That a Test Request has been created or a Default Test selected if running samples on the Autoloader. See [Setup Default Reports Option for a Specific Test](#) in [CHAPTER 8, Setup](#).

## Selecting the Applicable Running Option

Use the applicable instructions:

**IMPORTANT** Poor quality specimens may require inspection and special attention. Specimens that may contain fibrin, cell fragments, or other debris, or were difficult to collect such as oncology specimens may require special handling. Follow your laboratory's procedures for handling these types of specimens.

- [Running Samples Using the Autoloader](#)
- [Running a Sample Using the Single-tube Loader](#)

## Add Test Request for a Patient Sample

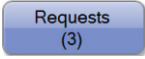
---

**IMPORTANT** If the LIS connection is enabled, the system automatically retrieves any test for the specimen ID upon barcode scanning (Use Host Query enabled) or upon order entry in LIS (Use Host Query not enabled).

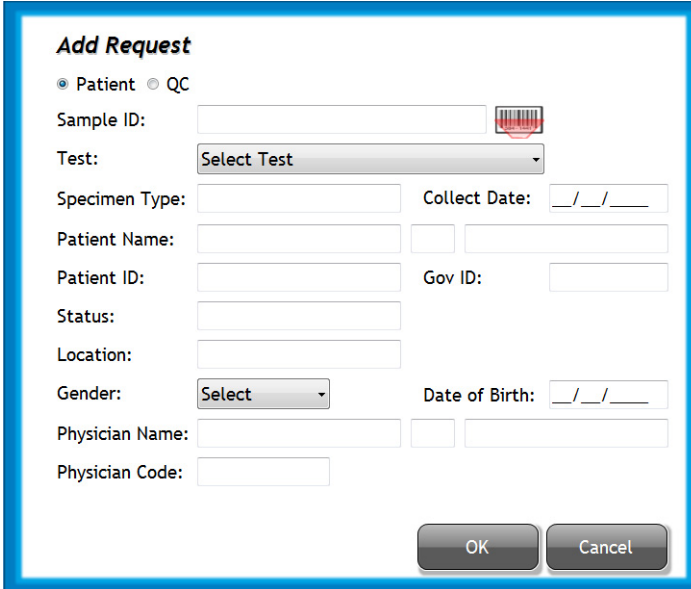
The test request can be created before the tubes are ready to be loaded into the system. Once the test request is created, the request appears on the Request Details List and it remains there up to a

maximum of 30 days, until the sample tubes are ready to be loaded on the Single-tube Loader or on the autoloader.

**NOTE** Unused Test Requests are purged by the system after 30 days.

1 Select  from the Main Screen. See [Figure A.1](#).


2 Select . The Add Request Screen is shown below.



**NOTE** For detailed descriptions for the Add Request for Patient Sample screen, see [Add Request for a Patient Sample Screen](#) in [APPENDIX A, Software Screens](#).

3 Ensure the **Patient** radial is selected.



**IMPORTANT** Note that leading and trailing spaces are removed from the Sample ID when Test Request is

added using .

4 Enter the sample ID. The automatic entry method is recommended:

**NOTE** For Sample ID read from a barcode, the minimum length is five characters. For manual entry, the minimum length for the Sample ID is one character. Do not use spaces before or after the Sample ID when entering into the Sample ID field. In addition, the backslash character (\) is not supported.

**Automatic Method:**

- a. Select  next to the Sample ID field. The barcode reader next to the Single-tube Loader activates.
- b. Scan the barcode on the specimen tube. If barcode reader deactivates, select  again.

**Manual Method:**

- a. Select and fill in the Sample ID field.

- 
- 5 Use the Test drop-down menu to select the desired test. Enter any other information for this specimen such as name, gender, Date of Birth, etc. as needed.

**NOTE** The Sample ID and Test are required to generate a request. All other fields are optional.

- 
- 6 Select .

---

## Running Samples Using the Autoloader

---

 **WARNING**

**Risk of biological contamination. Handle all specimens, samples, and all material coming into contact with them as if capable of transmitting infection, and dispose of with proper precautions.**

 **WARNING**

**Risk of personal injury from moving parts. Operating the instrument with doors or covers open can cause personal injury. Ensure that all covers and doors are closed.**

**IMPORTANT** Operators should pay attention to any errors that occur during the following analysis. If an error should occur, see [CHAPTER 9, Troubleshooting](#).

- 
- 1 Create a request using one or more of the following options:
    - a. Add a test request for a sample. For detailed instructions, see [Add Test Request for a Patient Sample](#).

The system automatically matches the Sample ID on the scanned barcode to the test request entered in advance.



- b. Use the Default Test option. If you need detailed instructions, see the [Setup Default Test \(Autoloader Only\)](#) in [CHAPTER 8, Setup](#).
- c. If LIS is enabled, Test Requests can be received from the LIS. See [LIS Setup Screen](#) in [CHAPTER 8, Setup](#).

**CAUTION**

**Risk of sample misidentification. Ensure that the sample ID on the barcode is a unique number. If you reuse the sample ID numbers, be sure to archive the old results to avoid duplicate numbers.**

**CAUTION**

**Risk of flow cell clog if the recommended number of pierces are exceeded. Specimen tubes can be pierced a maximum of eight (8) times with the following exceptions:**

- Sarstedt Monovette tubes can be pierced a maximum of five (5) times.
- The 2 mL Covidien 10.25mmX50mm Kendall Monoject tubes should be run in Single-tube Loader as open vial only.

**When using the Sarstedt Monovette tubes Beckman Coulter recommends that you remove the cap when using the Single-tube Loader.**

**IMPORTANT** If the system has insufficient reagents to process a request with the Autoloader, the message *The system has stopped because there were not enough reagents or wells to run a test* appears after loading the sample and/or closing the reagent door. Allow running samples to finish analysis and then replace the necessary reagents. See [Replacing Reagents and Consumables](#) in [CHAPTER 11, Replacement Procedures](#).

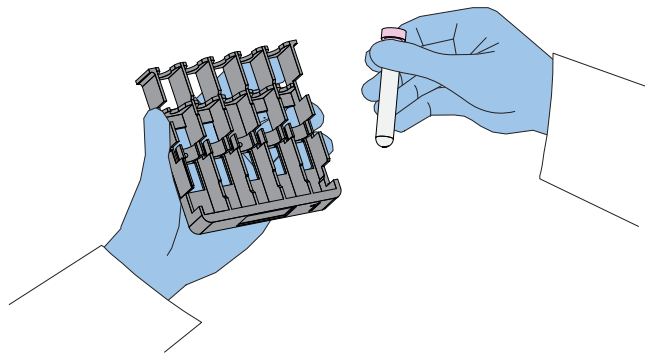
- 2 Verify all specimen tubes to be loaded in a cassette are cap-pierceable with a properly applied, unique barcode label. Make sure each tube complies with the autoloader tube list.

**NOTE** For compatible Tube List, see [Table C.1](#) in [APPENDIX C, Tube List](#).

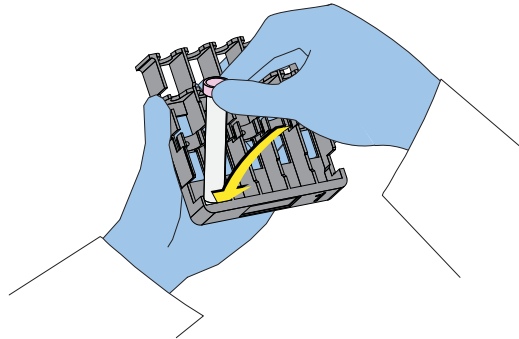
**WARNING**

Risk of biohazard spill and broken glass if the specimen tube is incorrectly placed with the pierceable cap facing the lower part of the cassette. Ensure that the specimen tubes are placed with the bottom of the tube contacting the lower part of the cassette. Always firmly hold cassettes from the sides not by the specimen tube.

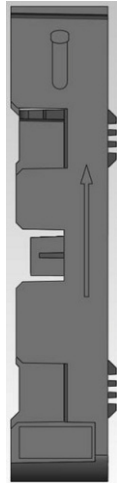
- 3 Insert each specimen tube into the appropriate cassette as follows:
- Firmly hold the cassette by the sides and proceed to insert one tube at a time.



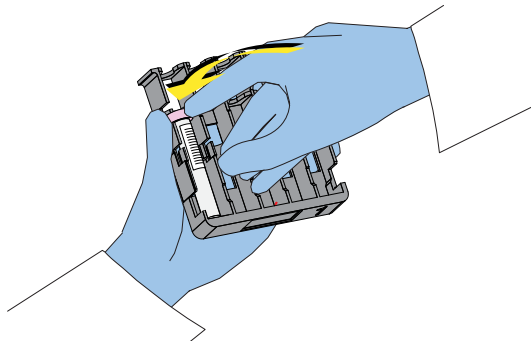
- Hold the tube from the cap and insert the bottom part of the tube inside the lower part of the specimen cassette.



A symbol on the right side of the cassette indicates the correct orientation of the specimen tube in the cassette.

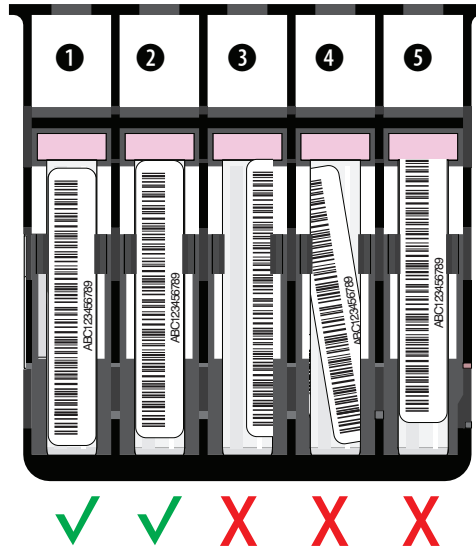


- c. Before securing the top part of the tube, align the barcode label so that it faces upward as the tube is fully secured into the cassette.
- d. Softly push the top part of the tube to lock into the cassette.



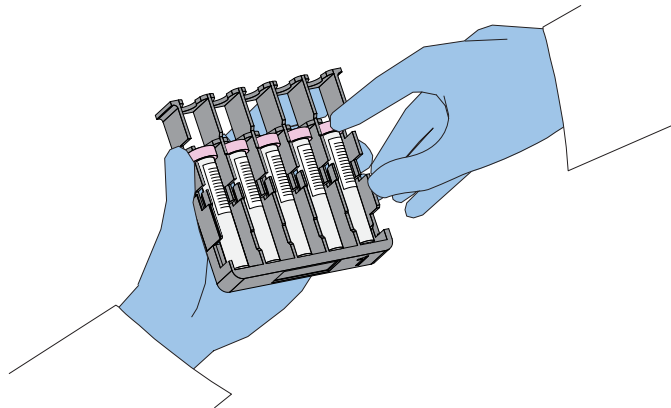
- e. Verify that the tube barcode is properly positioned in the center of the tube for the barcode reader as shown below. [Figure 5.1](#) shows specimen tube placement in cassettes.

**Figure 5.1** Specimen Tube and Barcode Placement in an Autoloader Cassette



**NOTE** Samples are automatically processed according to the unprocessed cassette position (bottom to top) and sample position within a cassette (Position 1 to 5). See [Figure 5.1](#).

- f. Repeat steps [a](#) through [e](#) until the cassette contains the specimen tubes that need to be processed.



**WARNING**

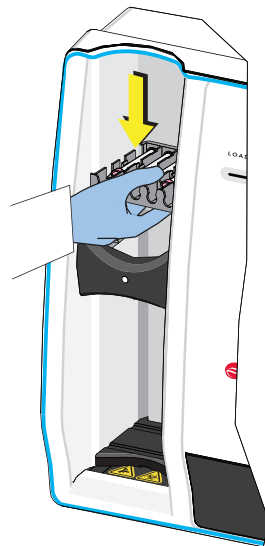
Risk of pinch-point injury if using the autoloader in a different manner than directed. Keep your hands away from the autoloader's moving parts.

**CAUTION**

Risk of instrument damage if attempting to fit more than eight cassettes at a time in the system. Only load eight cassettes at any given time. Do not force the autoloader.

- 4 Load each cassette in the autoloader as follows:
  - a. Hold the cassette from the cap-pierce side and insert it horizontally at the top portion of the autoloader. See [Figure 5.2](#).

**Figure 5.2** Specimen Cassette Placement on Autoloader



**NOTE** Place the cassette you want to run first at the bottom of the unprocessed pile and place the sample you want to run first in position one (1). See [Figure 5.1](#).

- b. Load up to eight cassettes at a time, in any desired order. Cassettes can be loaded at any time as long as the eight-cassette maximum is not exceeded. This includes processed and unprocessed cassettes.

After a cassette is loaded, the system mixes and aspirates the samples as follows:

- 1) The cassette is moved into the rocking station.
- 2) The cassette bar code is read. The bar code uniquely identifies the cassette.
- 3) The blood sample is gently rocked to produce an even distribution of cells prior to sampling.
- 4) The bar code reader reads the bar code label on each tube prior to starting the processing of the specimen.

- 5) Samples are aspirated from each specimen tube in the cassette. Then, the control arm pushes the cassette out of the rocking station and back through the exit port of the elevator.

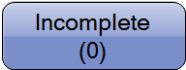
**NOTE** The continuous-loading capability allows you to remove processed or unprocessed cassettes at any time. The unprocessed cassettes remain suspended at the top of the autoloader. The processed cassettes rest at the bottom of the autoloader. If eight processed cassettes accumulate at the bottom of the autoloader, the system will stop until cassettes are removed from the bottom of the autoloader. See [Running Screen](#) in [APPENDIX A, Software Screens](#).

 **CAUTION**

**All results must be reviewed prior to release.**

- 5 Review the data according to your laboratory's protocol. Review all data plots and results, including exported results, prior to reporting results. See [Data Review](#). Suggested options include:
  - Auto Transmit to the LIS, if this option is on.
  - Manual review using your laboratory's guidelines.
  - Generate a report. See [Test Settings](#) in [CHAPTER 8 Setup](#).
  - Transmit data to the LIS and/or export results to a file.

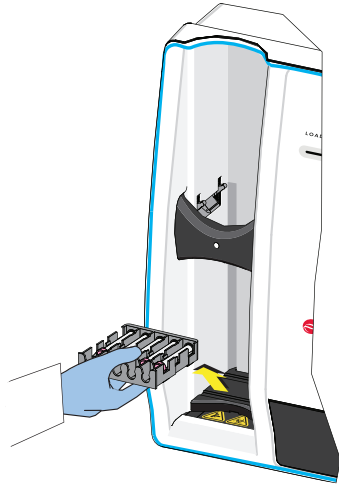
**NOTE** When running the application, refer to your application specific System Guide.

- 6 If a number other than 0 is shown is **Incomplete**, select  (located in the upper left area of the Workstation screen) to check that all the samples within the cassette were properly processed.

 **WARNING**

**The piercing needle may damage the cap septum of a Sarstedt tube. Inspect these tubes before removing from the autoloader and hold the cassette upright to avoid biohazardous spills.**

- 7 Remove any processed cassettes from the autoloader.



- 
- 8 Remove the individual specimen tubes from the cassette and store the specimen tubes according to laboratory protocol.
-

## Running a Sample Using the Single-tube Loader

---

 **WARNING**

Risk of biological contamination if the contents spill out of the specimen tube. Handle all specimens, samples, and all material coming into contact with them as if capable of transmitting infection, and dispose of with proper precautions.

 **WARNING**

Risk of injury from moving parts. Operating the instrument with doors or covers open can cause personal injury. Ensure that all covers and doors are closed.

 **CAUTION**

Risk of flow cell clog if the recommended number of pierces are exceeded. Specimen tubes can be pierced a maximum of eight (8) times with the following exceptions:


- Sarstedt Monovette tubes can be pierced a maximum of five (5) times.
- The 2 mL Covidien 10.25mmX50mm Kendall Monoject tubes should be run in Single-tube Loader as open vial only.

When using the Sarstedt Monovette tubes Beckman Coulter recommends that you remove the cap when using the Single-tube Loader.

**IMPORTANT** Do not place more than one specimen tube in the Single-tube loader. The system will not process specimens from the Single-tube loader if more than one specimen tube is present in the Single-tube loader.

**IMPORTANT** Operators should pay attention to any error messages that are displayed during the following analysis. If an error should occur, see [CHAPTER 9, Troubleshooting](#).

1 Create a request using one of the following options:

- a. Add a test request for a patient by selecting  on the Workstation Main screen. If you need detailed instructions, see [Add Test Request for a Patient Sample](#).
- b. Use the Default Test option if it is ON. If you need detailed instructions, see the [Setup Default Test \(Autoloader Only\)](#) in [CHAPTER 8, Setup](#).
- c. If LIS is enabled, send a test request to the system, or the system can automatically query (host query) the LIS for a request when it encounters a sample id for which there is not test request. If you need detailed instructions, see [LIS Setup Screen](#) in [CHAPTER 8, Setup](#).



**IMPORTANT** If the system has insufficient reagents to process a request on the Single-tube Loader, the message *The necessary reagents are not onboard! The sample cannot be run* appears after loading the sample and closing the single-tube door. The system does not have enough reagents to run the desired test. Allow running samples to finish analysis and then replace the necessary reagents. See [Replacing Reagents and Consumables](#) in [CHAPTER 11, Replacement Procedures](#).

- 2 Before loading a sample in the Single-tube Loader, verify the specimen tube complies with tube requirements for the Single-tube Loader.


**NOTE** For compatible tube specifications, see [Table 5.1](#) in [APPENDIX C, Tube List](#).

 **WARNING**

Risk of operator injury or damage to the Single-tube Loader door if the door is forced to open ahead of time. If the system is currently processing samples, there may be a delay before the door can be safely opened. Please wait for the Workstation to prompt you to open the door.

 **CAUTION**

Risk of triggering the wrong system actions if the single-tube loader door is not opened properly. Press on the single-tube door with one, single, solid motion and allow the system to open the door. Do not pull on the door to open it.

- 3 At the Main Screen, select  to open the single-tube door. If the system is available, the message *Please press on the single tube door, and then wait for the system to release it* appears. Open the door by pressing the top-middle part of the door in one single, solid motion. If the system is busy, the message *The system is busy! Press on the single-tube door, and then wait for the system to release it* is displayed. Open the door by pressing the top-middle part of the door in one single, solid motion, when the system is no longer busy, the door automatically opens. If there is a tube in the Single-tube Loader, the message *Please remove any tubes from the Single-tube*

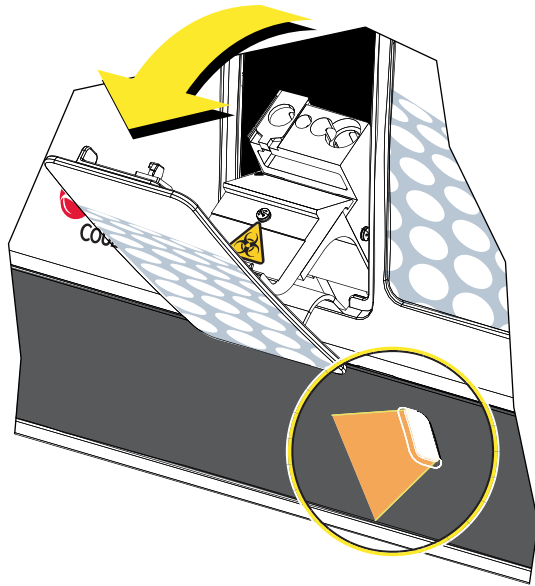
*loader* is displayed. Remove the tube and select . The Sample Information screen is displayed. See [Figure 4.1](#).

 **WARNING**

Risk of specimen mis-identification, ensure that previously processed specimen tubes are removed from the single tube loader.

- 4 Remove any specimen tube currently in the Single-tube Loader, and store according to your laboratory protocol.

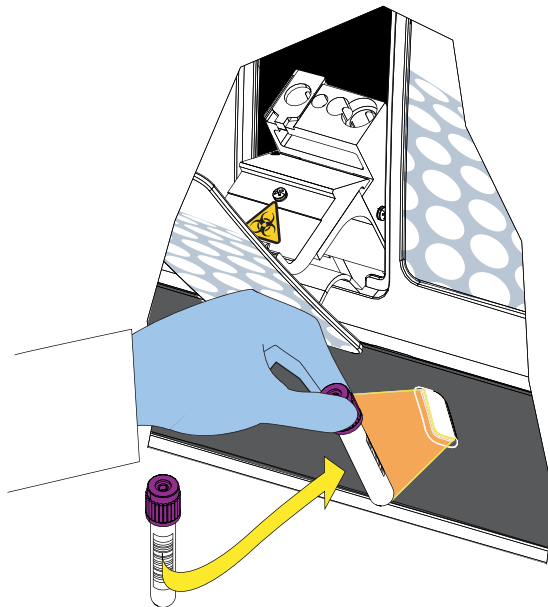
- 5 Verify the barcode reader is activated (lighted).



**WARNING**

**Risk of specimen mis-identification if the wrong tube is loaded after entering the specimen ID. Ensure that the tube with the specimen ID that is scanned or entered manually is the correct specimen tube.**

- 6 Enter the Sample ID manually or by scanning the barcode. To enter the Sample ID manually, type in the information into the Sample ID field. To enter the Sample by barcode, follow step 7.
- 7 Position the barcoded specimen tube so that the barcode is aligned and facing the barcode reader. Be sure to hold the barcoded tube vertically at a distance of about 10.2 cm (4 in.). If necessary, adjust the tube distance (back and forth) slowly while keeping the barcode straight and facing the barcode reader. The barcode reader beeps after the label is scanned.



- If a test request was entered in advance, enter the Sample ID and click on Lookup as shown below. The system automatically matches the Sample ID on the scanned barcode of the tube to the user request as shown below. The message *Request Found* appears, and data from the existing request populates the Sample Information screen. The data from the existing request is read-only. To edit the existing request, see [Edit a Request](#) in [APPENDIX A, Software Screens](#).

**NOTE** The Sample ID and Test are required to generate a request. All other fields are optional.

## Sample Processing

### Running a Sample Using the Single-tube Loader

**Sample Information** No Sample ID!

Patient  QC

Sample ID:

Test:

Specimen Type:  Collect Date:

Patient Name:

Patient ID:  Gov ID:

Status:

Location:

Gender:  Date of Birth:

Physician Name:

Physician Code:  **Remember to Mix the Sample!**

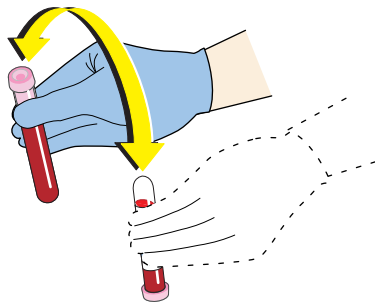
- If there is no existing Test Request, select a test and enter the sample information manually.

### CAUTION

**Risk of misleading results if sample is not properly mixed before presenting it to the Single-tube Loader. Mix the sample gently and thoroughly just before loading.**

- 8 Use one of the following options to gently mix the whole-blood specimen before placing the specimen tube in the Single-tube Loader:
  - Specimen tubes may be mixed on a rocker for one to three minutes immediately prior to analysis. If samples have been sitting more 2 hours, they may be mixed for three to five minutes.
  - Immediately before the specimen tube is inserted into the Single-tube Loader, mix the specimen by inverting the tube 8 to 10 times. Do not start mixing until the single-tube door is open and ready to receive the tube.

**NOTE** An inversion is one complete turn of the wrist (180° and back).



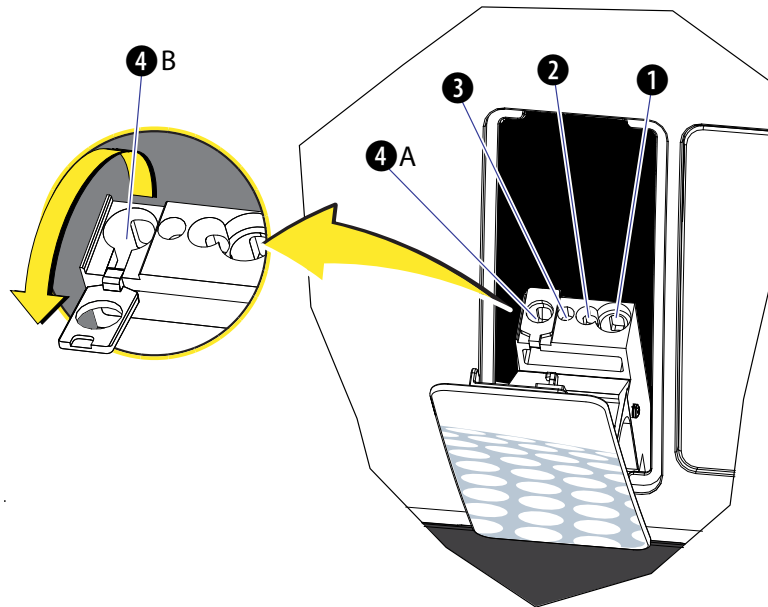
**! WARNING**

**Risk of injury and/or instrument damage if you force a specimen tube into the Single-tube Loader. Do not affix more than two labels on a specimen tube; tube should enter smoothly into the Single-tube Loader to avoid tube breakage, damage the loader, dislodging the specimen cap, and personal injury.**

- 9 Once mixing is complete, immediately insert the mixed specimen tube into the appropriate location in the Single-tube holder. See [Figure 5.3](#).

**NOTE** The Single-tube Loader can aspirate samples with either the cap on or off with the exception of Sarstedt tubes and tubes with caps that are not pierceable, that must always be run with the cap off in the Single-tube loader.

**Figure 5.3** Tube Holders



[Table 5.1](#) describes the positions where validated specimen tubes can be used in the Single-tube Loader.

**CAUTION**

**Risk of erroneous results or biohazardous exposure if a Sarstedt brand tube or 2 mL Covidien Kendall Monoject tube is run closed-vial in the Single-tube loader, only run Sarstedt tubes and 2 mL Covidien brand 10.25x50mm Kendall Monoject in open vial in the Single-tube loader.**

**Table 5.1** Single-tube Loader Positions from Right to Left


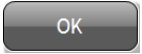
1	Uses 13 x 75 mm Hemogard, Conventional and Sarstedt type tubes, AQUIOS IMMUNO-TROL Cells control and AQUIOS IMMUNO-TROL Low Cells control tubes. <b>NOTE</b> The tubes which fit in type 1, 5, 6, 8 or 10 cassettes use this Single-tube position.
2	Uses a 10.25 x 50 mm specimen tube.
3	Position is not to be used. Do not place any tubes in this location.
4A	With flip in position, uses a 13 x 100 mm specimen tube. <b>NOTE</b> A Sarstedt 13 x 90 mm specimen tube can be used in position 4A.
4B	With flip moved out of position, uses a 16 x 100 mm specimen tube <b>NOTE</b> A Sarstedt 15 x 92 mm specimen tube can be used in position 4B.

**NOTE** Additional tube types may be available, refer to the application specific System Guides for more information.

**10** Close the Single-tube Loader door in one single, solid motion.

**WARNING**

**Risk of operator injury or damage to the Single-tube Loader door if you force the door to open ahead of time. If the system is currently processing samples, there may be a delay before the door can be safely opened. Wait for the Workstation to prompt you to open the door.**

**11** At the Main Screen, select  to open the single-tube door. If the system is available, the message *Please press on the single tube door, and then wait for the system to release it* appears. Open the door by pressing the top-middle part of the door in one single, solid motion. If the system is busy, the message *The system is busy! Press on the single-tube door, and then wait for the system to release it* is displayed. Open the door by pressing the top-middle part of the door in one single, solid motion, when the system is no longer busy, the door automatically opens. If there is a tube in the Single-tube Loader, the message *Please remove any tubes from the Single-tube loader* is displayed. Remove the tube and select . The Sample Information Screen is displayed. See [Figure 4.1](#).

**12** Store the specimen tube according to your laboratory’s protocol.

**13** Close the Single-tube Loader door immediately after removing the specimen tube.

 **CAUTION**

**All results must be reviewed prior to release.**

**14** Review the results according to your laboratory's protocol. Review all data plots and results, including exported results, prior to reporting results. See [Data Review](#). Suggested options include:

- a. Auto transmit to the LIS, if the option is on. See [Auto Transmit](#) in [CHAPTER 8, Setup](#).
- b. Manual review using your laboratory's guidelines.
- c. Generate a report. See [Test Settings](#) in [CHAPTER 8, Setup](#).
- d. Transmit data to the LIS and/or export results to a file.

**NOTE** When running the application, refer to the application specific System Guide.

## Data Review

### Review Data Displays

**IMPORTANT** There is a risk of reporting incorrect results. Data displays used to arrive at the test result for light scatter patterns, antibody staining profiles, and all gates and boundaries should be reviewed by a laboratory professional when interpreting the data. If results are suspect, follow your laboratory's procedures to resolve.

Data review should include the following:

- Review the light scatter patterns.
  - Verify any population of interest is above the discriminator to ensure no cell loss.
  - Verify any population of interest is separated as much as possible from other populations that are present (within biological constraints).
- Review the antibody staining patterns.
  - Verify overall expected staining patterns are observed; in other words, verify the fluorescence staining correlates to the antibody used in sample preparation.
  - Verify abnormally dim or negative sample staining patterns are in agreement with clinical presentation and other diagnostic data.
- Review Gate and Region boundaries.

Verify gates and regions encompass any populations of interest while at the same time exclude undesired events.





## Overview

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 **CAUTION**

Beckman Coulter does not claim to identify every abnormality in all samples. Beckman Coulter recommends using all available options, including flags, notifications, normal ranges, action ranges, system messages, and internal checks.

Beckman Coulter recommends avoiding the use of one type of message or output to summarize results or patient conditions. There may be conditions where the presence of a rare event may fail to trigger a flag or notification.

Look for data patterns when examining results. In all cases, follow your laboratory's policy for reviewing the sample results.

This chapter contains information about:









- [Action Toolbox](#)
- [Review Screen](#)
- [Load Regions and/or Patient Information](#)
- [Edit Regions and/or Patient Information](#)
- [Result Screen](#)
- [Flags And Notifications](#)

## Action Toolbox

Figure 6.1 Action Toolbox



Table 6.1 Action Toolbox: Defined

Item	Definition
	<p>Use to display the reagent information for the sample run. The reagent information includes: reagent name, lot number and vial number, closed vial expiration date, date system first detected the reagent and the subsequent open vial expiration date.</p> <p><b>NOTE</b> The AQUIOS CL Flow Cytometer system tracks the remaining tests of the AQUIOS Cleaning Agent.</p> <p><b>NOTE</b> The AQUIOS CL Flow Cytometer system does not track the AQUIOS Sodium Hypochlorite Solution. You must track the expiration date of the AQUIOS Sodium Hypochlorite Solution upon use.</p>
	<p>Use this icon to review, review and send to the LIS, reject or reject and rerequest result.</p> <p><b>NOTE</b> If connected to an LIS, check <b>Reviewed&gt;Send to LIS</b> to transmit the results to the LIS.</p>
	<p>Use to print the report.</p> <p><b>NOTE</b> Reports show the same graphs, results, Run Date and Analysis date as the display.</p>
	<p>Use to save report in a PDF format.</p> <p><b>NOTE</b> Reports show the same graphs and results as the display.</p>
	<p>Use to export results as an FCS listmode (.lmd) or an native format (.crd) file.</p>
	<p>Use to access the history of the changes performed on the regions and/or the patient information of the selected sample run. Select any entry in the Change History list to view the results after each saved change.</p> <p><b>IMPORTANT</b> Adjusting compensations or regions is not routine. Compensation and regions can only be adjusted by an Operator with special access, such as an Administrator or Reviewer/Editor.</p>
	<p>Use to adjust compensation manually or to change the region and/or patient information for a sample. The edit action toolbox appears when Edit is enabled.</p> <p>Changes to regions and/or patient information are tracked on the change history icon.</p>
	<p>Use to save results if regions, compensation or patient information have been edited.</p> <p><b>NOTE</b> The existing results are not lost; they are preserved in the Change History.</p>

The Reagent Screen is shown in Figure 6.2.

Figure 6.2 Reagent Screen [Tetra Application]

Reagent	Lot Number	Container	Expiration Date	Date Opened	Open Vial Expiration
AQUIOS Tetra-1 Panel	6080002	787	12/27/2014	09/08/2014	10/08/2014
AQUIOS Tetra-2+ Panel	6090001	471	11/23/2014	09/08/2014	10/08/2014
AQUIOS Lysing Reagent A	7901006	78	10/14/2014	09/08/2014	12/07/2014
AQUIOS Lysing Reagent B	8901006	78	10/14/2014	09/08/2014	12/07/2014
AQUIOS Lysing Reagent A	7901006	78	10/14/2014	09/08/2014	12/07/2014
AQUIOS Lysing Reagent B	8901006	78	10/14/2014	09/08/2014	12/07/2014
AQUIOS Sheath Solution	0016384	1	12/31/2016	08/14/2014	02/10/2015

**Sample ID** — The identifier number on the barcode of the specimen tube.

**Test** — The type of assay requested for the sample.

**Reagent** — The name of the reagent.

**Lot number** — The reagent lot number.

**Container** — The number of the container within a given lot number, which identifies the specific vial.

**Expiration Date** — The closed vial expiration date of the reagent.

**Date Opened** — The date the reagent was first placed on the system.

**Open Vial Expiration** — The open vial expiration date as calculated by the system after the first time the reagent is placed on the system.

**IMPORTANT** As soon as the reagent is opened, it should be loaded on the system to ensure accurate tracking of the Open Vial expiration date.


**NOTE** The open vial expiration may occur prior to the closed vial expiration date on the vial label, depending on when the system first reads the barcode.

**NOTE** The AQUIOS CL Flow Cytometer system tracks the remaining tests of the AQUIOS Cleaning Agent.



**NOTE** The AQUIOS CL Flow Cytometer system does not track the AQUIOS Sodium Hypochlorite Solution. You must track the expiration date of the AQUIOS Sodium Hypochlorite Solution upon use.

**NOTE** Refer to your application specific System Guide for the reagents listed.



**Auto Refresh** — Use the Auto Refresh to automatically refresh the screen to display the last completed run. The user can pause the refresh to review the on-screen runs on the  tab.

**NOTE** Entering the Edit mode will disable the automatic screen refresh. The Auto Refresh checkbox is unchecked.

**NOTE** Saving or cancelling the changes re-enables the automatic screen refresh, unless it was manually paused. Selecting  does not automatically re-enable the refresh as the changes are not saved. Selecting  refreshes the results after an edit is made, before permanently saving. When re-enabled the Auto Refresh checkbox is checked.

**NOTE** When a user selects a record from the completed runs table, the automatic refresh is automatically disabled and the Auto Refresh checkbox is unchecked.

**Results Details List Headings** — Use these headings to re-order the existing entries on the Results Details list in ascending or descending order.

**NOTE** Use the horizontal scroll-bar on the bottom of the screen to see the complete list of headings under the review details list. The Sample ID heading remains in its original position while you scroll through all the other headings.

**Sample ID:** The sample identifier for each tube.

**Patient:** The name of the patient.

**Test Name:** The type of assay requested for the sample.





**Run Date:** Date and time when the sample was analyzed.

**Patient ID:** The identifier assigned to the patient by the hospital.

**ID:** The Gov ID as entered in the Add Request screen.

**Results Details List** — Use this to track analyzed samples waiting to be reviewed. Select a sample in the list to view its results.

**Patient Information** — Use this to see the patient details entered by an operator or retrieved automatically from the LIS. The following patient details can be entered or modified on this screen: collection date, specimen type, patient name, patient ID, Gov. ID, status, location, gender, date of birth, physician name and physician code.

**NOTE** The  must be selected prior to making changes on this screen. Changes to any field can be accepted by selecting  or rejected by selecting . Selecting  refreshes the results after an edit is made, before permanently saving.

**NOTE** Non-highlighted cells (white) have no flags or notifications. The samples highlighted in red are flagged, the samples highlighted in orange have a notification.

**Sample ID:** Displays the sample identifier for this sample. No changes can be made to this field.

**Test:** Displays the test performed for this sample. No changes can be made to this field.

**Run date:** Displays the date the sample was prepared and run on the AQUIOS system. No changes can be made to this field.

**Flags:** A Flag indicates an issue that affects the results, follow the Recommended User Action in [Table 6.2, Generic Flags](#).

**NOTE** Some flags are application specific, refer to the application specific System Guide for additional information.

**Notifications:** Notifications are generated to convey an abnormal cell distribution or population which may be specimen specific. Follow the Recommended User Action in [Table 6.3, Notifications](#).

**Comments:** Use this area to enter any comments regarding the sample.

**NOTE** Some notifications are application specific, refer to the application specific System Guide for additional information.

**Results Data Table** — Use to view the patient assay results quantitatively, result flags, and defined reference values (normal and action ranges).

**Result:** The assay marker for the presented results and the units for that result.

**Value:** The quantitative result obtained for that marker. (For example: percent results represent the percentage of lymphocytes).


**Flag:** Results are flagged as H or L if outside the normal ranges and HH or LL if outside the action ranges.

**Normal range:** Reference values defined in the setup area under Test settings.

**Action range:** Reference values defined in the setup area under Test settings.

**NOTE** Normal Range and Action Range are ranges that can be user defined.

**Plots** — Use drop-down menu to select a pre-defined format to view the patient results data. The regions within the plots can be edited.

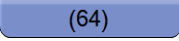
 — Select to bring up the Information window with more results for the sample and more details regarding the plate, run, well numbers, and additional statistics.

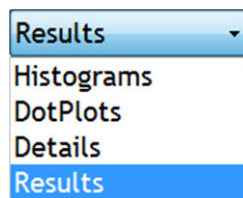
**Comments** — Use this area to enter any comments regarding the sample and information related to any changes made.

## Copy Image

- 1 Select a sample.
- 2 Right-click to copy image.



## Select a Graph Format for a Review Sample

- 1 After running samples, select  .
- 2 Select the sample of interest from the Review Details List.
- 3 Select the Graph Format drop-down menu and choose one of the optional formats for data display. The example below is for the Tetra Application.



**NOTE** The graphic above is application specific, refer to your application specific System Guide for more information.

## Review Reagent Information

- 1 Select  .
- 2 Select the sample of interest from the Review Details List.
- 3 Select  .

---

4 Review the Reagent information for the sample of interest.


---

5 Select  .

---

## Select Review Option for a Sample

---

1 Select  .

---

2 Select the sample of interest from the Review Details List.

- Flagged samples are highlighted in red.
- Samples with notifications are highlighted in orange.

---

3 Ensure that sample ran properly, see your application specific AQUIOS System Guide.

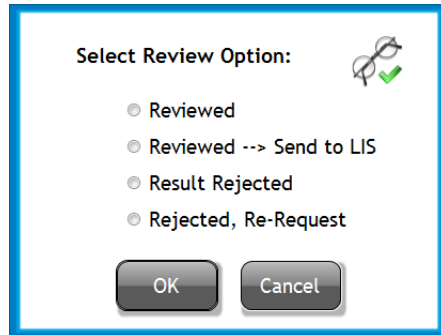
---

4 Select  .



**IMPORTANT** The user can only send the latest version of the run to the LIS. Once modified, the original result may be displayed, printed and viewed, but cannot be resent to the LIS.

5 Select the desired review option check box.

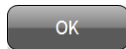


**Reviewed** — Indicates that the reviewer examined the results and confirms the data is acceptable.

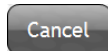
**Reviewed-->Send to LIS** — Indicates the reviewer examined the results and confirms the data is acceptable and transmits the data to the LIS.

**Result Rejected** — Indicates that the reviewer examined results and confirms the data is not acceptable.

**Rejected, Re-Request** — Indicates that the reviewer examined the results and confirms that the data is not acceptable. This generates a test request to allow repeat preparation and analysis of the sample.



— Accepts the selection and closes the window.



— Does not make any changes and closes the window.

**NOTE** Results that are Reviewed are removed from the Review Tab and are only available in the Results section of the screen. In the Results section of the screen, reviewed results are indicated by a green checkmark. Rejected results are indicated by a red “x.”

6 Select .

## Print a Review Sample

1 Select .

2 Select the sample of interest from the Review Details List.

---

3 Select  .

---

## Create PDF for a Review Sample

---

1 Select  .

---

2 Select the sample of interest from the Review Details List.

---

3 Select  .

---

4 Enter File name.

---

5 Select PDF file location.

---

6 Select  .

---

## Export Sample Results

---

1 Select  .

---

2 Select the sample of interest from the Review Details List.

---

3 Select  .

---

4 Enter File name, filter as (.crd), (.lmd), or (.csv).

5 Select the file location.

6 Select .


## Load Regions and/or Patient Information

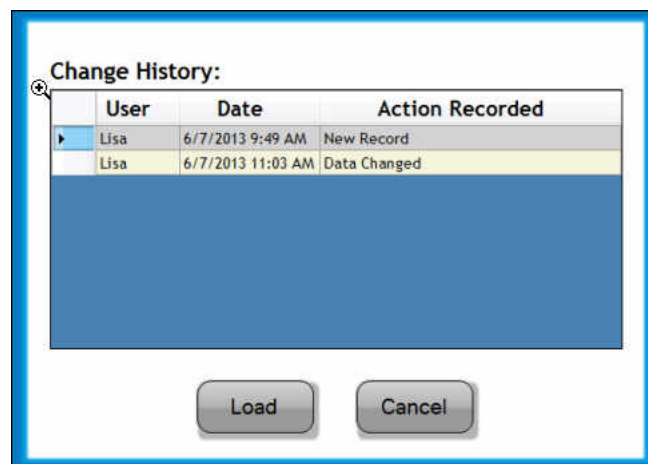
**IMPORTANT** The user can only send the latest version of the run to the LIS. Once modified, the original result may be displayed, printed and viewed, but cannot be resent to the LIS.

**NOTE** You can only restore results if a sample has been edited.

1 Select .

2 Select the sample of interest from the Review Details List.

3 Select  and the Change History dialog box appears.

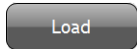


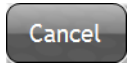
**User** — Displays the operator who made the changes

**Date** — Displays the date in which the results were modified.

**Action Recorded** — Displays the change type, that is data changed, such as Demographics.

**NOTE** If any information is changed in the Demographics section, including adding a "comment", the message *Demographics Changed* appears in the Action Recorded section.

 — Use to load and view the selected result file.

 — Closes the window.

---

**4** Select the file to load.

---

**5** Select  .

---

## Edit Regions and/or Patient Information

---

**IMPORTANT** The user can only send the latest version of the run to the LIS. Once modified, the original result may be displayed, printed and viewed, but cannot be resent to the LIS.


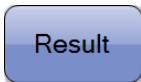
**IMPORTANT** Sample ID, Test, Run Date, and Serial # cannot be edited.

**IMPORTANT** Editing or adjusting regions is not routine. Editing regions can only be performed by an Operator with special access, such as an Administrator or Reviewer/Editor.



**Risk of incorrect results if daily Quality Control is not performed properly. Do not edit or adjust regions on control samples; editing regions should only be performed on patient samples.**


---

**1** Select  or  .

---

**2** Select the sample of interest from the Review Details List.


---


**3** Select  . The Edit action toolbox appears, and the fields for Sample ID, Test and Run Date turn gray to indicate that this information cannot be edited.


---

**4** Select any other field to add or change patient information.

5 Select and drag any region to change the region position over the data. Refer to the application specific System Guide for more information on editing regions.

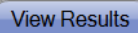
6 Select  to refresh the region statistics.

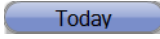
7 Select  to preserve the changes.

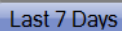
**NOTE** To see changes to regions or patient information, select . See [Load Regions and/or Patient Information](#) for more information.

## Result Screen

The Result screen ([Figure 6.4](#)) provides a search menu to navigate through the results database. The Search criteria is entered under the “Search” tab and the results for the query are displayed under



. Note that results can also be accessed and viewed through  or

.

**NOTE** Refer to [Figure 6.4](#) for any result screen items not described under this section. Also, refer to the review screens ([Figure 6.3](#), [Figure 6.4](#), [Figure 6.5](#), [Figure 6.6](#), and [Figure 6.7](#)) for the following sections: patient information, action toolbox, results data table and plots.

To review the status of a sample, see the Review Option icons below under the action toolbox.



indicates that the sample was reviewed and released.



indicates that the sample was reviewed and rejected.



indicates that the sample was not reviewed.

**NOTE** Once the Review option is selected, the sample is removed from ,

but it can be accessed through .

Figure 6.4 Result Screen, Search Tab

**Sample ID** — Use to search results by the specimen identifier.

**Patient ID** — Use to search results by the number assigned to the patient by the hospital.

**Gov. ID** — Use to search results by an additional ID number for the patient.

**Patient name** — Use to search results by the name of the patient.

**Test** — Use to search results by the test.

**NOTE** This is a required field. You must select a Test in order to do a search.

**Instrument** — Use to select the instrument from which to display the results.


**Start date** — Use to select the first day of data to be included in the search.

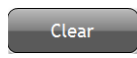
**End date** — Use to select the last day of data to be included in the search.


**Append to current search check box** — Use to add the current search to the previous saved search.


**QC results check box** — Enable to include only control QC samples in the search.

**Reviewed Only check box** — Enable to include only reviewed results.

 — Performs the search as requested.

 — Use to erase the entered search fields.

 — Use to export all the files selected under the search criteria to one of five file types- [.csv (spreadsheet), .crd (native file), FCS 2.0 .lmd, FCS 3.1 .lmd, or .pdf]

 — Use to access the Advanced Search dialog window for a detailed Query. See

[Figure 6.5.](#)

The Advance Search Dialog is shown below in [Figure 6.5](#). For more information see, [Advanced Search](#).

**Figure 6.5** Advanced Search Dialog Window

**Advanced Search**

**Patient Details:**  
 Name:    DOB:     
 Gender:  Status:  Location:   
 Physician Name:     
 Physician Code:   
 Sample ID:  Collect Date:     
 Patient ID:  Gov. ID:

**Reagent Details:**  
 Reagent:  All  
 Lot:  All  
 Vial:  All

**Instrument:**  
 All

**Test Details:**  
 Name:  Select Test Date Run (Range):      
 Results: 

Name	Low	High

### Patient Details

**Name:** Use to search results by the patient first name, middle initial, or last name.

**DOB:** Use to search results by the patient's date of birth.

**Sex:** Use to search results by the patient's gender.

**Status:** Use to search results by the patient's diagnostic code.

**Location:** Use to search results by the location where the blood was collected.

**Physician name:** Use to search results by the name of the doctor requesting the test.

**Physician code:** Use to search results by the code of the doctor who requested the test.

**Sample ID:** Use to search results by the sample identifier.

**Collect date:** Use to search results by the date on which the blood was drawn from the patient.

**Patient ID:** Use to search results by the number assigned to the patient by the hospital.

**Gov ID:** Use to search results by an additional ID or number associated with the patient.

### Test Details

**Name:** Use to search results by the specific assay used. This is a required field.

**Date Run (range):** Use to search results by the date and time when the sample was analyzed.

### Reagent Details

**Reagent:** Use to search results by the reagent used.

**Lot:** Use the scroll-down menu to choose the lot number to be included in the search criteria. This is a required field if **Reagent** is selected.

**Vial:** Use the scroll-down menu to choose the vial number to be included in the search criteria.

**Instrument** — Use to search results by the Instrument ID.

**Results table** — Use to search by a low/high range of patient results.

- Query** — Use to confirm the selected criteria and obtain the result list of the search request
- Clear** — Use to erase the entered fields.
- Cancel** — Use to cancel the advanced search.

Figure 6.6 Result Screen, View Results Tab “Minimized Field View” [Tetra Application]

Requests (0) Running (0) Incomplete (0) Review (7)

Search View Results Auto Refresh Today Last 7 Days

Sample ID: 89308936674 Test: Tetra Combo  
Run Date: 02/14/2015 12:56 AM Collect Date: / /  
Inst. SN: AV44010

Specimen Type: Patient Name: Patient ID: Gov. ID: Status: Location: Gender: Select - Date of Birth: / / Physician Name: Physician Code: Run Flags: Run Notifications: Comments:

Result	Value	Flag	Normal Range	Action Range
Average CD3+ (T Cells) Percent	59.42%			
Average CD3+ (T Cells) Count/uL	405			
CD3+CD4+ Helper T Cells Percent	15.66%			
CD3+CD4+ Helper T Cells Count/uL	104			
CD3+CD8+ Suppressor T Cells Percent	40.92%			
CD3+CD8+ (Suppressor T Cells) Count/uL	267			
CD3+CD19+ B Cells Percent	19.21%			
CD3+CD19+ B Cells Count/uL	134			
CD3+CD56+CD16+ NK Cells Percent	20.62%			
CD3+CD56+CD16+ NK Cells Count/uL	143			
CD4/CD8 Ratio	0.39			
Total Lymphocytes (T+B+NK) Percent	96.25%			
CD3+ Reliability Check	4.85%			
CD3+ Intrascan Check	1.95%			
CD45+ Low SS Count/uL	667			
CD45+ Low SS Percent CD45+	13.79%			
CD45+ Count/uL	4,840			
CD3+ (T Cells) Percent Tetra1	60.40%			
CD3+ (T Cells) Count/uL Tetra1	403			
CD3+ (T Cells) Percent Tetra 2	58.45%			
CD3+ (T Cells) Count/uL Tetra 2	406			

Fields Exclude Load Save

QC Result Setup Maint Barcode Stat Exit

Start LIS RMS Reagent Levels: Ok 48 Remaining Wells Open Reagent Door Database: Default User: Admin Help About 9:51 AM



**View Results details list headings** — Use these headings to re-order the existing entries on the review details in ascending or descending order.

**Patient name:** The blood donor name.

**Test Name:** The type of assay requested.

**Collection date:** The date the sample was drawn

**Sample ID:** The sample identifier for each specimen tube

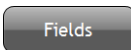
**Run date:** Date and time in which the sample was analyzed


**Patient ID:** The identifier number assigned to the patient by the hospital.


**Gov ID:** An additional ID number


**NOTE** The sample ID always remains the first field on the screen even when the scroll bar is used.


**Details List** — Displays the results filtered by the defined search tab criteria. Double-click a patient from the View Results details list to populate the screen with the selected result.


 — Use to add or remove the data fields as columns in the details list. See [Figure 6.8](#).

 — Use to remove runs from query on the “View Results” details list.

 — Use to access previously saved queries. See [Figure 6.10](#).

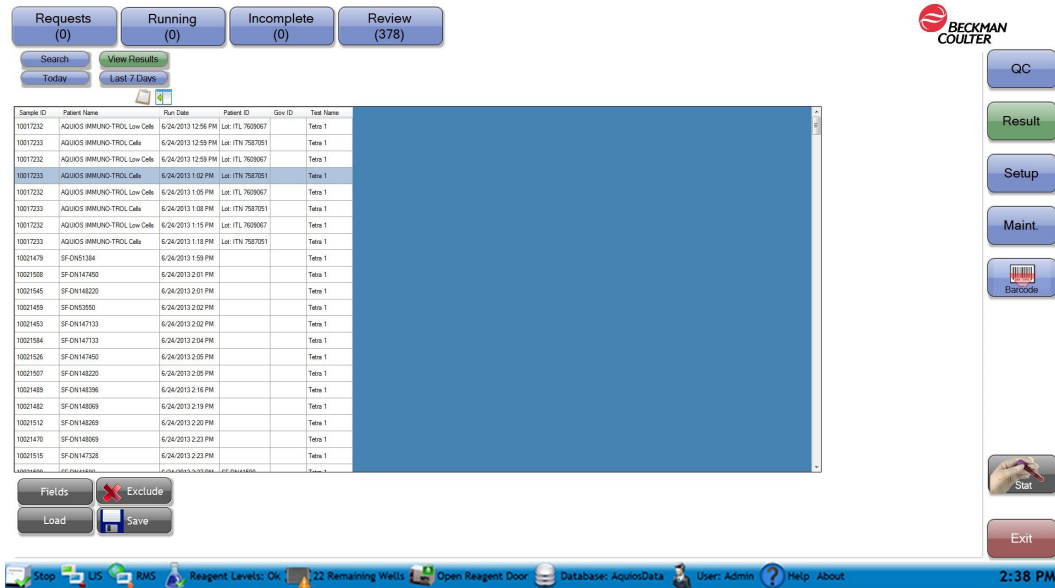
 — Use to save a new query. See [Figure 6.9](#).



 — Use to select all items under the Search Results detail list.

 — Select right arrow to expand to view all selected data fields. Select the left arrow to minimize field view to access patient information and data plots.

**NOTE** The Results Screen is application specific, refer to the application specific System Guide for more information.

Figure 6.7 Result Screen, View Results Tab “Expand Field View” [Tetra Application]



To access this screen, select , to return to Figure 6.6, select  to minimize field.


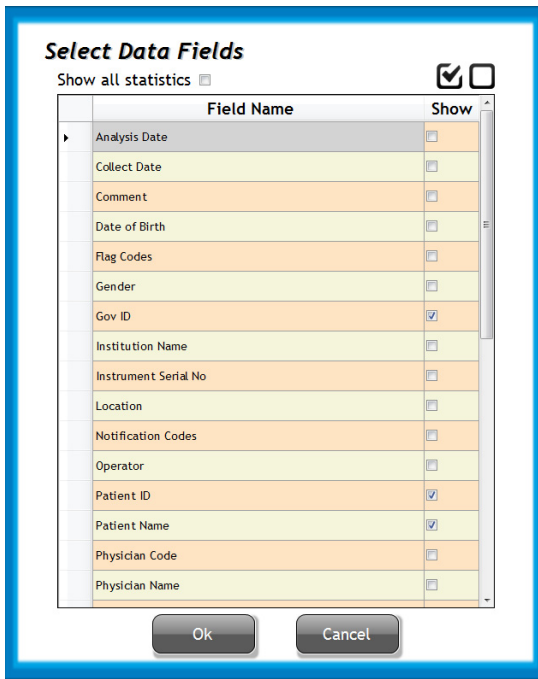

The Select Data Fields screen is accessed by selecting  from Figure 6.8.

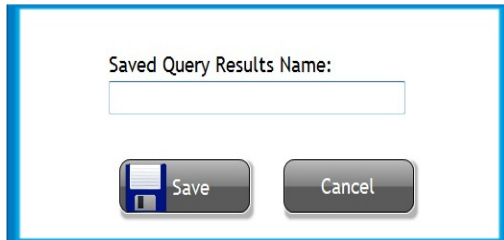
Figure 6.8 Select Data Fields



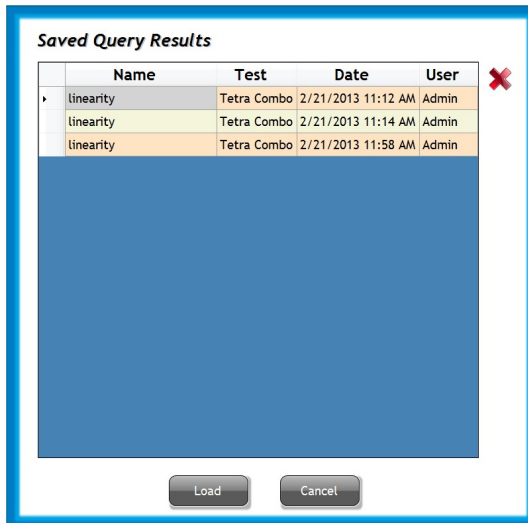
**NOTE** Use the arrow to scroll up or down the Data Fields list. Selecting the box with the checkmark places a checkmark in all boxes, and allows all fields to be shown.

The Save Query Results Name screen is used to provide an identifier name for the query and is accessed by selecting  as shown in Figure 6.9.

**Figure 6.9** Save Query Results Name



**Figure 6.10** Load Saved Query Results




**Saved Query Results table** — Use to view all saved queries available to load


**Name:** The identifier name for the query

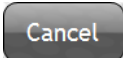
**Test:** The test used in the query

**Date:** The date the query was last saved

**User:** The user who saved the query

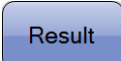
 — Use to erase a query from the saved query results

 — Use load to view the selected query

 — Use to exit the saved query results window without any changes

## Search Results By Criteria

---

1 Select . See [Figure 6.4](#).

---

2 Select . [Figure 6.4](#) displays under the Search Tab.

---

3 Enter search criteria you wish to use. Test is the only required field.

- Sample ID
- Patient ID
- Gov ID
- Patient Name
- Test
- Instrument
- Start Date
- End Date

---

4 Select **Append to Current Search** if you have already searched for samples and want to add the current criteria to the search.

**NOTE** Test names must match when using **Append to Current Search**.

---

5 Select the **QC Results** check box if you want to include quality control samples in your search criteria.

**NOTE** The system includes all QC runs which meet the search criteria.

**NOTE** Selecting the Reviewed Only checkbox queries only reviewed results.

---

6 Select .

---

7 Select .

---

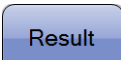
## Clear Search Criteria

1 Select . See Figure 6.4.

2 Select .

3 Select .

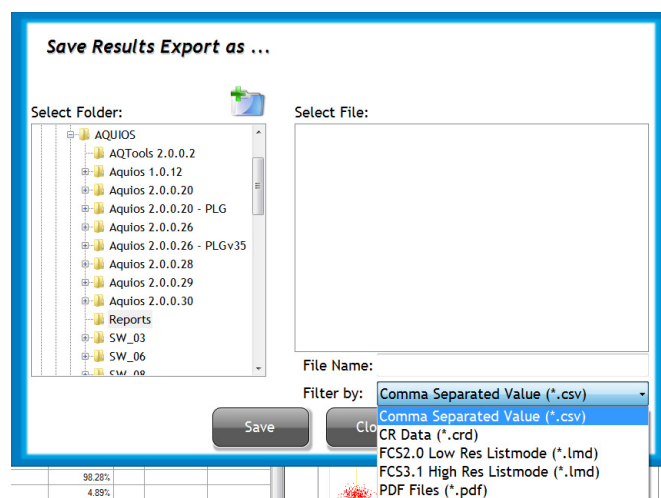
## Export Results to a CSV or CRD File

1 Select . See Figure 6.4.

2 Select .

3 Enter your search criteria.

4 Select . The *Save Result Export As* Screen displays.



---

**5** Select either **Comma Separated Value (\*.csv)** to save a spreadsheet file or **CR Data (\*.crd)** to save a file in native format from the **Filter by** drop-down menu.

---

**6** Enter File name.

---

**7** Select file location.

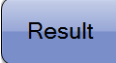
---

**8** Select .

---

## Export Results to a LMD File

---

**1** Select . See [Figure 6.4](#).

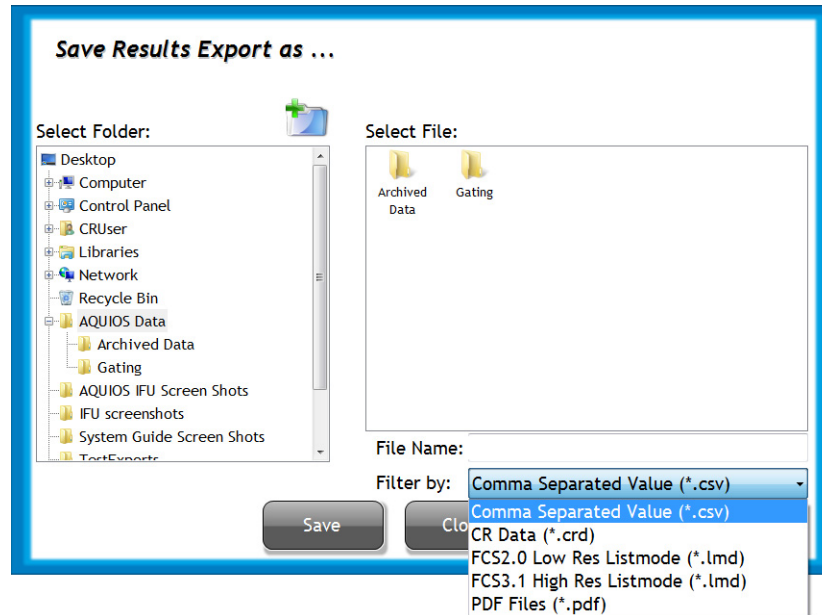
---

**2** Select .

---

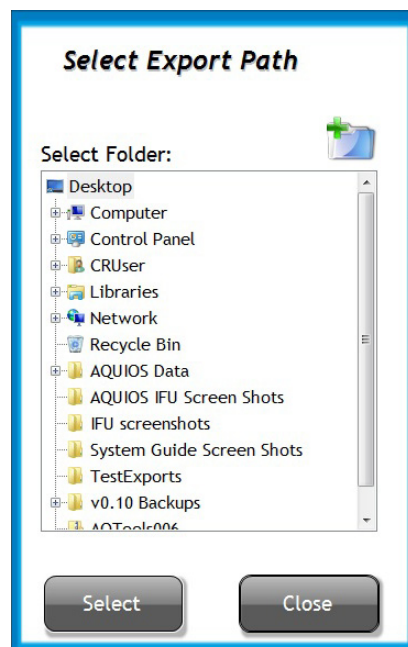
**3** Enter your search criteria.

- 4 Select . The *Save Result Export As* Screen displays.



- 5 Select **Listmode Files (\*.lmd)** from the **Filter by** drop-down menu.

- 6 The *Select Export Path* Screen displays.

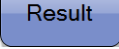


7 Select the export path.

8 Select .

**NOTE** The files are automatically named and placed in the selected export path. The PDF filenames are automatically generated in the form TestName SampleID AnalysisDateTime TubeNo. If there are multiple exports for the same run, the software will append a number "(x)" (starting at "(2)") at the end of the filename (before the .lmd extension) to identify the files.

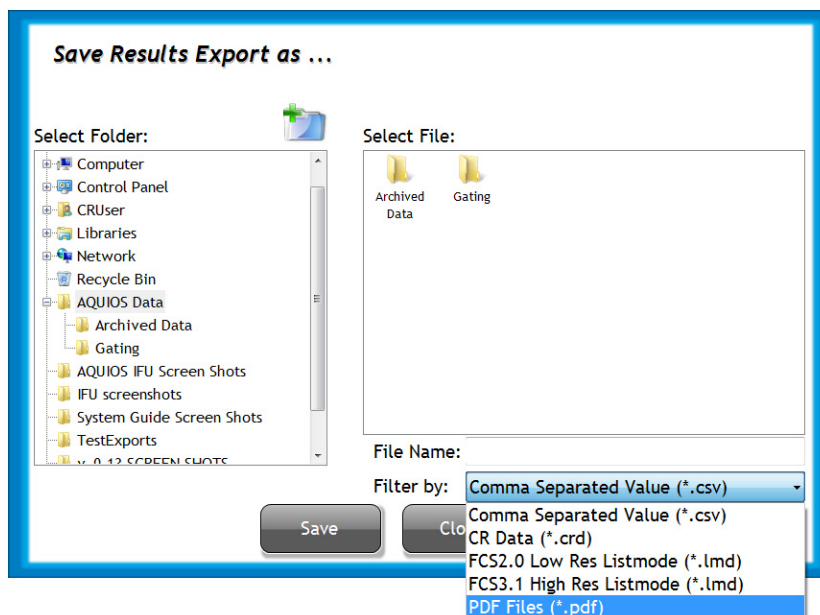
## Export Results to a PDF File

1 Select . See [Figure 6.4](#).

2 Select .

3 Enter your search criteria.

4 Select . The *Save Result Export As* Screen displays.



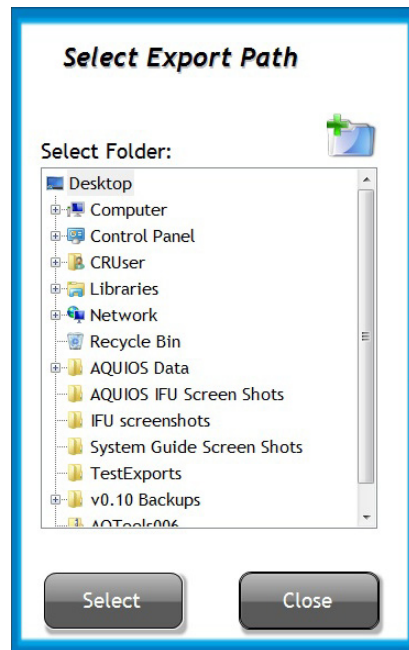


---

5 Select **PDF Files (\*.pdf)** from the **Filter by** drop-down menu.

---

6 The *Select Export Path* Screen displays.



---

7 Select the export path.

---

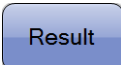
8 Select .

**NOTE** The files will be automatically named and placed in the selected export path.

---

## Advanced Search

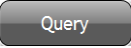
---

1 Select . See [Figure 6.4](#).

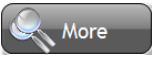
---

2 Select . Enter Search Criteria.

---

3 Select . If additional Advanced Search features are required, please continue to the next step. If not, go to step 9.

---

4 Select  to open the Advanced Search window for more advance features. See [Figure 6.5](#).

---

5 Search by Patient details:

- Name
- DOB
- Gender
- Status
- Location
- Physician name
- Physician code
- Sample ID
- Collect date
- Gov. ID
- Patient ID

---

6 Search by Test Details:

**NOTE** Not all results in the specified result range indicated are returned because the results are rounded. For more information about rounding results, see [Quality Control Checks](#) in [CHAPTER 4, Quality Control](#).

- Name
- Date Run Range
- Results

---


7 Search by Reagent Details

- Reagent
- Lot
- Vial

---

8 Select .

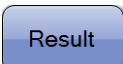
---

9 Select . See [Figure 6.6](#).

---

## Define Data Fields for Search Tab

---

1 Select . See [Figure 6.4](#).

---

2 Select . Enter search criteria.

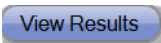
---

3 Select  to open the Advanced Search window for more advanced features.

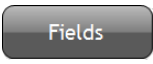
a. [Figure 6.5](#) shows the Advanced Search window.

b. Select .

---

4 Select . See [Figure 6.6](#).

---

5 Select . The select data fields window appears. See [Figure 6.8](#).

---

6 Use **Show** box to select or deselect data fields.

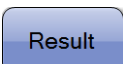
---

7 Select .

---

## Exclude a Run from Search Tab


---

1 Select . See [Figure 6.4](#).

---

2 Select . Enter search criteria.


---

3 **Optional:** Select  to open the **Advanced Search** window for more advanced features. See [Figure 6.5](#).

---

4 Select .

---

5 Select . See [Figure 6.5](#).

---

6 Highlight desired run to exclude.


---

7 Select .

---

## Load Query Result

---

1 Select . See [Figure 6.6](#).

---

2 Select .

---

3 Choose the Query Result to Load.

---

4 Select . The Saved Query Results List appears. See [Figure 6.9](#).

**NOTE** The results at the time of **Query Save** are displayed, not the realtime results.

---

## Append to Current Search

Append to current search can be selected after doing a query.

**NOTE** Append works with the same Test only.

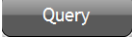
---

1 Enter the search criteria.

---

2 Select the **Append to Current Search** checkbox.

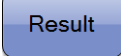
---

3 Select . The new query is appended to the loaded query.

---

## Save Query Result

---

1 Select . See [Figure 6.4](#).

**NOTE** You must load a query prior to appending a current search. [Figure 6.4](#) displays under the Search Tab.


---

2 Select . Enter search criteria.

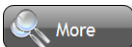
---

3 Select .


---

4 Select . If additional Advanced Search features are required, please continue to the next step.

---

5 Select  to open the Advanced Search window for more advanced features. See [Figure 6.5](#) to view the Advanced Search window.

---

6 Select . The Save Query Result screen appears. See [Figure 6.9](#).

---

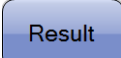
7 Enter query name.

---

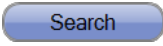
8 Select .

---


## Select All

- 
- 1 Select . See [Figure 6.4](#).


---

  - 2 Select . Enter search criteria.



---

  - 3 Select .

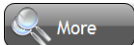
---

  - 4 Select . If additional Advanced Search features are required, please continue to the next step.

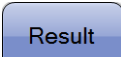
---

  - 5 Select . All items under  details list are selected and can be copied and pasted into an Excel spreadsheet.

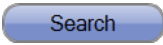
---

  - 6 **Optional:** Select  to open the Advanced Search window for more advanced features. See [Figure 6.5](#) to view the Advanced Search window.
- 


## Expand /Minimize Data Fields

- 
- 1 Select . See [Figure 6.4](#).


---

  - 2 Select . Enter search criteria.

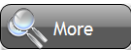
---

  - 3 Select .

---

  - 4 Select . If additional Advanced Search features are required, please continue to the next step.

5 Select  to see data fields or select  to see patient details, action toolbox and graphs.

6 **Optional:** Select  to open the Advanced Search window for more advanced features. See [Figure 6.5](#) to view the Advanced Search window

## Flags And Notifications

The flag and notification messages appear under the Review and Result screens. Samples with flags are highlighted in red, while samples with notifications are highlighted in orange.

All results having flags and/or notifications are automatically sent to the review tab for review. Only samples without notifications and flags can be setup for automatic transmission. However, it is strongly recommended that a laboratory professional review all results, regardless of Flags and Notifications, prior to data release. To modify the criteria for automatic transmission, see [Auto Transmit](#) in [CHAPTER 8, Setup](#).

When a flag or notification occurs, results are generated and placed in the Review Tab. The flag appears on the “Flags” line of the report. For application specific flags and notifications, refer to the application specific System Guide.

## Flags

A Flag indicates an issue that affects the results, follow the Recommended User Action in the table below. See [Table 6.2](#).

**Table 6.2** Generic Flags

Flag	Definition	Recommended User Action
<b>General Error</b>	An error occurred that did not fall into one of the categories below.	<ol style="list-style-type: none"> <li>1. Run a Bleach Cycle.</li> <li>2. Reject, Re-Request from the Review Options menu.</li> <li>3. If the problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<b>Clog or Bubble</b>	Based on count rate and population CV's.	<ol style="list-style-type: none"> <li>1. Run a Bleach Cycle.</li> <li>2. Reject, Re-Request from the Review Options menu.</li> <li>3. If the problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<b>ReRun</b>	The system automatically re-ran the sample due to count rate or population CV's.	This flag appears in conjunction with other flags. The recommended action for the other flags should be followed.

**Table 6.2** Generic Flags (*Continued*)

Flag	Definition	Recommended User Action
<b>Short Draw</b>	Failure to detect sufficient blood.	<ol style="list-style-type: none"> <li>1. Verify that there is sufficient sample in the tube.</li> <li>2. Run a Bleach Cycle.</li> <li>3. Reject, Re-Request from the Review Options menu.</li> <li>4. If the problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<b>Expired reagent</b>	Based on barcode expiration dates (open, on-board, and closed vial), The reagent is run after the expiration date has passed.	<ol style="list-style-type: none"> <li>1. Replace expired reagent with a non-expired reagent.</li> <li>2. Reject, Re-Request from the Review Options menu.</li> <li>3. If the problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<b>Missing QC</b>	Occurs if the Setup option <b>QC Tracking</b> was enabled and QC was not run successfully.	<ol style="list-style-type: none"> <li>1. Confirm the Setup Option QC Tracking was set as expected.</li> <li>2. Perform Daily QC procedure, see <a href="#">Daily QC in CHAPTER 4, Quality Control</a>.</li> <li>3. Reject, Re-Request from the Review Options menu.</li> <li>4. If the problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<b>High Count Rate</b>	Based on events/second.	<ol style="list-style-type: none"> <li>1. Review the sample results from the <a href="#">Review Screen</a>. This flag could be donor dependent.</li> <li>2. Reject, Re-Request from the Review Options menu.</li> <li>3. If the problem persists across different samples, contact your local Beckman Coulter Representative.</li> </ol>
<b>Laser Power Error</b>	Insufficient laser power.	<ol style="list-style-type: none"> <li>1. Select Result Rejected from the Review Options Menu.</li> <li>2. Perform a <a href="#">Shutdown</a> in <a href="#">CHAPTER 7, Shutdown</a>.</li> <li>3. Perform a startup of the <a href="#">Startup</a> in <a href="#">CHAPTER 3, Daily Startup</a>.</li> <li>4. Review maintenance log and if the problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<b>Vacuum Low</b>	Insufficient vacuum.	<ol style="list-style-type: none"> <li>1. Select Result Rejected from the Review Options Menu.</li> <li>2. Perform a <a href="#">Shutdown</a> in <a href="#">CHAPTER 7, Shutdown</a>.</li> <li>3. Perform a startup of the <a href="#">Startup</a> in <a href="#">CHAPTER 3, Daily Startup</a>.</li> <li>4. Review maintenance log and if the problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<b>Power Supply Error</b>	Detected by measuring the power supply voltages.	<ol style="list-style-type: none"> <li>1. Select Result Rejected from the Review Options Menu.</li> <li>2. Perform a <a href="#">Shutdown</a> in <a href="#">CHAPTER 7, Shutdown</a>.</li> <li>3. Perform a startup of the <a href="#">Startup</a> in <a href="#">CHAPTER 3, Daily Startup</a>.</li> <li>4. Review maintenance log and if the problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<b>Over Incubation</b>	Sample incubation time exceeded.	<ol style="list-style-type: none"> <li>1. Run a Bleach Cycle.</li> <li>2. Reject, Re-Request from the Review Options menu.</li> <li>3. If the problem persists, contact your local Beckman Coulter Representative.</li> </ol>



**Table 6.2** Generic Flags (Continued)

Flag	Definition	Recommended User Action
<b>Over Lyse Incubation</b>	Lyse incubation time exceeded.	<ol style="list-style-type: none"> <li>1. Run a Bleach Cycle.</li> <li>2. Reject, Re-Request from the Review Options menu.</li> <li>3. If the problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<b>Control Range Failure</b>	Control results are outside of the acceptable ranges.	<ol style="list-style-type: none"> <li>1. Run a Bleach Cycle.</li> <li>2. Check the controls' expiration date.</li> <li>3. Check if the controls' blood level is sufficient.</li> <li>4. Repeat Quality Control. See <a href="#">Daily QC</a> in <a href="#">CHAPTER 4, Quality Control</a> for details.</li> <li>5. If the problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<b>Control Instrument QC Failure</b>	Control cell populations are indistinct or in the wrong locations.	<ol style="list-style-type: none"> <li>1. Perform Daily QC procedure, see <a href="#">Daily QC</a> in <a href="#">CHAPTER 4, Quality Control</a>.</li> <li>2. Reject, Re-Request from the Review Options menu.</li> <li>3. If the problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<b>Onboard Expiration</b>	A reagent has exceeded the maximum allowed time on board the system.	<ol style="list-style-type: none"> <li>1. Replace onboard expired reagent with a non-expired reagent.</li> <li>2. Reject, Re-Request from the Review Options menu.</li> <li>3. If the problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<b>Error Loading Results</b>	The system was unable to load or save results for a run or test.	<ol style="list-style-type: none"> <li>1. Shutdown and restart system (cytometer, supply cart, and workstation).</li> <li>2. If the problem persists, contact your local Beckman Coulter Representative.</li> </ol>

## Notifications

Notifications are generated to convey an abnormal cell distribution or population which may be specimen specific. Follow the Recommended User Action in the table. See [Table 6.3](#).

**Table 6.3** Notifications

Notifications	Definition	Recommended User Action
<b>Action Range</b>	Result was outside the user defined action range.	Follow your laboratory's policies and procedures for out-of-range results.

**Table 6.3** Notifications (*Continued*)

Notifications	Definition	Recommended User Action
<b>User Modified</b>	The demographics or the gating for this run were modified by a user	<ol style="list-style-type: none"> <li>1. This notification is for informational use only, no further action is required.</li> <li>2. To retrieve original run or verify the user modification, select the History icon.</li> </ol>
<b>Sample ID Reused</b>	<p>Only patient runs are identified with this notification. This occurs when:</p> <ol style="list-style-type: none"> <li>1. The Sample ID for this specimen run has been used in a prior run (patient or control) within the last 24 hours.</li> <li>2. There is a duplicate Sample ID in the Running tab for this run.</li> </ol>	<ol style="list-style-type: none"> <li>1. Ensure this is a re-run of a previous run.</li> <li>2. Check Sample ID of the specimen to ensure it is correct one for the specimen.</li> </ol>

## Shutdown

---

This chapter contains information on the following:

- [Shutdown](#)
- [Extended Shutdown](#)

**IMPORTANT** Ensure that the carousel and reagents are not left onboard the system longer than their maximum daily stability per package insert instructions.

**IMPORTANT** Ensure that shutdown is performed at least once every 24 hours, or when daily work is completed, or before turning off the system power.



**Risk of personal injury or contamination. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection.**





**Risk of biohazardous contamination. Clean up any blood spill as quickly as possible. Dispose of all contaminated disposable cleaning materials in accordance with your local regulations and acceptable laboratory practices.**

- 1 Ensure that there is at least 2 mL of freshly dispensed AQUIOS Sodium Hypochlorite Solution in a clean 12 x 75 mm tube before performing a Shutdown. See [Replacing the AQUIOS Sodium Hypochlorite Solution Tube](#) in [CHAPTER 11, Replacement Procedures](#) for more information on replacing AQUIOS Sodium Hypochlorite Solution.

**NOTE** Ensure there is one unused well in the plate.

- 2 Select  from the Status Bar.

- a. If no samples are running when you select , the *Do you want to shut the system down...?* dialog appears.
- b. If samples are running when you select , the *Samples are running. Do you want to shut down when they are finished?* dialog appears.

- 
- 3 Select .

**NOTE** The Stop identifier changes to Start once the Shutdown is complete.

---

**IMPORTANT** Remove the reagents and store per the package insert instructions.

- 4 When the STOP/Shutdown cycle is complete, the dialog *Please remove all reagents from the system and store as per labeling instructions* appears.

- 
- 5 Open the reagent door by pressing the top middle part of the door in one single, solid motion.

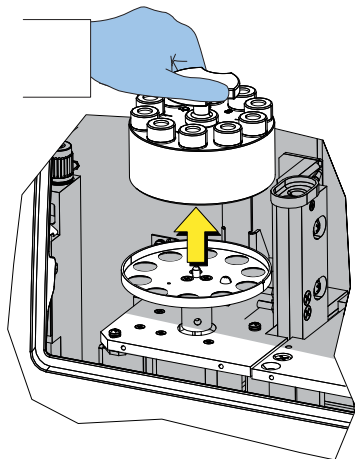


- 
- 6 Discard the tube of AQUIOS Sodium Hypochlorite Solution.

---

**IMPORTANT** Remove the reagents and store per the package insert instructions.

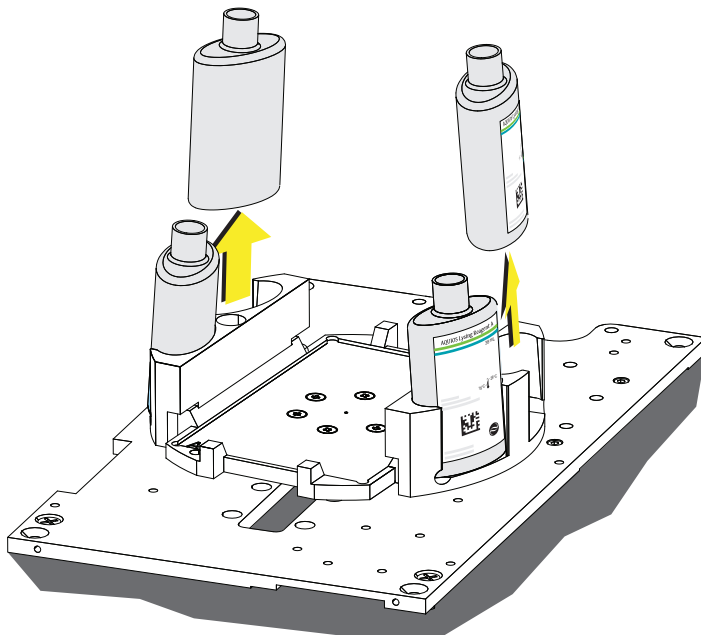
- 7 Remove the carousel with AQUIOS Monoclonal Antibody Panel reagents and store the carousel upright in the refrigerator.



---

**IMPORTANT** Remove the reagents and store according to the package insert instructions.

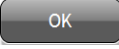
- 8 Remove the additional application specific reagents from the system and place the respective caps on the reagents.




- 
- 9 Discard the onboard AQUIOS Deep Well Plate.

10 Close the reagent door.



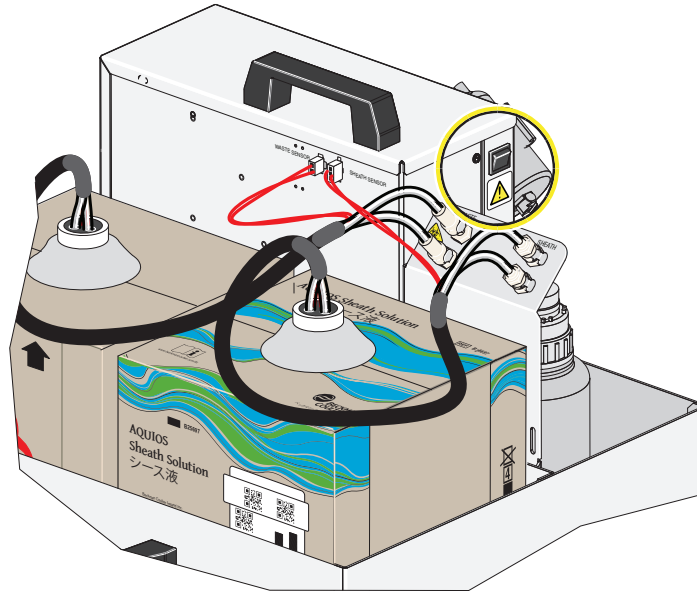
11 Select  when the dialog *Please remove all reagents from the system and store as per labeling instructions* appears.

12 Select  to close the software and return to the Windows main screen. The dialog *Exit, are you sure?* appears.

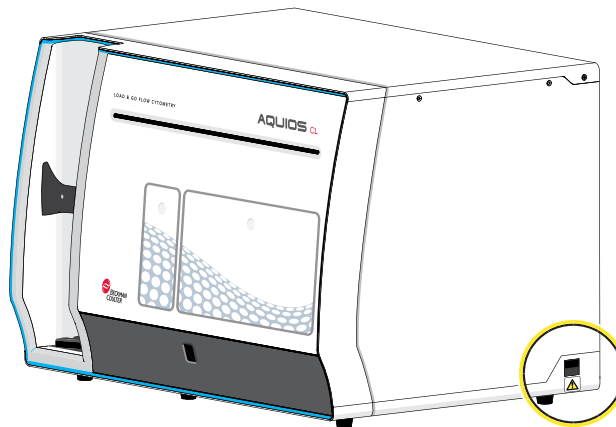
13 Select .

**NOTE** If you select , you can not exit the software.

**14** Turn off the power to the Supply Cart.



**15** Turn off the Cytometer power.

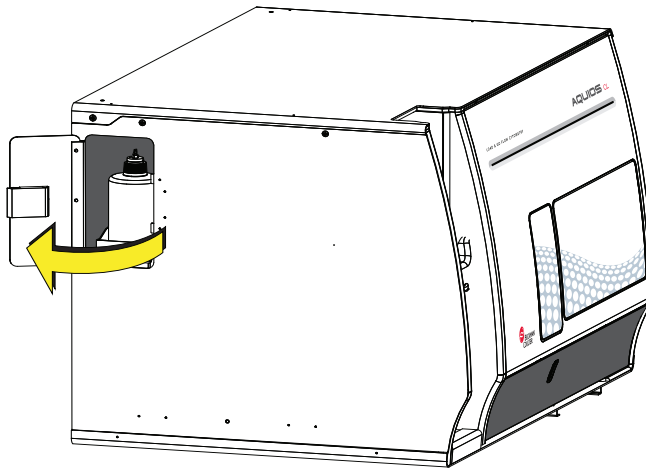


**16** Use the Windows Shutdown menu to turn off the Workstation and wait for the Workstation to shutdown.

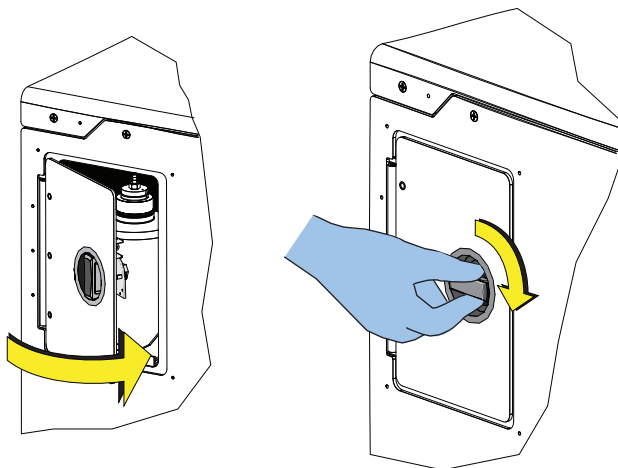
## Extended Shutdown

Perform this procedure whenever the instrument will not be in use for a period of 7 days or longer.

- 1 Allow any samples on the system to finish running.
- 2 Ensure a new deep-well plate is on the plate holder. See [Replacing the AQUIOS Deep Well Plate](#) in [CHAPTER 11, Replacement Procedures](#).
- 3 Perform a [Shutdown](#) cycle, but do not turn the power off to the system, or log out of the software. Do not remove the plate from the system once the cycle is complete.
- 4 Open the cleaning agent door, and replace the cleaning agent with a bottle of deionized water.



- 5 Close the cleaning agent door.






- 6 Open the reagent door and replace the tube of Sodium Hypochlorite with a fresh tube of deionized water. See [Replacing the AQUIOS Sodium Hypochlorite Solution Tube](#) in [CHAPTER 11, Replacement Procedures](#).



- 7 Close the reagent door.



- 8 Replace the sheath solution container in the Supply Cart with a container of deionized water. Refer to [Replacing the AQUIOS Sheath Solution Cubitainer](#) in [CHAPTER 11, Replacement Procedures](#).

- 9 Select  to perform a Start Up cycle.

- 10 Once the cycle is complete, perform another [Shutdown](#) cycle with the water on board.

- 11 Once the STOP cycle has completed, refer to steps 7 through 16 in [Shutdown](#).

---

**12** To start the AQUIOS after an extended shutdown, open the cleaning agent door and replace the bottle of deionized water with a bottle of cleaning agent. Close the cleaning agent door. Refer to [CHAPTER 3, Daily Startup](#) and [CHAPTER 4, Quality Control](#) for Start up and Daily QC instructions.

---

**13** Select  **Open Reagent Door** on the Status Bar.

---

**14** Dispose of the tube with 2mL of deionized water and add a new 12 x 75 mm tube with approximately 2 mL of AQUIOS Sodium Hypochlorite Solution in the same position. See [Replacing the AQUIOS Sodium Hypochlorite Solution Tube](#) in [CHAPTER 11, Replacement Procedures](#).

---

## Setup Screens

This chapter contains information on the following:

- Setup Screens
- Reports
- RMS (Windows 7 Only)
- Maintenance Screen
- Status Bar And Message Area Identifiers
- Login

## User Setup

The User Setup screen (Figure 8.1) can only be edited by System Administrators. It allows you to set up and manage user accounts. All users can access the Change Password and Switch User feature.


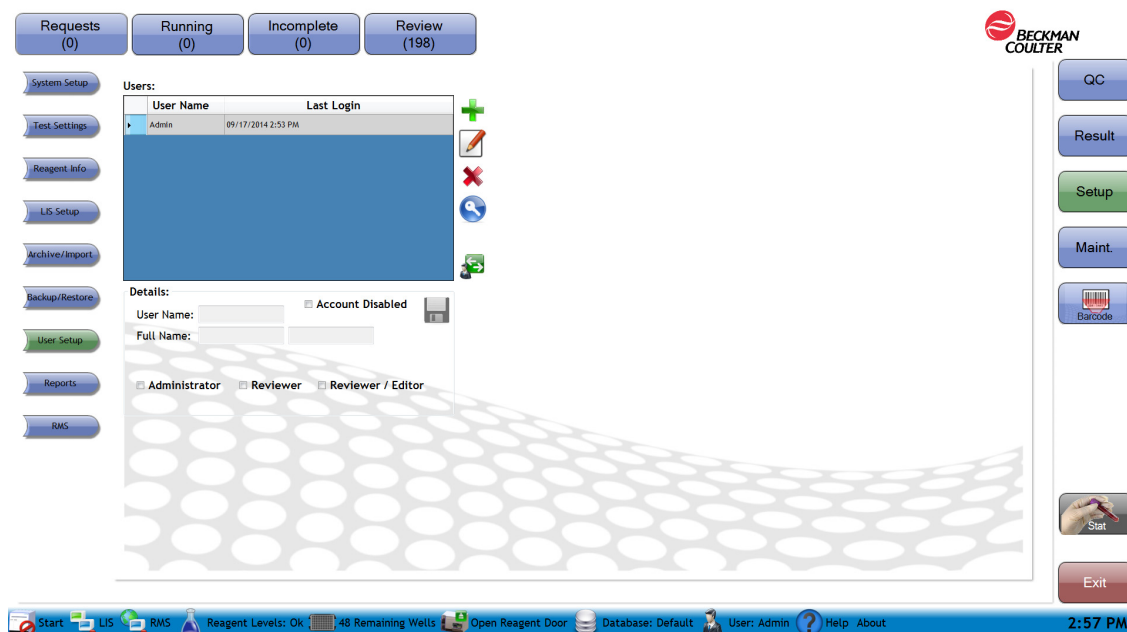
You can also access the screen through  under the instrument status bar. Set up users according to your laboratory's policies and procedures for data security. Do not disclose your password to anyone.

Figure 8.1 User Setup Screen



**Users table** — Use as a reference list to track the users with system access. The table shows the user name, date and time of the last login for each user.



- Use to add a new user, complete the details section and save the entry.



- Use to edit the information of the selected existing user. The user's information is displayed under the details section and the administrator may edit it.



- Select a user from the list and use this to delete the user.



— Use to reset the password of the selected user. The user is prompted to setup the new password on the next login session. Enter the new password twice to confirm the new password. See [Reset User Password](#).



— Use to log out the current user and bring up the Login window without exiting the software. See [Change User](#).

#### Details:

**User Name:** Enter a log in name for the user. This will be used on the log in screen instead of the user full name.

**Full Name:** Enter user's first and last name

#### Account Disabled checkmark:

**Checked:** Use to deny account access to the selected user.

**Un-checked:** Use to allow account access to the selected user

#### Administrator checkmark:

**Checked:** The user is authorized to perform all the activities of the Reviewer/Editor. In addition, this user can also, create and delete users, disable user accounts, modify the settings in the Setup area of the software.

**Un-checked:** Use to remove administrator access to the user.

#### Reviewer checkmark:

**Checked:** The user is authorized to review and transmit samples to the LIS by using the Review option icon on the review screen. User is able to generate and perform test requests, and review and release results. However, reviewers cannot edit generated results.

**Un-checked:** The user cannot review or transmit samples to the LIS.

#### Reviewer/Editor checkmark:

**Checked:** The user is authorized to perform all the activities of the Reviewer. In addition, this user is also able to modify and edit gates, regions, compensation, demographics and add comments for the results generated.

**Un-checked:** The user cannot review or transmit samples, or edit regions or compensations.




- Use to save the changes to the user information.


## Create an Account for Administrator, Reviewer, or Reviewer/Editor

**NOTE** Only System Administrators can add, edit, delete, or disable users.


---

1 Select  and then User Setup OR select User from the Status Bar. See [Figure 8.2](#).

---

2 Select  or select  from the status bar. [Figure 8.1](#) appears.

---

3 Select the .

---

4 Enter Details for the new user (Username, Full name)

**NOTE** The password is not entered here by the Administrator. The user is prompted to enter and confirm the new password on their first login session. When a new user logs in for the first time, they will need to enter their password twice. See step below.

---

5 Select the appropriate checkbox for the desired function.

---

6 Select . The message *New User Created* is displayed for about 5 seconds.


**IMPORTANT** Refer to [APPENDIX F, Password Security](#) for requirements for creating your password.

7 The new user creates a password at first login:

a. Select [Change User](#), and enter the new user name.

b. Select .

c. Confirm the password by entering it twice in the confirm password popup.


d. Select . The message *Invalid User Name or Password* is displayed for about 5 seconds.

e. Enter the password and select  and now the new user login is complete.


---

## Disable User Account

---

1 Select  as shown in [Figure 8.2](#).

---

2 Select  or select  from the status bar. [Figure 8.1](#) appears.

---

3 Select the user from the list.

---

4 Select .

---

5 Select Account Disabled under the details section.

---


6 Select .

---



## Delete User

**NOTE** You must have administrator privileges to delete a user.

---

1 Select  as shown in [Figure 8.2](#).


---

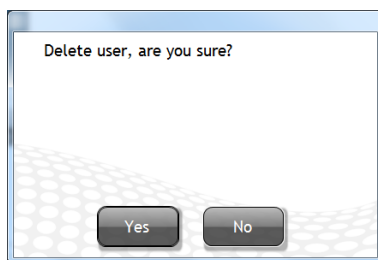
2 Select  or select  from the status bar. [Figure 8.1](#) appears.

---

3 Select the user from the list.

---





4 Select . The *Delete User Are you Sure?* message appears.

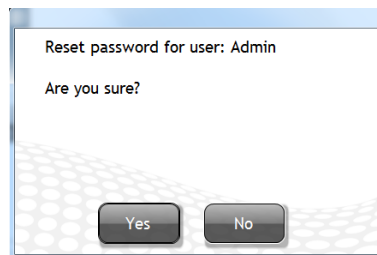


- 
- 5 Select .
- 

### Reset User Password

---




- 1 Select  as shown in [Figure 8.2](#).
- 
- 2 Select  or select  from the status bar. [Figure 8.1](#) appears.
- 
- 3 Select the user from list
- 
- 4 Select . *Reset password for user: xxxx Are you sure?* appears.




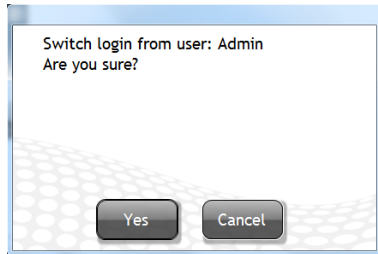
- 
- 5 Select .
- 

### Change User

---

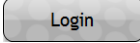
- 1 Select  as shown in [Figure 8.2](#).
- 
- 2 Select  or select  from the status bar. [Figure 8.1](#) appears.

- 
- 3 Select . *Switch Login from user: xxxx, Are you sure?* appears.




- 
- 4 Select .


- 
- 5 The Login Screen ([Figure 8.19](#)) appears.

- 
- 6 Enter the new Username, Password, and select .

---

## Edit User

- 
- 1 Select  as shown in [Figure 8.2](#).

- 
- 2 Select  or select  from the status bar. [Figure 8.1](#) appears.

- 
- 3 Select the user from the list.

- 
- 4 Select .


- 
- 5 Edit Details for the selected User (Full name, Password).

**NOTE** Username cannot be edited.

- 
- 6 Edit Details checkboxes that apply to the existing user (Administrator, Reviewer, Reviewer/Editor, Account Disabled).



## 7 Select .

**NOTE** The password is not entered here by the Administrator. The user will be prompted to enter and confirm the new password on the first login session.  allows you to change your password.

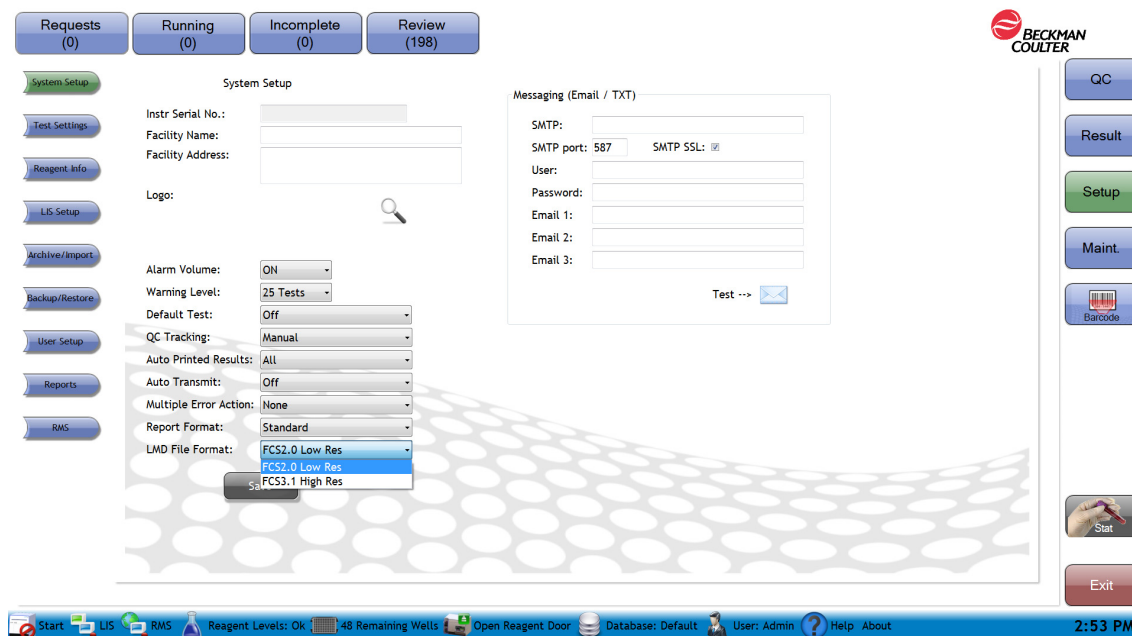
## System Setup Screen

The System Setup screen (Figure 8.2) defines the system preferences throughout the software. You must be logged in as an administrator to make changes to the setup screen. Other users may view the settings but not change them.

The System Setup screen allows you to customize reports by entering the facility name, address and facility logo. General system preferences can also be customized through this screen.

**NOTE** In a shared database environment, changes to the Setup screens that are made on one instrument are not refreshed on other instruments until exiting and reentering the software. The settings that are displayed on each instrument are what is used for that particular instrument.

Figure 8.2 System Setup Screen



**Instrument serial number** — Displays the instrument serial number.

**NOTE** Only a Beckman Coulter Service Representative can change this field. The serial number is also found on the back on the instrument.

**Facility name** — Use to enter the name of the facility issuing the report. This information will appear on the reports.

**Facility address** — Use to enter the address of the facility issuing the report. This information will appear on the reports.

**Facility Logo** — Use to upload the logo of the facility issuing the report. The Logo will appear on the reports.

**Alarm volume** — Use drop-down menu to enable or disable (on, off) the audible alarm that accompanies an error message.

**Warning level** — Use the drop-down menu to specify how much in advance you want to be warned before the system runs out of reagents or available wells. The system setup warning level is for AQUIOS Lysing Reagent Kit, and AQUIOS Deep Well Plate. The warning levels can be activated at: 1, 3, 5, 10, 15, 20, or 25 tests remaining. Zero values means warning messages are off and Reagents warning will not display on the status bar.

**NOTE** The assay warning levels for AQUIOS Antibody panels are available under the Test Settings warning levels.

**Default Test** — Use the drop-down menu to select a default test for the autoloader or to turn off this functionality. The selected test will be used to run all autoloader samples that do not have a Test Request.

**NOTE** This feature is used primarily when there is only one type of test run in the laboratory.

**On:** Use to turn on the Default Test autoloader functionality.

**Off:** Use to turn off the Default Test autoloader functionality.

**NOTE** If Default Test is Off, Autoloader tubes without a Test Request will remain unprocessed. The sample will appear as no request under the Incomplete screen.

**QC Tracking** — Use the drop-down menu to define how often the system will remind you to run QC. The system default setting is "Daily." Beckman Coulter strongly recommends you maintain this default setting to ensure you are reminded each day to perform QC as this is the recommended method of ensuring the AQUIOS system is performing properly.

**NOTE** If QC is not run as specified, the system will run patient samples, but the runs will be flagged with a "Missing QC" flag.

**Manual:** Use to turn off the reminder to run QC.

**Every 8 hours:** Use to prompt user to perform QC every 8 hours.

**Every 12 hours:** Use to prompt user to perform QC every 12 hours.

**Daily:** Use to prompt user to perform QC once every 24 hours.

**Weekly:** Use to prompt user to perform QC once a week.

**Auto printed results** — Use the drop-down menu to enable printing.

**None:** Use for no print-outs.

**All:** Use to generate a print-out every time a specimen is run.

**Flags:** Prints a report, only if there were flags.

**Flags and Notifications:** Prints a report, only if there were flags or notifications.

**CAUTION**

**Risk of reporting erroneous results if you select Auto Transmit and do not review your results. If you select Auto Transmit, you must validate your selection in order to avoid erroneous results.**

**Auto Transmit** — Use the drop-down menu to select **On**, or **Off**.

**NOTE** If **On** is selected, only runs without flags or notifications are transmitted to LIS and the transmitted results are not viewable under the review tab, only under the Results area.

**Multiple Error Action** — This occurs when one or more of the generic flags are generated on 3 consecutive runs.

**None:** The system takes no action and continues sample processing.

**Notify:** The operator is notified via on-screen message. The system can also notify the operator via text messaging or notification preference.

**Stop:** The system stops sample processing and notifies the operator.

**Report Format** — Choose the Standard or Reduced Header.

**LMD File Format** — Choose the FCS file format for exported listmode files.

- **FCS3.1 High Res**
- **FCS2.0 Low Res**





— Use to save any changes to the system setup.

**Messaging/Email** — Defines mail settings so that error and warning messages can be emailed or sent via text message.

## View Instrument Serial Number

---

1 Select  as shown in [Figure 8.2](#).


2 Select .

3 View the system identifier number under the Instrument Serial Number field.

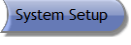
**NOTE** Only a Beckman Coulter Representative can change this field. The serial number can be found on the instrument serial number plate or the supply cart serial number plate.

## View or Setup Facility Name & Address

---

1 Select  as shown in [Figure 8.2](#).

---

2 Select .

---

3 Enter Facility Name.

---

4 Enter Facility Address.


---

5 Select .

---

### View or Upload Facility Logo

---

1 Select  as shown in [Figure 8.2](#).

---

2 Select .

---

3 Select the  next to the Logo box.

---

4 Browse for facility logo.

---

5 Select .

---

6 Upload your facility's Logo.


---

7 Select .

---

### Alarm Setup

---

1 Select  as shown in [Figure 8.2](#).

---

2 Select .

---

3 Use the Alarm drop-down menu to enable or disable (ON or OFF) the alarm.


---

4 Select .

---

### Setup Warning Level

---

1 Select  as shown in [Figure 8.2](#).

---

2 Select .

---

3 Use the Warning Level drop-down menu to set up the system to warn you at the selected number of tests remaining based on AQUIOS application specific reagents, not including the monoclonal antibodies.


---

4 Select .

---

### Setup Default Test (Autoloader Only)

---

1 Select  as shown in [Figure 8.2](#).

---

2 Select .

---

3 Use the Default Test drop-down menu to assign a default assay for autoloader samples without a request. The default tests could be any test, or no default test. If default test is Off, the autoloader samples without a request go to the Incomplete screen.

---

4 Select  .


---

### Setup QC Tracking

---

1 Select  as shown in [Figure 8.2](#).

---

2 Select  .

---

3 Use the QC Tracking drop-down menu to define how often the system will require you to run QC without having a flag. The system default setting is “Daily”. The frequency could be every 8 Hours, every 12 Hours, Daily, Weekly, or Manual.

---

4 Select  .


---

### Setup Auto Printed Results



**All results should be reviewed by a laboratory professional when interpreting the data. If results are suspect, follow your laboratory's procedures to resolve.**

---

1 Select  as shown in [Figure 8.2](#).

---

2 Select  .

---

3 Use the Auto Printed Results drop-down menu to select automatic printing for None, All, Flags, or Flags and Notifications.

---

4 Select  .

---

## Auto Transmit

- 1 Select **On** to turn on the Auto Transmit feature. If the LIS is enabled, results with no flags and notifications are automatically sent to the LIS.
- 2 Select **off** to turn off the auto transmit feature and results will not automatically be sent to the LIS.

**NOTE** Results with flags or notifications cannot be sent to the LIS using Auto Transmit. You must review these results and transmit them individually.

**NOTE** The results that are automatically transmitted are not marked as "Reviewed".

## Test Settings

Use the Test Settings screen (Figure 8.3) to define your test preferences. Test Settings are application specific.

Figure 8.3 Test Settings Screen [Tetra Application]

Requests (0) Running (0) Incomplete (0) Review (198)

System Setup  
Test Settings  
Reagent Info  
LIS Setup  
Archive/Import  
Backup/Restore  
User Setup  
Reports  
RMS

Test: Tetra 1  Hide Test  
Default Report Option: Results  
Warning Level: 0 Tests  
LIS Test Code: TETRA1

Result	Units	LIS Code	Normal		Action	
			Low	High	Low	High
CD3+ (T Cells)	Percent	CD3PCT				
CD3+ (T Cells)	Count/uL	CD3CNT				
CD3+/CD4+ (Helper T Cells)	Percent	CD4PCT				
CD3+/CD4+ (Helper T Cells)	Count/uL	CD4CNT				
CD3+/CD8+ (Suppressor T Cells)	Percent	CD8PCT				
CD3+/CD8+ (Suppressor T Cells)	Count/uL	CD8CNT				
CD4/CD8 Ratio		*BRATIO				
*CD3+ Reliability Check		*CD3REL				

Note: Percents must be entered as decimal.  
Example 20% = .2

View Advanced Settings Edit Save

QC  
Result  
Setup  
Maint.  
Barcode  
Stat  
Exit

Start LIS RMS Reagent Levels: OK 48 Remaining Wells Open Reagent Door Database: Default User: Admin Help About 3:00 PM

**Test** — Use the drop-down menu to select a test to view or modify.

**Hide Test checkbox** — Removes tests from the drop-down list that is used to select a test. When a test is selected and the "Hide Test" box is checked, the indicated test is hidden from Users. Consequently, the identified test cannot be selected when test requests are generated. For example, if the "Hide Test" is enabled for Tetra1 in the Test Settings screen, when a user goes to the "Requests" screen and clicks the "+" to add a new request, the "Tetra1" test will not be available as one of the tests in the "Test" drop-down. Only users with Administrator rights can enable or disable a test from being hidden.

**Default report option** — Select from the drop-down menu the preferred pre-defined plots to show on the screen and in the reports. Refer to application specific System Guide.

**Warning level** — Use the drop-down menu to schedule how far in advance you will be warned before the antibody reagents are depleted. The warning levels are 1, 3, 5, 10, 15, 20, and 25. Zero values means the Settings are off and Reagents warning will not display on the Status bar. The out of reagent message will be displayed and cannot be disabled.

**LIS Test Code** — Code used by the LIS to identify this test. This code cannot be used for more than one test in the system.

**Result Table** — The result table includes:

**Result:** These are pre-defined results for the test, filled in by the system.

**Units:** These are the formats in which the results are presented.

**NOTE** Percent values should be entered as a decimal. For example 35% should be entered as 0.35.

**LIS Code:** Code used when transmitting this result to the LIS. This code cannot be repeated within the test.


**Normal Ranges (Low, High):** Use to type normal range values for the test. When a sample is run, results outside the ranges are marked as “H” or “L” as appropriate in the reports and on the review and results screens.


**IMPORTANT** Tests with results outside the action range will not auto transmit to LIS.

**Action Ranges (Low, High):** Use to enter action range values for the test. When a sample is run, results outside the ranges are marked as “HH” or “LL” in the reports and on the review and results screens.

**NOTE** Action Ranges take precedence over Normal Ranges.

**NOTE** For Controls, assay ranges take precedence over Action Ranges.


 — View settings and select/de-select results to display. The screen is a read-only format; it cannot be edited, except to Show or Hide results.

 — Use to modify the test settings.

 — Use to save modifications to the test settings.

## Setup Default Reports Option for a Specific Test

---

1 Select  as shown in [Figure 8.2](#).

---

2 Select . See [Figure 8.3](#).

---

3 Use the Test drop-down menu to select the assay.




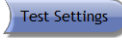
- 
- 4 Use the Default Report Option drop-down menu to setup the preferred report format for the selected test.
- 

- 5 Select .
- 

### Setup Antibody Reagent Warning Levels for a Specific Test

---

- 1 Select  as shown in [Figure 8.2](#).
- 

- 2 Select . See [Figure 8.3](#).
- 


- 3 Use the Test drop-down menu to select the test.
- 


- 4 Use the Warning Level drop-down menu to set up the system to warn you at the selected number of test remaining for the specified test.
- 

- 5 Select .
- 

### View or Edit Normal and Action Values for a Specific Test

---

- 1 Select  as shown in [Figure 8.2](#).
- 

- 2 Select . See [Figure 8.3](#).
- 

- 3 Use the Test drop-down menu to select the assay.
- 

- 4 View the Result Table for the specific test.
-

5 Select .

**NOTE** When in Edit Mode, *In Edit Mode* is displayed in red text above the Result Table.

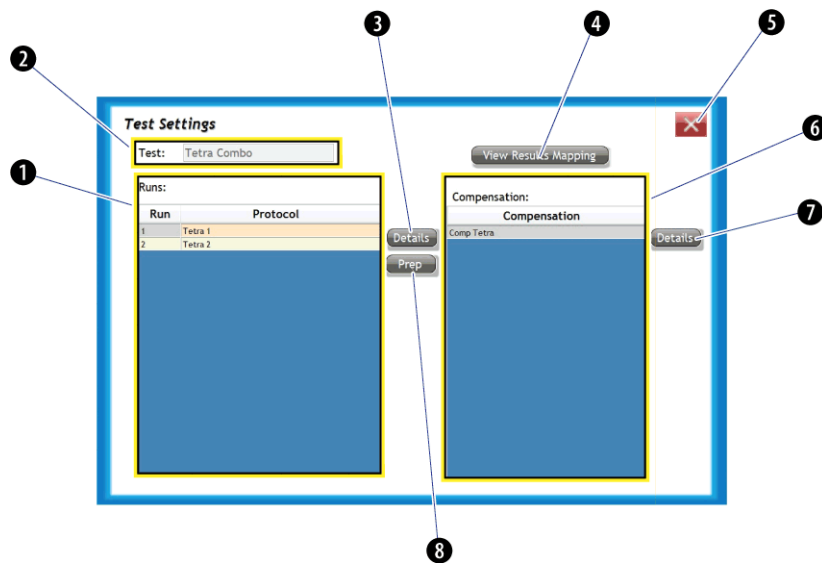
6 Edit the Normal or Action Ranges.

7 Select .

The View Advanced Settings screen (Figure 8.4) is used to access run details, run prep, compensation details, and review results mapping screens for the selected test. The Test Settings, View Advance Settings Screen are application specific. For this example, the test used was Tetra Combo (Figure 8.4).

**NOTE** These settings are for reference only and can not be modified by the user, except for Hide and Show on View Results Mapping and Import in Compensation Details.

**Figure 8.4** Test Settings, View Advance Settings Screen [Tetra Application]



**Table 8.1** Test Settings, View Advanced Settings Screen (Read-Only): Defined

Item	Definition
1	<b>Runs Table</b> - Displays the available runs and protocols for the selected test.
2	<b>Test</b> - Displays the selected test.
3	<b>Details (Runs)</b> - Use to view the voltage, gain, and discriminator settings, as well as the flow rate used for the selected test.
4	<b>View Results Mapping</b> - Use to display the Results Mapping screen and view the formula definition used for each result, and to show or hide a result.

**Table 8.1** Test Settings, View Advanced Settings Screen (Read-Only): Defined (Continued)

Item	Definition
5	<b>Close</b> - Use to close the screen.
6	<b>Compensation Table</b> - Use to view the current compensation settings for the selected test.
7	<b>Details (Compensation)</b> - Use to access the Compensation Details screen to view when compensation values were saved.
8	<b>Prep (Runs)</b> - Use to access the Run Prep screen and view the settings used to prepare and lyse the samples, such as volumes, mix cycles, and mix speed.

The Results Mapping screen (Figure 8.5) is used to display the formula definition used for each result, and are application specific.

**IMPORTANT** You can show results or hide results from this display menu. If changes are made, select



, then select save on the Test Settings screen to ensure that the changes are implemented.

**Figure 8.5** Test Results Map [Tetra Application]

Row Name	Column Name	Definition	Hidden
Average CD3+ (T Cells)	Percent	( ( [Combo Tetra 1 ][CD3+ All][Count] / [Combo Tetra 1 ][LymphsCorrected][Count] ) + ( [Combo Tetra 2 ][CD3+ All][Count] / [Combo Tetra 2 ][LymphsCorrected][Count] ) ) / 2	False
Average CD3+ (T Cells)	Count/uL	( [Combo Tetra 1 ][CD3+ All][Counts/uL] + [Combo Tetra 2 ][CD3+ All][Counts/uL] ) / 2	False
CD3+/CD4+ (Helper T Cells)	Percent	( [Combo Tetra 1 ][8+ 4][Count] + [Combo Tetra 1 ][LymphsCorrected][Count] ) / [Combo Tetra 1 ][LymphsCorrected][Count]	False
CD3+/CD4+ (Helper T Cells)	Count/uL	[Combo Tetra 1 ][8+ 4][Counts/uL] + [Combo Tetra 1 ][8+ 4][Counts/uL]	False
CD3-/CD8+ (Suppressor T Cells)	Percent	( [Combo Tetra 1 ][8+ 4][Count] + [Combo Tetra 1 ][LymphsCorrected][Count] ) / [Combo Tetra 1 ][LymphsCorrected][Count]	False
CD3-/CD8+ (Suppressor T Cells)	Count/uL	[Combo Tetra 1 ][8+ 4][Counts/uL] + [Combo Tetra 1 ][8+ 4][Counts/uL]	False
CD3-/CD19+ (B Cells)	Percent	[Combo Tetra 2 ][19+56-][Count] / [Combo Tetra 2 ][LymphsCorrected][Count]	False
CD3-/CD19+ (B Cells)	Count/uL	[Combo Tetra 2 ][19+56-][Counts/uL]	False
CD3-/CD56+CD16+ (NK Cells)	Percent	[Combo Tetra 2 ][NKTotal][Count] / [Combo Tetra 2 ][LymphsCorrected][Count]	False
CD3-/CD56+CD16+ (NK Cells)	Count/uL	[Combo Tetra 2 ][NKTotal][Counts/uL]	False
CD4:CD8 Ratio	Ratio	( [Combo Tetra 1 ][8+ 4][Count] + [Combo Tetra 1 ][8+ 4][Count] ) / ( [Combo Tetra 1 ][8+ 4][Count] + [Combo Tetra 1 ][8+ 4][Count] )	False
		( [Combo Tetra 2 ][CD3+ All][Count] + [Combo Tetra	

**Row name** — Displays the measured statistics

**Column name** — Displays the units for the measured statistics


**Definition** — Displays the formula definition for each statistic to be displayed

**Hidden** — Indicates whether a result is displayed, on the screen, printed on the report and transmitted to LIS. True means the results is not displayed, printed or transmitted. False means result is displayed, printed and transmitted.



— Do not display the result, do not print it, and do not transmit to the LIS.

**Show Result** — Display the result, print it, and transmit it to the LIS.

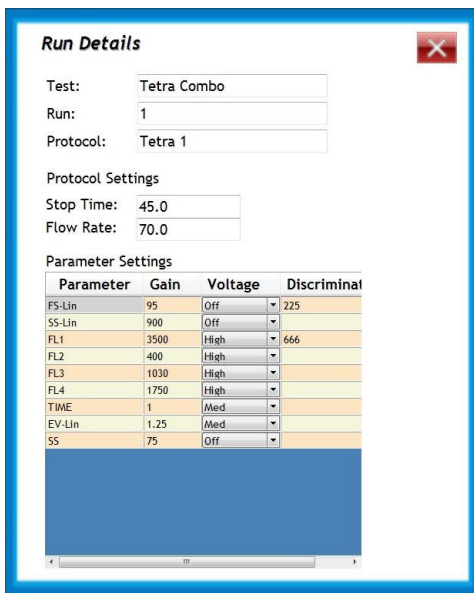
 — Use to exit this screen. After exiting, if changes were made to Hide or Show Results, select

**Save** on the Test Settings screen to save changes.

The Test Settings, Run Details screen (Figure 8.6) is used to view the protocol and parameter settings for a specific test, run, and protocol.

**IMPORTANT** These settings can not be changed. This display is for information purposes only.

**Figure 8.6** Test Settings, Run Details Screen [Tetra Application]



**Test** — Displays the selected test

**Run** — Displays the run number

**Protocol** — Displays the selected protocol

**Protocol Settings:**

**Stop Time:** Displays the sample analysis time in seconds

**Flow Rate:** Displays the rate of fluid flow in  $\mu\text{L}/\text{minute}$

**Parameter Settings:**

**Parameter:** Displays the parameters measured for the selected protocol

**Gain:** Displays the software gain applied to the data

**Voltage:** Displays the voltage (high, medium, low or turned off) on the detector for each parameter

**Discriminator:** Displays the minimum threshold for a given parameter

The Test Settings, Prep Details screen (Figure 8.7) is used to view the settings used to prepare and lyse the samples, such as volumes, mix cycles, and mix speed. This information is application specific.

**IMPORTANT** These settings can not be changed. This display is for information purposes only.

Figure 8.7 Test Settings, Prep Details [Tetra Application]

**Prep Details**

Run: 1 Protocol: Tetra 1

Blood Volume: 43.0 Analyze Length: 95

Flow Count Volume: 0.0 Analyze Window: 240

Prep:

Length (how long it takes to prep): 51

Incubation Length: 900

Reagent	Volume	Mix Cycles	Mix Speed
AQUIOS Tetra-1 Panel 18	18	13	1.35

Lyse:

A Reagent: AQUIOS Lysing Reagent A A Volume: 335.0

B Reagent: AQUIOS Lysing Reagent B B Volume: 100.0

Length (how long it takes to lyse): 51

Incubation Length: 30

Lyse Window: 1800

Reagent	Volume	Mix Cycles	MixSpeed
---------	--------	------------	----------

**Run** — Displays the test associated with the prep details.

**Blood Volume** — Displays the  $\mu\text{L}$  of blood dispensed in the well.

**Flow Count Volume** — Displays the  $\mu\text{L}$  of Flow Count dispensed in the well.

**NOTE** Flow Count is an application specific reagent.

**Protocol** — Displays the protocol.

**Analyze Length** — Displays the length of time it takes to analyze a sample in seconds.

**Analyze Window** — Displays the maximum number of seconds in which a sample can be analyzed.

**Prep:**

**Prep Length:** Displays how many seconds it takes to prepare a sample.

**Incubation Length:** Displays how many seconds the sample is incubated.

**IMPORTANT** This area is for the lytic agents being used with the selected test.

**Lyse:**

**Lyse A Reagent:** Application specific depending on the test being run.

**Lyse B Reagent:** Application specific depending on the test being run.

**Lyse A Volume:** Application specific depending on the test being run.

**Lyse B Volume:** Application specific depending on the test being run.

**Lyse Length:** Displays the length of time it takes to lyse a sample in seconds.

**Lyse Incubation Length:** Displays the minimum incubation time in seconds allowed for the lyse reagents.

**Lyse Window:** Displays the maximum incubation time in seconds allowed for the lyse reagent.

**Reagent Tables:**

**Reagent:** Use to view the selected reagent

**Volume:** Displays the volume used for the given reagent in  $\mu\text{L}$ .

**Mix Cycles:** Displays how many times the reagent is mixed

**Mix Speed:** Displays how fast the reagent is mixed in cycles/sec

The Test Settings, Compensation Details screen (Figure 8.8) is used to view any changes by date and source made in the compensation.

**Figure 8.8** Test Settings, Compensation Details Screen [Tetra Application]

The screenshot shows a window titled "Compensation Details" with a close button (X) and an "Import Values" button. Below the title bar, there is a text field labeled "Compensation:" containing the text "Comp Tetra". Underneath, the word "Values:" is followed by a table with three columns: "User", "Date", and "Source". The table contains 20 rows of data, all with "Admin" as the user and "False" as the source. The dates range from 7/2/2012 to 9/10/2012.

User	Date	Source
Admin	7/2/2012 6:58 PM	False
Admin	9/6/2012 1:30 PM	False
Admin	9/6/2012 1:33 PM	False
Admin	9/6/2012 1:45 PM	False
Admin	9/6/2012 1:48 PM	False
Admin	9/6/2012 1:48 PM	False
Admin	9/6/2012 1:50 PM	False
Admin	9/6/2012 1:51 PM	False
Admin	9/6/2012 4:17 PM	False
Admin	9/6/2012 4:25 PM	False
Admin	9/6/2012 4:28 PM	False
Admin	9/6/2012 4:30 PM	False
Admin	9/6/2012 4:32 PM	False
Admin	9/6/2012 4:34 PM	False
Admin	9/6/2012 4:40 PM	False
Admin	9/6/2012 4:41 PM	False
Admin	9/6/2012 4:42 PM	False
Admin	9/10/2012 3:52 PM	False

**NOTE** You can manually adjust the compensation values through the review or result screen (Figure 8.8). However, adjusting compensation is not a routine adjustment. Compensation can only be adjusted by an Operator with special access, such as an Administrator or Reviewer/Editor.

**Compensation** — Displays the test the compensation settings apply to.

**Import Values** — Use to import compensation values previously saved by your Beckman Coulter Representative.

#### Compensation Values Table:

**User:** Displays the user that performed a compensation change

**Date:** Displays the date in which the compensation was changed

**Source:** Use to view if the compensation was imported (True) or defined by the user (False).

## Reagent Info

The Reagent Info screen (Figure 8.9) allows you to obtain information about the different reagents used by the system. There are two recommended methods for loading the new reagent information into the Setup Reagent Info screen. Some reagents can be automatically entered by the system

while others are scanned by selecting the

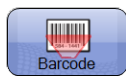
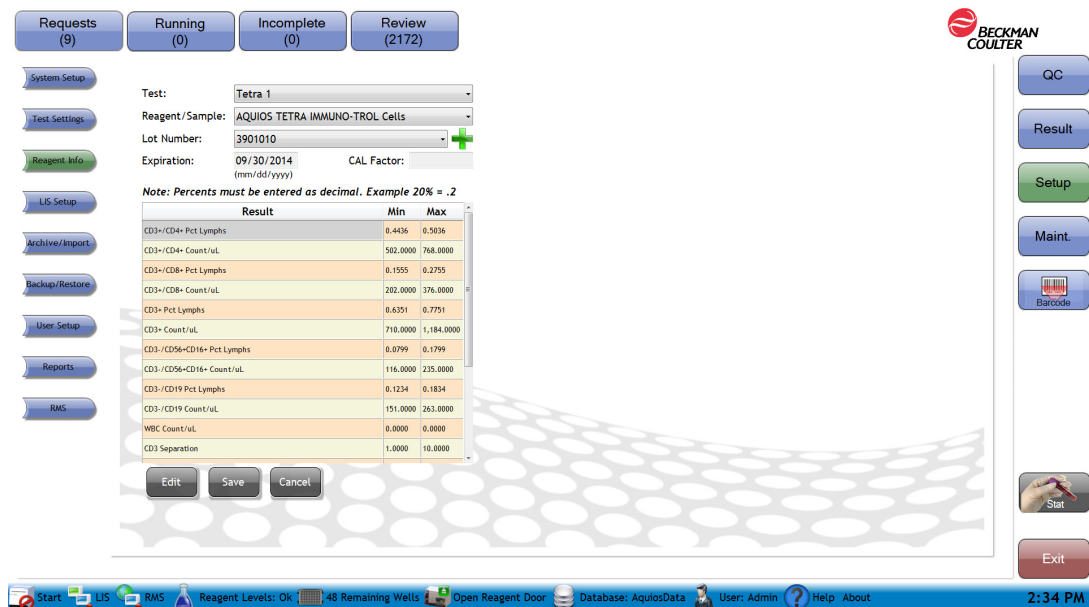


Figure 8.9 Reagent Info Screen [Tetra Application]



Requests (9) Running (0) Incomplete (0) Review (2172)

System Setup  
Test Settings  
**Reagent Info**  
LIS Setup  
Archive/Import  
Backup/Restore  
User Setup  
Reports  
RMS

Test: Tetra 1  
Reagent/Sample: AQUIOS TETRA IMMUNO-TROL Cells  
Lot Number: 3901010  
Expiration: 09/30/2014 CAL Factor:  
(mm/dd/yyyy)

Note: Percents must be entered as decimal. Example 20% = .2

Result	Min	Max
CD3+CD4+ Pct Lymphs	0.4436	0.5036
CD3+CD4+ Count/uL	502.0000	768.0000
CD3+CD8+ Pct Lymphs	0.1555	0.2755
CD3+CD8+ Count/uL	202.0000	376.0000
CD3+ Pct Lymphs	0.6351	0.7751
CD3+ Count/uL	710.0000	1,184.0000
CD3-/CD56-CD16+ Pct Lymphs	0.0799	0.1799
CD3-/CD56-CD16+ Count/uL	116.0000	235.0000
CD3-/CD19 Pct Lymphs	0.1234	0.1834
CD3-/CD19 Count/uL	151.0000	263.0000
WBC Count/uL	0.0000	0.0000
CD3 Separation	1.0000	10.0000

Edit Save Cancel

QC  
Result  
Setup  
Maint.  
Barcode  
Stat  
Exit


Start LIS RMS Reagent Levels: Ok 48 Remaining Wells Open Reagent Door Database: AquiosData User: Admin Help About 2:34 PM

**Test** — Use the drop-down menu to select the test to filter the Reagent/Sample to show reagents used in the selected test.

**Reagent/Sample** — Use the drop-down menu to select the reagent or control name.

**NOTE** The 96 well plate does not display Lot number or Expiration date.

**Lot number** — Use the drop-down menu to select the lot number.

 - Use to enter a new lot number and its expiration date for manual entry of assay values of the controls.

 **CAUTION**

**Risk of Expired reagent flags. If you enter an incorrect control expiration date and run the control, you cannot edit the Expiration Date. When the control expires, the system flags the control runs with Expired Reagent flag.**

**Expiration** — Use to enter or view the expiration date of the reagent or control lot.

**CAL Factor** — The CAL Factor is obtained by scanning the AQUIOS Flow-Count Barcode and is only used when AQUIOS Flow-Count is installed. The CAL factor of the selected AQUIOS Flow-Count is displayed. For Non Flow-Count reagents the CAL Factor is blank and non-editable. This field is application specific.


**NOTE** The CAL Factor and expiration date can not be modified.


**Reagent Results Table** — Use to view assay values for control reagents only. Refer to application specific controls.


**Result:** Results to be monitored for this control reagent

**Min:** Minimum acceptable value for the result

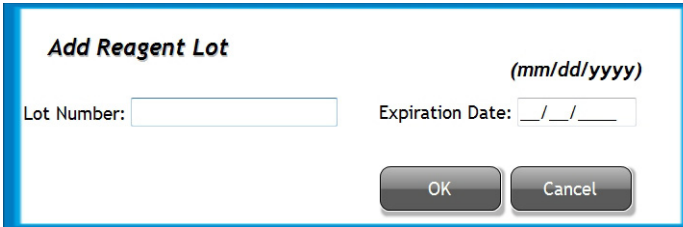
**Max:** Maximum acceptable value for the result

 — Use to allow the information shown to be edited.

 — Use to save changes to the reagent info screen.

 — Use to ignore changes made on the reagent info screen.

**Figure 8.10** Add Control lot number and expiration date in the Reagent Dialog box.

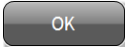



**NOTE** Control lot numbers and expiration dates can be entered manually.



**Lot number** — Use to enter the new Control lot number.


**Expiration date** — Use to enter the new control expiration date.

 — Use to exit and save changes to the Add Reagent Lot dialog.

 — Use to exit and ignore changes to the Add Reagent Lot dialog.

## View Reagent Information

---

1 Select  as shown in [Figure 8.2](#).

---

2 Select . See [Figure 8.9](#).

---

3 Use the Test drop-down menu to select the Test.

---

4 Use the Reagent/Sample drop-down menu to select the reagent or control.

---


5 Use the Lot Number drop-down menu to select the Reagent or control Lot. The information for the selected Reagent or control Lot displays on the screen.

**NOTE** When an assay sheet is scanned, the values do not appear on the Reagent Info window until you exit and re-select the window.

---

## Edit Control Information

---

1 Select  as shown in [Figure 8.2](#).

---

2 Select . See [Figure 8.9](#).

---

3 Use the Reagent/Sample drop-down menu to select the Control.

**NOTE** The expiration date of used control lots cannot be modified.

---

4 Use the Lot Number drop-down menu to select the Control Lot.

---

5 Select .

---

6 Edit the Expiration Date field.

**NOTE** The expiration date can only be modified if it is a control and it has not been previously run.

---

**IMPORTANT** Ensure that both Results and Separations are entered from the assay sheet.

---

7 Edit the Reagent Results Table for any control.


---

8 Select .

---

### Add New Controls Lot Manually

---

1 Select  as shown in [Figure 8.2](#).

---

2 Select . See [Figure 8.9](#).

---

3 Select  and [Figure 8.10](#) appears.

---

4 Enter the Lot Number for the new control lot.

---

5 Enter the Expiration Date for the new control lot.

---

6 Select .

---

7 Proceed to the next steps.

a. Select . See [Figure 8.9](#).

**IMPORTANT** Ensure that both Results and Separations are entered from the assay sheet.

b. Enter the Control Assay values from the package insert on the Reagent Results Table.

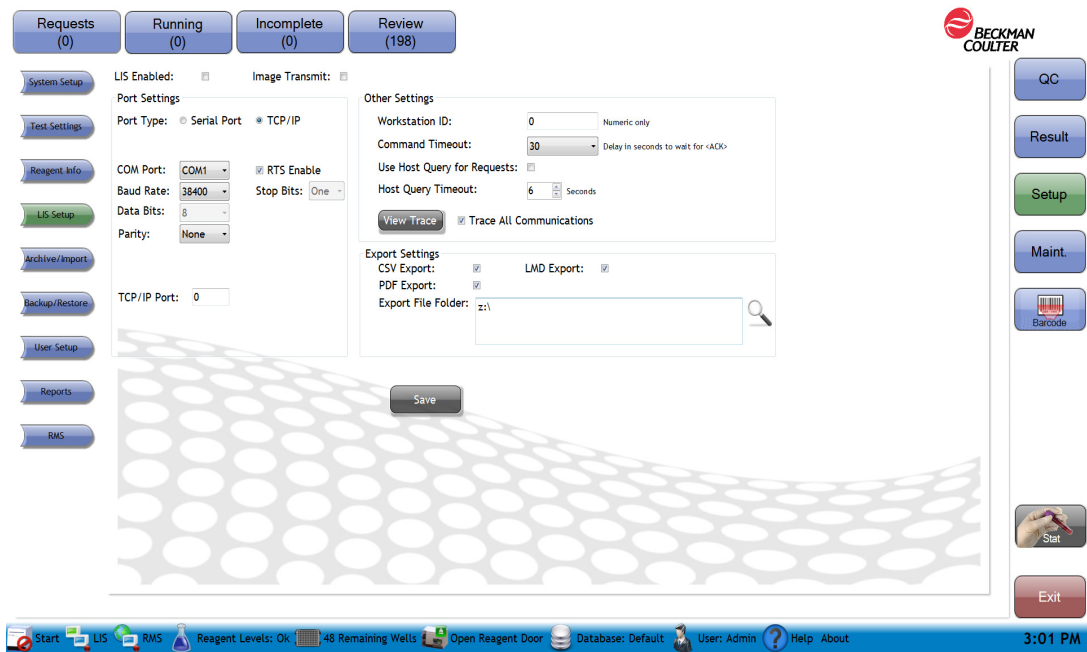
c. Select .

## LIS Setup Screen

### LIS Setup

The LIS Setup Screen is shown in [Figure 8.11](#).

**Figure 8.11** LIS Setup Screen



**LIS Enabled** — Check this box to use an LIS and establish a connection to the LIS.

**Port Type** — Select Serial Port or TCP/IP.

**Image Transmit** — Select Image Transmit to select all plot images per Test Settings will be transmitted to the LIS along with the results.

**NOTE** The Image Transmit checkbox will be disabled and unchecked if the Serial Port radio button is checked.

**NOTE** All settings are shared among network instruments except **LIS Setup > Workstation ID**.

**Serial Port Settings** — If the Port Type is Serial Port, select the serial port settings here.

**COM Port:** Serial port connected to the LIS. Serial ports supported by the system are Com 1 through Com 18.

**Baud Rate:** Data rate in bits per second (bps). The data rates supported by the system are 4800, 9600, 19200, 38400, and 57600 bps.

**Data Bits:** Data bits/character transmitted. The system only supports 8 data bits/character.

**Stop Bits:** Sent at the end of every character to allow the receiving system to detect the end of a character and to re-synchronize. The system only supports one stop bit.

**Parity:** Used to detect errors in the transmission by sending extra bits denoting the number of "1" bits in each character. The system supports None, Odd, and Even.

**RTS Enable:** Enables the use of the RTS control signal. The Ready To Send (RTS) control signal tells the device to be ready to accept data from the system.

**TCP/IP Settings** — If the Port Type is TCP/IP, select the network settings here.

**NOTE** LIS system needs to restart the connection with the instrument if the communication is lost.

**Local IP Port:** This is the port number to be used by a client for communicating with this system.

**Other Settings** —

**Workstation ID:** The name that the remote computer uses to identify the flow cytometer. Numeric entry only.

**Command Timeout:** Used by the system as a timeout to denote the maximum amount of time, in seconds, to wait for an <ACK> when communicating with the remote system. The options in seconds are 5, 10, 15, 20, 25, and 30.

**Use Host Query for Requests:** If On, the system transmits a host query request message to the LIS upon scanning a specimen barcode within the cassette. It waits for this test order before it times out. Only the systems connected directly to the LIS transmits the Host Query request. In the case where systems are connected in a networked database environment, each system connected directly to the LIS supports this feature. If this feature is not enabled, but LIS is enabled and connected, orders will appear on the requests screen upon entry in the LIS.

**Host Query Timeout:** Specifies the host query time out from 6 to 90 seconds.

**Trace All Communications:** If On, keeps a log in the database of all information sent to and received from the LIS. The maximum number of entry lines in the log is 3000. The oldest half of the entries in the log are automatically purged when the maximum is exceeded.

**View Trace:** If Trace All communications is On, shows the information being sent to the LIS as text.

**Export Settings** — These actions are triggered when a sample run is transmitted to the LIS (either automatically, or via review). Files are named as follows: SampleId\_yyyyMMddHHmmss.pdf/csv/lmd.

**NOTE** The sample ID will have any Windows invalid file name characters removed.

**CSV Export:** If On, the system exports results to a CSV spreadsheet file.

**PDF Export:** If On, the system exports a report printout for the run to a PDF file.

**Export File Folder:** Folder where the system saves the exported files. A message is generated if either of the export options are on, and it is an invalid file folder.

**LMD Export:** If On, the system exports FCS Standard listmode files for all runs in the panel regardless of transmission status.

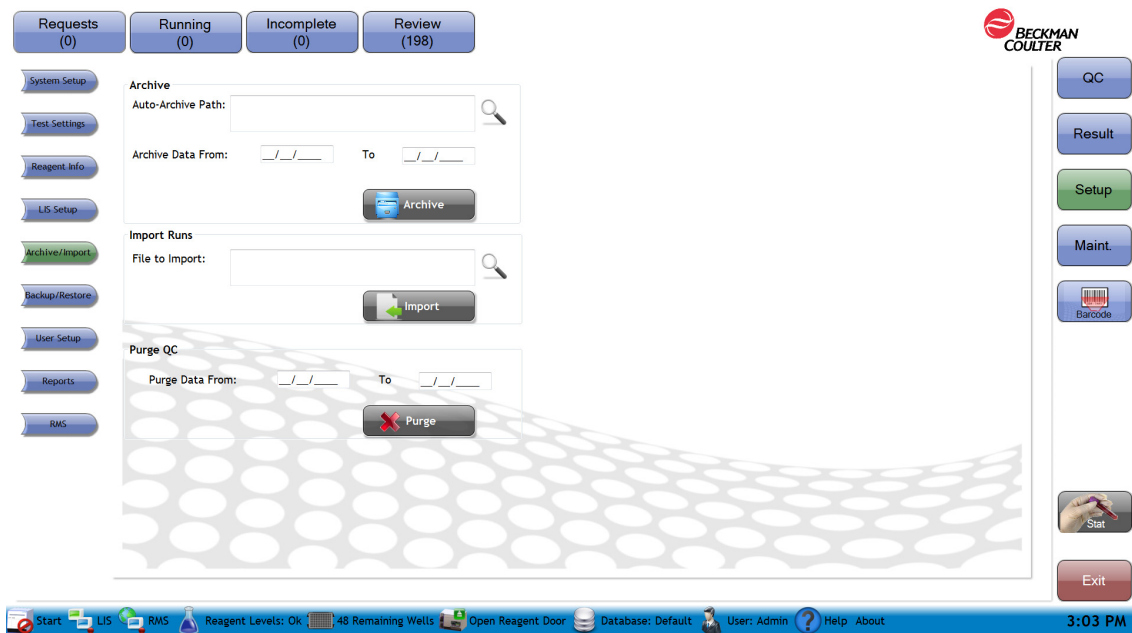
**Save** — Save all changes. The user must exit the software and relaunch it for the changes to take effect.

**NOTE** To connect the AQUIOS system to the Laboratory Information System (LIS), contact the LIS professional who is responsible for your LIS connection. Be sure to verify that your LIS connection is working properly after initial setup.

## Archive/Import Screen

Archive saves Reviewed results to a native format (CRD) file at the specified location and deletes the archived results from the database. Only results between the From and To dates are archived. See [Figure 8.12](#).

Figure 8.12 Archive/Import Screen



### Archive:

**Auto-archive path:** Use to specify the network or local folder where to save the archive file. See “Select the Archive Path” screen.

**Archive Data From, To:** Use to enter a date range to select files for archival



: Use to create an archive file based on the entered criteria. The archived results are deleted from the database.

**Import Runs** — Use to import information from a previously archived file to the database.

**File to import:** Use to locate the file to be restored/imported



: Select this to restore the information in the archived file to the database.


**Purge QC** — Deletes QC runs from the database for the date period specified.

**Purge Data From To:** Only data with the run date within the specified date range are purged.






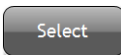
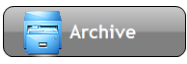
: Select this to delete QC runs from the database for the date period specified.

## Setup Archive

You can use  to transfer results and the associated raw data from one AQUIOS workstation to another.




**NOTE** When you import runs, reagent information is removed.

**NOTE** Data archived or exported using another version of the software cannot be imported using a different version of software.

- 1 Select  as shown in [Figure 8.2](#).
- 2 Select . [Figure 8.12](#) appears.
- 3 Select  next to Archive to select the path where to save the file.
- 4 Select .
- 5 Enter the From and To dates. Results from these dates, including those dates, are archived.
- 6 Select .

## Import Runs

Use to import the results from an archived file back into the database. Also use to Import a CRD file that was exported from the QC, Review, or Result screens.

- 1 Select  as shown in [Figure 8.2](#).
- 2 Select . [Figure 8.12](#) appears.
- 3 Select  next to Import File. The Import File Screen appears.

4 Select the file to import.

5 Select .

6 Select .

## Backup/Restore Screen

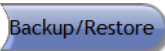
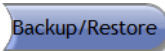
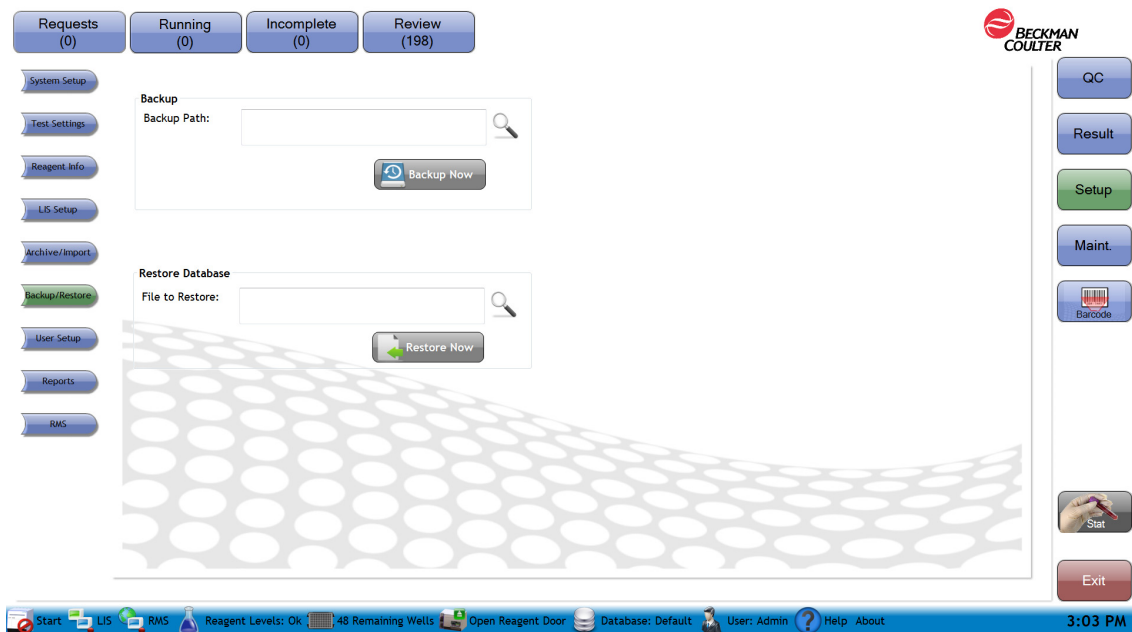

Use  to make a backup copy of the entire database.  can also be used to transfer a database to another computer. See [Figure 8.13](#).

Figure 8.13 Backup/Restore Screen

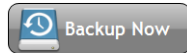





**Backup** — Use to make a backup copy of the entire database.


**Backup Path:** Select  next to the backup path to select the location where to save the backup file.

**NOTE** The name of the backup file can not be changed. If you change the name, the system can no longer restore the backup file.

 : Use to backup the database now

**Restore Database** — Use to restore a database from a backup.


**File to Restore:** Select  next to File to Restore to select the backed up database file to restore.

 : Use to restore the database now

**NOTE** Once restore is performed all existing data is lost. Backup before restoring if necessary.

## Backup Database


---

1 Select  as shown in [Figure 8.2](#).

---

2 Select .

---

3 Select  next to Backup to select the path where to save the backup file.

**NOTE** The name of the backup file can not be changed. If you change the name, the system can no longer restore the backup file.

---


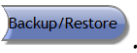


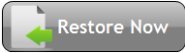
4 Select .

---

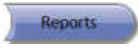
5 Select .

---

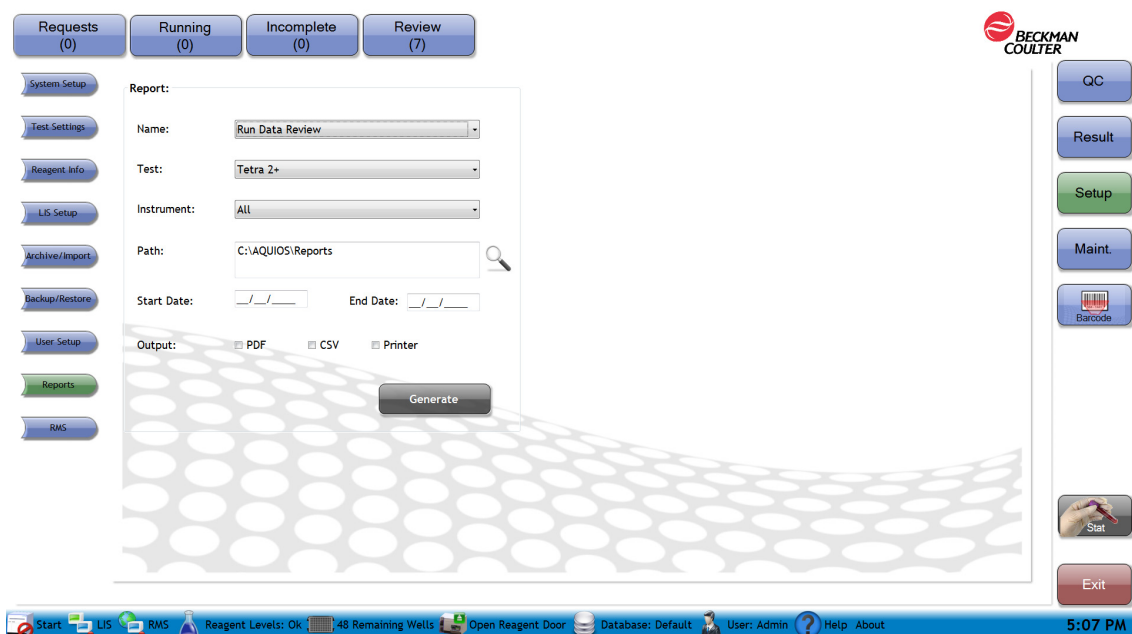
## Restore Database

- 1 Select  as shown in [Figure 8.2](#).
- 2 Select .
- 3 Select  next to File to Restore to select the file and restore entire database.
- 4 Select .
- 5 Select .

## Reports

Use  to create reports. See [Figure 8.14](#).

**Figure 8.14** Reports [Tetra Application]



Requests (0) Running (0) Incomplete (0) Review (7)

System Setup Test Settings Reagent Info LIS Setup Archive/Import Backup/Restore User Setup Reports RMS

Report:

Name: Run Data Review

Test: Tetra 2+

Instrument: All

Path: C:\AQI\OS\Reports

Start Date: / / End Date: / /

Output:  PDF  CSV  Printer

Generate

QC Result Setup Maint. Barcode Stat Exit

Start LIS RMS Reagent Levels: Ok 48 Remaining Wells Open Reagent Door Database: Default User: Admin Help About 5:07 PM

**Name** — List of reports which may be printed. Select either the Run Data Review or the Activity Report from the drop-down.

**Run Data Review:** The patient default test report utilizing the report header format designated in the System Setup Area.

**Activity Report:** The instrument activity and error report.

**Test** — Selection of test available. The combo box is disabled for the Activity Report.

**Instrument** — Provides a filter by Instrument.

**Path** — Path of where the output report should be saved.

**Start and End Date** — Start and End dates of the report.

**Output** — Type of output report, PDF, CSV, and/or Printer.

**Generate** — On selection, leads to the creation of the defined report.

**Run Data Review:** The PDF output filenames will be in the format “Test Name SampleID “yyyyMMddHHmmss.pdf/”, with analysis date and time. For PDFs, each run within the date range will be saved as separate PDF with format specified in System Setup Report Format option. Note the sample ID will have any Windows invalid file name characters removed.


The CSV output filename will be in the format “Report Name yyyyMMddHHmmss.csv”, with the current date and time.

**NOTE** If a file already exists with the required filename, the software will append a number “(x)” (starting at “(2)”) at the end of the filename (before the .pdf/csv extension).

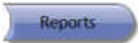
**Activity Report:** The output file names will be in the format “Activity Report Instrument Serial Number yyyyMMddHHmmss.pdf/csv”, where the first date is the report start date and second date is the report end date.

**NOTE** If a file already exists with the required filename, the software will append a number “(x)” (starting at “(2)”) at the end of the filename (before the .pdf/csv extension).

## Create Report

- 
- 1 Select  as shown in [Figure 8.2](#).

---

  - 2 Select .

---



  - 3 Select name of report, either **Run Data Review** or **Activity Report**.

---

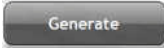
  - 4 Select the test of interest if applicable.

---

  - 5 Select individual instrument or ALL.

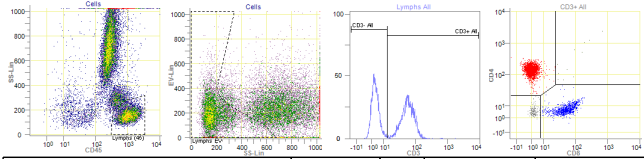
6 Select  next to Path to select the path where to save the report, then choose .

7 Select the start and end dates.

8 Select the type of report you want to generate, PDF, CSV, and/or Printer (see examples), select . The Run Data Review report or Activity Report saves to the selected filepath.

**Run Data Review - PDF example (Tetra Application)**

Sample ID: 89350571776      Test: Tetra 1 v1.2  
 Run Date: 12 Feb 2015 03:06:00      Analysis Date: 12 Feb 2015 03:06:00  
 User: Admin      Collect Date:  
 Specimen Type:      Patient Name:  
 Patient ID:      Gov. ID:  
 Status:      Location:  
 Gender:      Date Of Birth:  
 Physician:      Physician Code:  
 Instrument Serial #: AV44010  
 Run Flags: **Laser Power Error**  
 Run Notifications: **Potential sample or gating issue**  
 Comments:



Result	Value	Flag	Normal Range	Action Range
CD3+ (T Cells) Percent	68.41%			
CD3+ (T Cells) Count/uL	919			
CD3+/CD4+ (Helper T Cells) Percent	47.06%			
CD3+/CD4+ (Helper T Cells) Count/uL	632			
CD3+/CD8+ (Suppressor T Cells) Percent	18.60%			
CD3+/CD8+ (Suppressor T Cells) Count/uL	250			
CD4:CD8 Ratio	2.53			
*CD3+ Reliability Check	2.79%			
CD45+ Low SS Count/uL	1,343			
CD45+ Low SS Percent CD45+	28.84%			
CD45+ Count/uL	4,658			

\* For Analytical QC purposes only | \*\* Population Statistics      12 Feb 2015 15:58:57 Page #1 of 1 Aquios v2.0.0.30

**NOTE** For the Reduced Header report, the footer text “\*For Analytical QC purposes only” is only displayed when the report contains QC Results (\*). The footer text “\*Population Statistics” is only displayed when the report contains Population Statistics (\*\*).

### Run Data Review - CSV example

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O		
1	Run Date	Operator	Test Name	Flag Codes	Notification Codes	Analysis Date	Instrument Se	Institution	Plate ID	Reviewed	Patient Name	Date of Bi	Gender	Status	Location	Goy
2	1/23/2015 13:55	Admin	Tetra Combo			1/21/2015 13:57	CR312023		1.14E+09	FALSE	DNI46933	Tcombo				
3	1/21/2015 13:59	Admin	Tetra Combo			1/21/2015 14:00	CR312023		1.14E+09	FALSE	DNI47673	Tcombo				
4	1/21/2015 14:02	Admin	Tetra Combo			1/21/2015 14:04	CR312023		1.14E+09	FALSE	DNI48256	Tcombo				
5	1/23/2015 14:52	Admin	Tetra Combo	Over Lyse Incubation, Control Range Failure		1/23/2015 14:54	CR313038		1.14E+09	FALSE	AQUIOS IMMUNO-TROL	Cells				Compensation Passed
6	1/23/2015 14:55	Admin	Tetra Combo	Control Range Failure		1/23/2015 14:57	CR313038		1.14E+09	FALSE	AQUIOS IMMUNO-TROL	Low Cells				Compensation Passed
7																

### Activity Report - PDF example

#### Activity Report

Instrument SN: AW13001 | Date: 02/12/2014 - 02/12/2015

#### Patient Runs:

**Total:** 1  
**Reruns - Automatic:** 4    **Manual:** 9

#### Control Runs:

**QC:** 39  
**Background:** 0    **Carryover:** 0    **Repeatability:** 0

#### Error Summary

Error Type	Count
AutoLoader	0
Sheath Waste Fluidics	21
General	0
Sample Prep	0
Plate	0
Analyzer	0
LIS	0

#### Patient Runs

**Total:** Indicates the total number of patient runs within the date range.

**Reruns - Automatic:** Number of instances of the system automatically re-running a tube due to clog/bubble detection.

**Manual:** Number of tests rerun manually.

#### Control Runs

**QC:** Number of QC control runs.

**Error Summary** — Count of errors report by the instrument by type.

## RMS (Windows 7 Only)

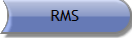
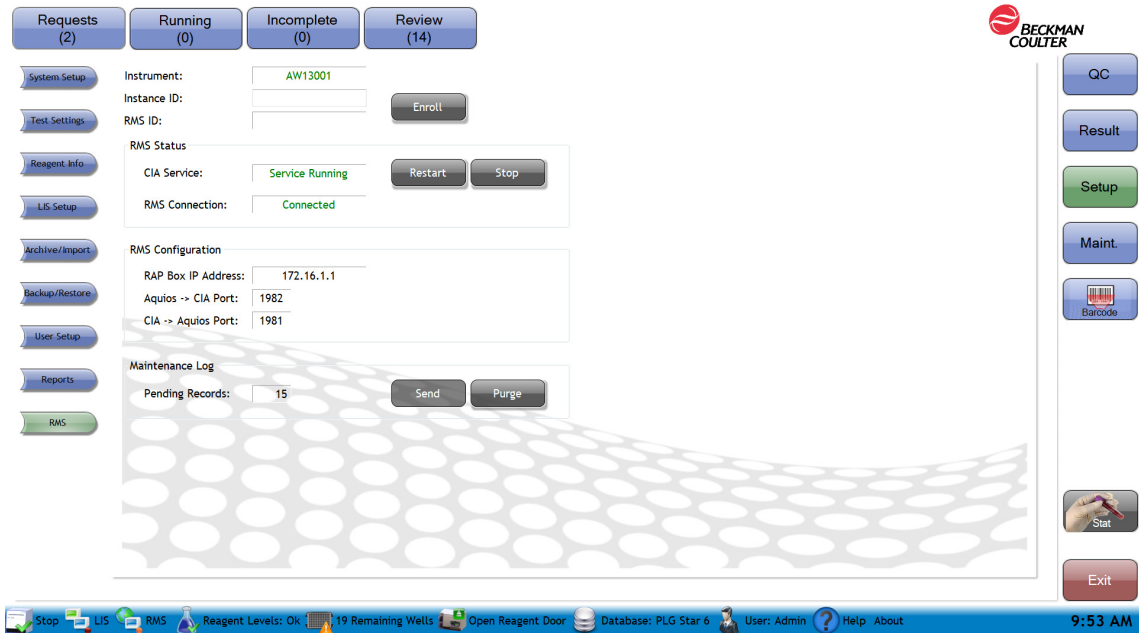



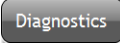
Use  to access the ProService capabilities. This function is for Service only.

Figure 8.15 RMS



## Maintenance Screen

The Maintenance screen (Figure 8.16) contains  and  to trigger cleaning cycles and  and  to trigger the Gravimetrics check and Diagnostics (service only) functions. The Maintenance log displays the routine maintenance performed by the user and the system events, warnings and error messages.

**Figure 8.16** Maintenance Screen



Date	Instrument	User	Type	Action Performed
02/14/2015 8:25 PM	AV44010	Admin	User	New2
02/14/2015 8:23 PM	AV44010	Admin	User	New1
02/14/2015 8:20 PM	AV44010	Admin	User	123
02/14/2015 8:12 PM	AV44010	Admin	User	12345
02/14/2015 6:38 PM	AV44010	System	Routine Tasks	Startup complete.
02/14/2015 6:38 PM	AV44010	System	Vacuum	Vacuum: 14.80233
02/14/2015 6:38 PM	AV44010	System	Voltages	Power Supply Voltages: USB 5V: 5.11 Valve Hold Voltage 8V: 8.11 Valve, IMS, Syringe 24V: 24.92 PMT 15V: 15.05 FPGA 5V analog: 5.03 FPGA 5V digital: 5.00 FPGA -5V analog: -5.01
02/14/2015 6:38 PM	AV44010	System	Laser Settings	Laser Power = 20.0 Laser Current = 0.294
02/14/2015 5:58 PM	AV44010	Admin	User	ABCD2
02/14/2015 5:56 PM	AV44010	Admin	User	ABCD1
02/14/2015 5:54 PM	AV44010	Admin	User	ABCD



- Saves the instrument settings to a PDF file. The system asks for the file name and location where to save the PDF.



- Prints the maintenance log for the instrument to the default printer.



- Saves the maintenance log to a PDF file. The system asks for the file name and location where to save the PDF file.



- Select an entry to add information to the table. The Date and User are filled in by the system. Action Performed is filled in by the user.

**Date** — Date that the event/entry occurred.

**User** — Person who was logged into the system when the entry was made into the maintenance log.


**Type** — User (indicates that the information was typed in by the user), Voltages, Laser Settings, Reagents, Routine Tasks, Maintenance, Potential Errors, System, Vacuum or System Crash.

**Action Performed** — Shows the actual result or measured value. For example:

- Actual voltage, laser power and current, or cal factor
- Startup complete or Shutdown complete
- Reagent that was added
- Detailed error message (only Wash Station, Clogs, and Motors errors are recorded.)

**Filter by:** Select one of the following options to filter results by: All, User, Compensation, Laser Settings, Voltages, System Crash, Maintenance, Routine Tasks, Reagents, Potential Errors, System, and Vacuum

**Instrument Drop Down** — Use to select the instrument with the appropriate serial number.

 Gravimetrics

— Used to access the Gravimetrics screens used for performing the syringe gravimetrics and verifying the syringe pipetting accuracy.

**NOTE** The instrument must be running.

 Flush

— Use to empty fluid from the flow cell, then refills the same locations, running sheath fluid and cleaning agent at a high rate through the flow cell. It is useful for clearing blockages from the flow cell. Wait until the system completes analysis of all running samples in progress before selecting Flush.

 Bleach

— Use to perform a cleaning cycle with AQUIOS Sodium Hypochlorite Solution. Do this only after the system completes analysis of all running samples in progress. [Table 6.2, Generic Flags](#) provides information on when a bleach cycle is required.

 Diagnostics

— For Service Use Only.

## View Maintenance Log Information

---



- 1 Select  as shown in [Figure 8.16](#).



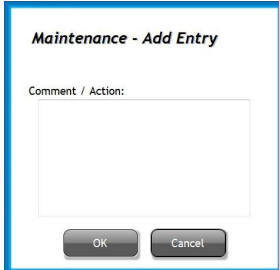
- 
- 2 Use the drop-down menu to select maintenance log view by:
- All
  - User
  - Compensation
  - Laser Settings
  - Voltages
  - System Crash
  - Maintenance
  - Routine Tasks
  - Reagents
  - Potential Errors
  - Vacuum
- 

## Enter Maintenance User Log Entry

---

- 1 Select  as shown in [Figure 8.16](#).
- 
- 2 Select . The Maintenance Add Entry window appears.

### Add Maintenance - Add Entry



*Maintenance - Add Entry*

Comment / Action:

OK Cancel

- 
- 3 Enter Comment/Action.


4 Select .

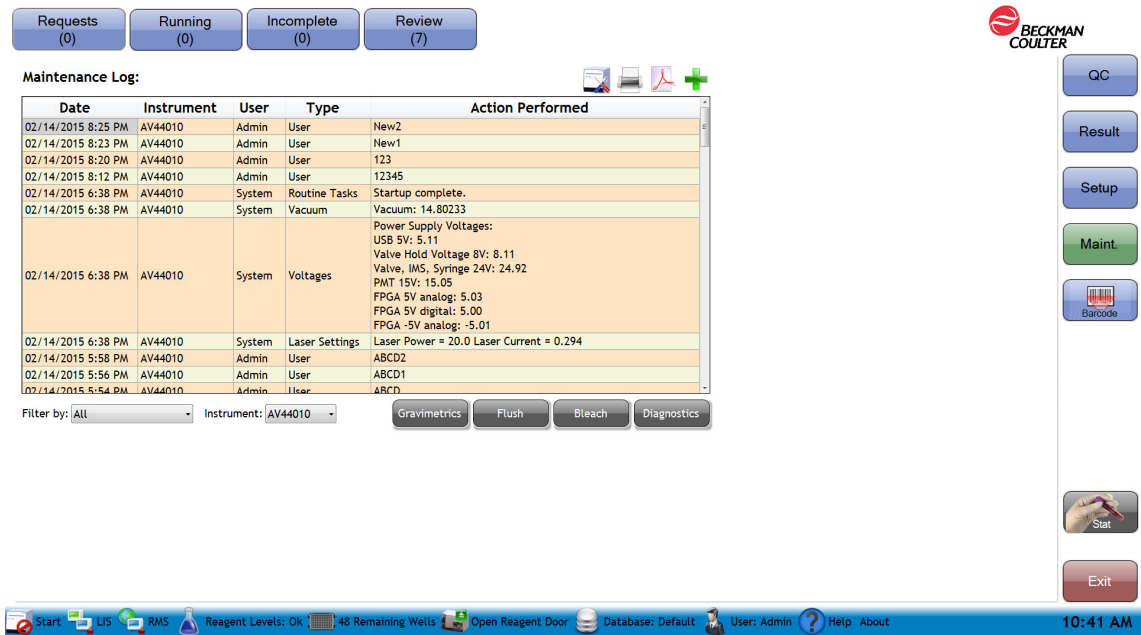
**NOTE** System actions, warnings, and errors are automatically entered in the Maintenance Log by the software.

## Run Flush Cycle

1 Allow all samples currently being analyzed to complete before performing a flush cycle.

**NOTE** If samples are currently being analyzed, a system message appears, stating *Unable to perform Flush. The system is processing samples.*

2 Select  from the side menu to display the Maintenance screen.



Requests (0) Running (0) Incomplete (0) Review (7)

Maintenance Log:

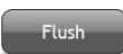
Date	Instrument	User	Type	Action Performed
02/14/2015 8:25 PM	AV44010	Admin	User	New2
02/14/2015 8:23 PM	AV44010	Admin	User	New1
02/14/2015 8:20 PM	AV44010	Admin	User	123
02/14/2015 8:12 PM	AV44010	Admin	User	12345
02/14/2015 6:38 PM	AV44010	System	Routine Tasks	Startup complete.
02/14/2015 6:38 PM	AV44010	System	Vacuum	Vacuum: 14.80233
02/14/2015 6:38 PM	AV44010	System	Voltages	Power Supply Voltages: USB 5V: 5.11 Valve Hold Voltage 8V: 8.11 Valve, IMS, Syringe 24V: 24.92 PMT 15V: 15.05 FPGA 5V analog: 5.03 FPGA 5V digital: 5.00 FPGA -5V analog: -5.01
02/14/2015 6:38 PM	AV44010	System	Laser Settings	Laser Power = 20.0 Laser Current = 0.294
02/14/2015 5:58 PM	AV44010	Admin	User	ABCD2
02/14/2015 5:56 PM	AV44010	Admin	User	ABCD1
02/14/2015 5:54 PM	AV44010	Admin	User	ABCD


Filter by: All Instrument: AV44010

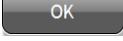
Gravimetrics Flush Bleach Diagnostics

QC Result Setup Maint. Barcode Stat Exit

Start LIS RMS Reagent Levels: Ok 48 Remaining Wells Open Reagent Door Database: Default User: Admin Help About 10:41 AM

3 Select . The message *Are you sure you want to Flush the instrument?* is displayed.

4 Select . The message *The system is Flushing please wait* is displayed.

- 5 The message *Flush complete* is displayed. Select . The Flush cycle is logged in the Maintenance Log.



The screenshot displays the Beckman Coulter maintenance interface. At the top, there are four status buttons: Requests (0), Running (0), Incomplete (3), and Review (34). The main area is titled "Maintenance Log:" and contains a table with the following data:

Date	Instrument	User	Type	Action Performed
1/17/2014 9:36 AM	AV039001	System	Routine Tasks	Flush performed.
1/17/2014 9:27 AM	AV039001	System	Vacuum	Vacuum: 15.35465
1/17/2014 9:27 AM	AV039001	System	Routine Tasks	Startup complete.
1/17/2014 9:27 AM	AV039001	System	Voltages	Power Supply Voltages: USB 5V: 5.11 Valve Hold Voltage 8V: 8.16 Valve, IMS, Syringe 24V: 25.08 PMT 15V: 14.96 FPGA 5V analog: 5.03 FPGA 5V digital: 5.00 FPGA -5V analog: -5.01
1/17/2014 9:27 AM	AV039001	System	Laser Settings	Laser Power = 20.0 Laser Current = 0.359
1/16/2014 7:40 PM	AV039001	System	Routine Tasks	Shutdown complete.
1/16/2014 6:58 PM	AV039001	System	Potential Errors	System flushing, possible clog.
1/16/2014 6:50 PM	AV039001	System	Potential Errors	System flushing, possible clog.
1/16/2014 6:44 PM	AV039001	System	Potential Errors	System flushing, possible clog.
1/16/2014 6:39 PM	AV039001	System	Reagents	Reagent added: AQUIOS Lysing Reagent B Lot: 8901004

Below the table, there are filter options: "Filter by: All" and "Instrument: AV039001". At the bottom of the log area, there are buttons for "Gravimetrics", "Flush", "Bleach", and "Diagnostics".

On the right side of the screen, there is a vertical toolbar with the following buttons: "QC", "Result", "Setup", "Maint.", "Barcode", "Start", and "Exit". The "Beckman Coulter" logo is visible at the top right of this toolbar area.

The bottom status bar shows system information: "Stop", "LIS", "Reagent Levels: Low", "43 Remaining Wells", "Open Reagent Door", "Database: Default", "User: Admin", and "Help About".

## Run Bleach Cycle

 **WARNING**

Risk of chemical injury from bleach. To avoid contact with bleach, use barrier protection, including protective eye wear, gloves, and suitable laboratory attire. Refer to the Safety Data Sheet for details about chemical exposure before using chemicals.

 **WARNING**

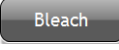
Risk of biohazardous contamination. Clean up any blood spill as quickly as possible. Dispose of all contaminated disposable cleaning materials in accordance with your local regulations and acceptable laboratory practices.

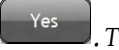
**IMPORTANT** Prior to starting a Bleach Cycle, ensure that a tube of AQUIOS Sodium Hypochlorite in the holder.

- 1 Allow all samples currently being analyzed to finish before performing a bleach cycle.

**NOTE** If samples are currently being analyzed, a system message appears, stating *You cannot perform a Bleach while the system is processing samples.*

- 2 Select  as shown in [Figure 8.16](#).

- 3 Select . *Are you sure you want to Bleach the instrument?* appears.

- 4 Select . *The system is bleaching please wait* appears. *Bleaching complete* then appears. The Bleach cycle is logged in the Maintenance log.

- 5 Select .

## Syringe Gravimetrics

Syringe Gravimetrics must be performed every six months to verify the performance of the Analyzer and Prep syringes on the system.

### Materials Required (supplied)

- 40 tube holder
- Empty Gravimetrics bottle

Refer to [Customer Replaceable Parts](#).

### Materials Required (not supplied)

- 16 each, 12 x 55mm polypropylene test tubes
- Analytical laboratory scale
- Deionized water

Refer to [Customer Replaceable Parts](#).

**NOTE** Ensure that the Sample Prep Probe indicator light is green before performing this test.

### Performing Syringe Gravimetrics

1 Select **Maint.** on the right side of the main screen.

The screenshot shows the Beckman Coulter maintenance interface. At the top, there are four buttons: 'Requests (0)', 'Running (0)', 'Incomplete (0)', and 'Review (7)'. Below these is the 'Maintenance Log' section, which contains a table with the following data:

Date	Instrument	User	Type	Action Performed
02/14/2015 8:25 PM	AV44010	Admin	User	New2
02/14/2015 8:23 PM	AV44010	Admin	User	New1
02/14/2015 8:20 PM	AV44010	Admin	User	123
02/14/2015 8:12 PM	AV44010	Admin	User	12345
02/14/2015 6:38 PM	AV44010	System	Routine Tasks	Startup complete.
02/14/2015 6:38 PM	AV44010	System	Vacuum	Vacuum: 14.80233
02/14/2015 6:38 PM	AV44010	System	Voltagess	Power Supply Voltages: USB 5V: 5.11 Valve Hold Voltage 8V: 8.11 Valve, IMS, Syringe 24V: 24.92 PMT 15V: 15.05 FPGA SV analog: 5.03 FPGA SV digital: 5.00 FPGA -5V analog: -5.01
02/14/2015 6:38 PM	AV44010	System	Laser Settings	Laser Power = 20.0 Laser Current = 0.294
02/14/2015 5:58 PM	AV44010	Admin	User	ABCD2
02/14/2015 5:56 PM	AV44010	Admin	User	ABCD1
02/14/2015 5:54 PM	AV44010	Admin	User	ABCD

Below the table, there are filters for 'Filter by: All' and 'Instrument: AV44010', and buttons for 'Gravimetrics', 'Flush', 'Bleach', and 'Diagnostics'. On the right side of the screen, there is a vertical sidebar with buttons for 'QC', 'Result', 'Setup', 'Maint.' (highlighted in green), 'Barcode', 'Stat', and 'Exit'. The bottom status bar shows 'Start', 'LIS', 'RMS', 'Reagent Levels: OK', '48 Remaining Wells', 'Open Reagent Door', 'Database: Default', 'User: Admin', 'Help About', and the time '10:41 AM'.

- 2 Select **Gravimetrics** from the Maintenance Screen, a message will appear *The software will need to be restarted once the Gravimetrics screen is available. Are you sure you want to continue Gravimetrics?* Select **Yes** or **No**.

**Syringe Gravimetrics**

Reagent Door Unlocked

Perform Gravimetrics  
Calculate Results

To perform gravimetrics, please label 16 12x55 tubes with A1 through B8. Weigh each tube, and record the weights on this screen. Place the tubes in a 40 tube rack. Place the rack on the system. Next place a bottle full of DI water in the reagent location next to A1. Then close the reagent door, and press perform gravimetrics. After the routine completes, weigh the tubes. Record the weights on this screen, and then press calculate results. Save the results to log them in the system log.

Analyzer Syringe Row A			Prep Syringe Row B				
	Before	After	Difference		Before	After	Difference
A1				B1			
A2				B2			
A3				B3			
A4				B4			
A5				B5			
A6				B6			
A7				B7			
A8				B8			
CV				CV			
Average				Average			
Pct Diff from Target (1.2 grams)				Pct Diff from Target (0.4 grams)			
Pass/Fail (+/- 2%), CV < 1%				Pass/Fail (+/- 2%), CV < 1%			

Log and Exit Cancel

- 3 Obtain and label 16 12x55 tubes with A1-A8, B1-B8 with a permanent marker, for placement in the 40-tube holder.
- 4 Measure the weight of the empty A-1 tube.
- 5 Record the weight of the empty A-1 tube on the Syringe Gravimetrics screen under the Before column next to the respective tube number.

**Syringe Gravimetrics**

Reagent Door Unlocked

Perform Gravimetrics  
Calculate Results

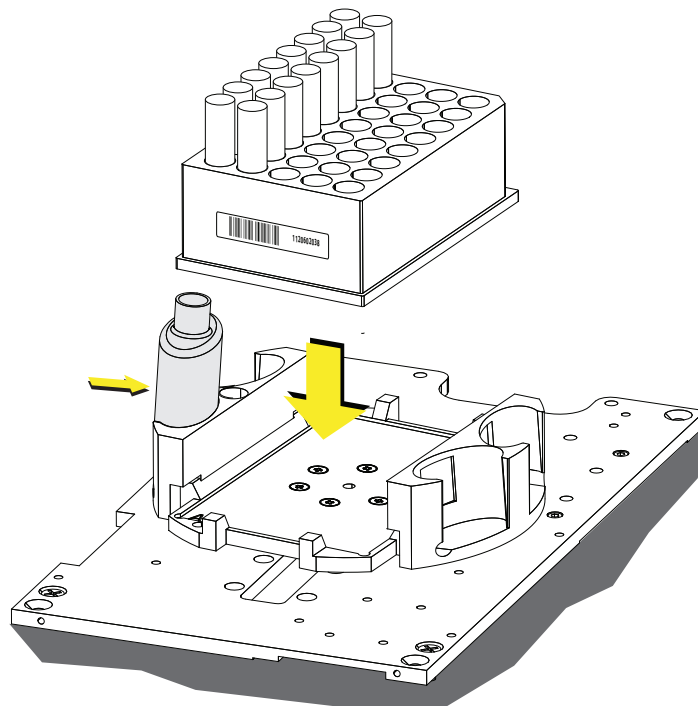
To perform gravimetrics, please label 16 12x55 tubes with A1 through B8. Weigh each tube, and record the weights on this screen. Place the tubes in a 40 tube rack. Place the rack on the system. Next place a bottle full of DI water in the reagent location next to A1. Then close the reagent door, and press perform gravimetrics. After the routine completes, weigh the tubes. Record the weights on this screen, and then press calculate results. Save the results to log them in the system log.

Analyzer Syringe Row A			Prep Syringe Row B				
	Before	After	Difference		Before	After	Difference
A1	1.41067			B1	1.40576		
A2	1.40890			B2	1.41002		
A3	1.40860			B3	1.40700		
A4	1.41924			B4	1.40825		
A5	1.40713			B5	1.41887		
A6	1.40564			B6	1.40352		
A7	1.40580			B7	1.41362		
A8	1.40744			B8	1.40614		
CV				CV			
Average				Average			
Pct Diff from Target (1.2 grams)				Pct Diff from Target (0.4 grams)			
Pass/Fail (+/- 2%), CV < 1%				Pass/Fail (+/- 2%), CV < 1%			

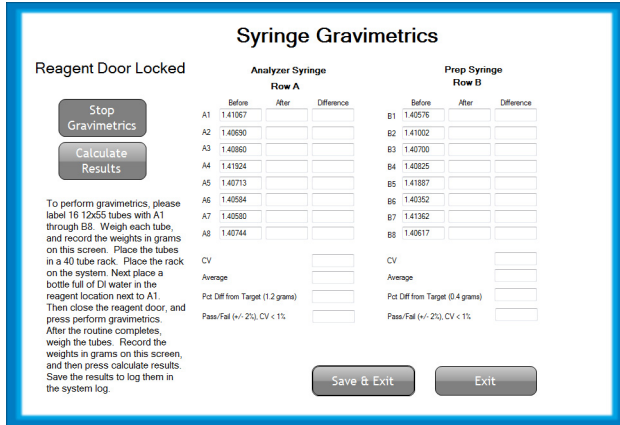
Log and Exit Cancel

- 6 Repeat steps 4-5 for each labeled tube until you have completed all the A tubes and the B tubes required for the procedure.

- 7** Open the reagent door. If there is a 96 well plate in place, remove the plate and insert the 40 tube holder plate. Remove and cap any reagents that may be on the system.
- 8** Fill an empty Gravimetrics bottle with DI water and place the bottle in the reagent location next to A1 as indicated on the plate.
- 9** Place the previously weighed tubes in a 40-tube holder on the plate loader inside the instrument and close the reagent door, ensuring to press the top center firmly so that the latch engages.



10 Select .



**Syringe Gravimetrics**

Reagent Door Locked

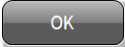
Stop Gravimetrics  
Calculate Results

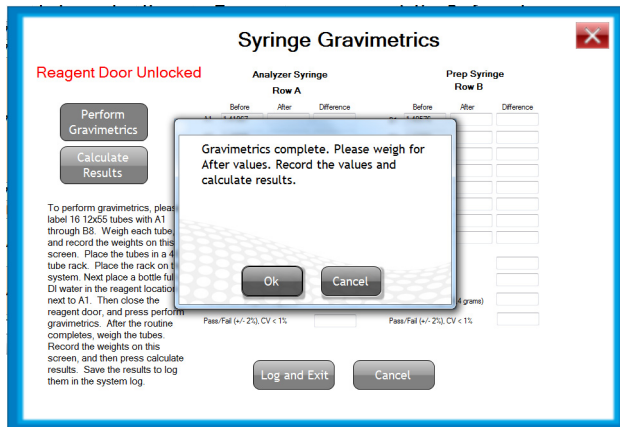
To perform gravimetrics, please label 16 12x55 tubes with A1 through B8. Weigh each tube, and record the weights in grams on this screen. Place the tubes in a 40 tube rack. Place the rack on the system. Next place a bottle full of DI water in the reagent location next to A1. Then close the reagent door, and press perform gravimetrics. After the routine completes, weigh the tubes. Record the weights in grams on this screen, and then press calculate results. Save the results to log them in the system log.

Analyzer Syringe			Prep Syringe		
Row A			Row B		
Before	After	Difference	Before	After	Difference
A1 1.41067			B1 1.40576		
A2 1.40990			B2 1.41002		
A3 1.40860			B3 1.40700		
A4 1.41924			B4 1.40625		
A5 1.40713			B5 1.41887		
A6 1.40594			B6 1.40352		
A7 1.40580			B7 1.41362		
A8 1.40744			B8 1.40617		
CV			CV		
Average			Average		
Pct Diff from Target (1.2 grams)			Pct Diff from Target (0.4 grams)		
Pass/Fail (+/- 2%), CV < 1%			Pass/Fail (+/- 2%), CV < 1%		

Save & Exit    Exit

The system performs the gravimetric cycle, aspirating and dispensing the DI water to the relevant tubes.

11 When the cycle is complete, the system notifies with the following message: *Gravimetrics complete. Please weigh for after values. Record the values and calculate results.* Select .



**Syringe Gravimetrics**

Reagent Door Unlocked

Perform Gravimetrics  
Calculate Results

To perform gravimetrics, please label 16 12x55 tubes with A1 through B8. Weigh each tube, and record the weights on this screen. Place the tubes in a 40 tube rack. Place the rack on the system. Next place a bottle full of DI water in the reagent location next to A1. Then close the reagent door, and press perform gravimetrics. After the routine completes, weigh the tubes. Record the weights on this screen, and then press calculate results. Save the results to log them in the system log.

Gravimetrics complete. Please weigh for After values. Record the values and calculate results.

Ok    Cancel

Log and Exit    Cancel

12 Open the reagent door by pressing the top middle part of the door in one single, solid motion, and remove the 40-tube rack and the Gravimetrics bottle with DI water from the system.

13 Close the reagent door.

14 Remove the tube labeled A-1 and weigh the tube.



- 15 Record the weight of tube A-1 now containing DI water on the Syringe Gravimetrics screen in the After column next to the respective tube number.

**Syringe Gravimetrics**  
Reagent Door Unlocked

**Analyzer Syringe**  
Row A

	Before	After	Difference
A1	1.41067	2.61151	
A2	1.40690	2.61094	
A3	1.40860	2.61533	
A4	1.41924	2.62408	
A5	1.40713	2.61400	
A6	1.40584	2.61076	
A7	1.40580	2.61148	
A8	1.40744	2.61427	

**Prep Syringe**  
Row B

	Before	After	Difference
B1	1.40576	1.80551	
B2	1.41002	1.81001	
B3	1.40700	1.80689	
B4	1.40825	1.80808	
B5	1.41887	1.81861	
B6	1.40352	1.80298	
B7	1.41362	1.81314	
B8	1.40617	1.80528	

Buttons: Perform Gravimetrics, Calculate Results, Save & Exit, Exit

Instructions: To perform gravimetrics, please label 16 12x55 tubes with A1 through B8. Weigh each tube, and record the weights in grams on this screen. Place the tubes in a 40 tube rack. Place the rack on the system. Next place a bottle full of DI water in the reagent location next to A1. Then close the reagent door, and press perform gravimetrics. After the routine completes, weigh the tubes. Record the weights in grams on this screen, and then press calculate results. Save the results to log them in the system log.

- 16 Repeat steps 14 and 15 for each labeled tube until you have completed all the A tubes and the B tubes in the 40 tube rack.

- 17 Select **Calculate Results**, and the system calculates the results and reports either pass or fail.

**Syringe Gravimetrics**  
Reagent Door Unlocked

**Analyzer Syringe**  
Row A

	Before	After	Difference
A1	1.41067	2.61151	1.20084
A2	1.40690	2.61094	1.20404
A3	1.40860	2.61533	1.20673
A4	1.41924	2.62408	1.20484
A5	1.40713	2.61400	1.20687
A6	1.40584	2.61076	1.20492
A7	1.40580	2.61148	1.20568
A8	1.40744	2.61427	1.20683

**Prep Syringe**  
Row B

	Before	After	Difference
B1	1.40576	1.80551	0.39975
B2	1.41002	1.81001	0.39999
B3	1.40700	1.80689	0.39989
B4	1.40825	1.80808	0.39983
B5	1.41887	1.81861	0.39974
B6	1.40352	1.80298	0.39946
B7	1.41362	1.81314	0.39952
B8	1.40617	1.80528	0.39911

CV: 0.17% (A), 0.07% (B)  
Average: 1.205094 (A), 0.3996512 (B)  
Pct Diff from Target (1.2 grams): 0.42% (A), Pct Diff from Target (0.4 grams): -0.08% (B)  
Pass/Fail (+/- 2%), CV < 1%: Pass (A), Pass (B)


Buttons: Perform Gravimetrics, Calculate Results, Save & Exit, Exit


Instructions: To perform gravimetrics, please label 16 12x55 tubes with A1 through B8. Weigh each tube, and record the weights in grams on this screen. Place the tubes in a 40 tube rack. Place the rack on the system. Next place a bottle full of DI water in the reagent location next to A1. Then close the reagent door, and press perform gravimetrics. After the routine completes, weigh the tubes. Record the weights in grams on this screen, and then press calculate results. Save the results to log them in the system log.


- 18 If the results fail, repeat the Gravimetrics test. If the problem persists, contact your Beckman Coulter Representative. If the results have passed the criteria, select **Save & Exit** to save the results to the system maintenance log.

- 19 The system will then exit the software.

20 Select the AQUIOS icon from the desktop to relaunch the software and Login.

21 Select  to have the system perform a quick startup.

22 Select  to review the maintenance log for the system. The results for the gravimetrics appears in the maintenance log as shown below.



The screenshot shows the Beckman Coulter software interface. At the top, there are buttons for 'Requests (0)', 'Running (0)', 'Incomplete (0)', and 'Review (7)'. Below these is the 'Maintenance Log' window, which is open to show a table of maintenance events. The table has columns for Date, Instrument, User, Type, and Action Performed. The log shows several entries for 'Routine Tasks' and 'Vacuum' performed on 2/27/2014. The 'Action Performed' column contains detailed gravimetric data and analyzer statistics.

Date	Instrument	User	Type	Action Performed
2/27/2014 3:54 PM	CR313041	System	Routine Tasks	Syringe Gravimetrics A1:1.20084 A2:1.20404 A3:1.20673 A4:1.20484 A5:1.20687 A6:1.20492 A7:1.20568 A8:1.20683 B1:0.39975 B2:0.39999 B3:0.39989 B4:0.39983 B5:0.39974 B6:0.39946 B7:0.39952 B8:0.75914 Analyzer CV: 0.17% Analyzer Average: 1.205094 Analyzer Pct Diff from Target (1.2 grams): 0.42% Analyzer Pass/Fail (+/- 2%), CV < 1%: Pass Prep CV: 28.58% Prep Average: 0.444665 Prep Pct Diff from Target (0.4 grams): 10.04% Prep Pass/Fail (+/- 2%), CV < 1%: Fail
2/27/2014 3:38 PM	CR313041	System	Vacuum	Vacuum: 14.80233
2/27/2014 3:38 PM	CR313041	System	Routine Tasks	Startup complete.

Below the table, there are filter options: 'Filter by: All' and 'Instrument: AV44010'. At the bottom of the screenshot is the status bar with various system indicators and the time '10:41 AM'.

## Status Bar And Message Area Identifiers

### Status Bar





You can find the Status Bar at the bottom of the main screen. See [Figure 8.17](#).

Figure 8.17 Status Bar



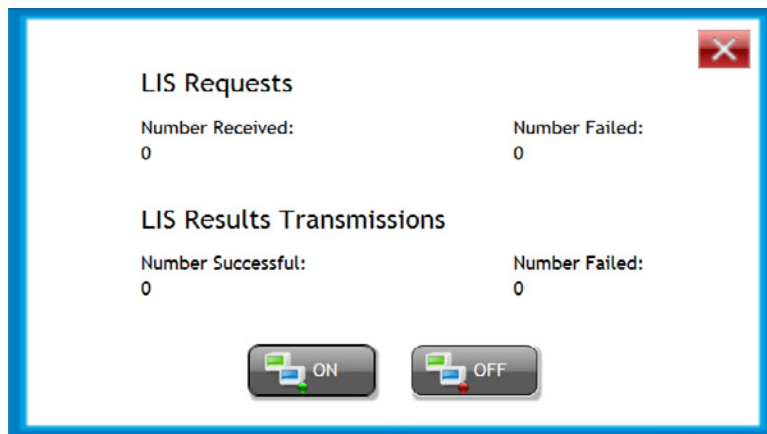
## Instrument Status

Instrument Status indicates if the instrument is ready to run samples.

- Select  to perform an instrument Startup cycle.  changes to  when startup is complete.
- Select  to perform a Shutdown cycle.

## LIS Status Screen

Figure 8.18 LIS Status Screen



### LIS Requests

- **Number Received** - This indicates the number of test requests received from the LIS without errors and acknowledged by the AQUIOS system.
- **Number Failed** - This indicates the number of LIS test requests that were not acknowledged by the AQUIOS system due to one or more errors in transmission.

### LIS Results Transmission

- **Number Successful** - This indicates the number of runs successfully transmitted to the LIS.
- **Number Failed** - This indicated the number of results that were not transmitted to the LIS due to one or more errors in the transmission.

## Login

The Login screen (Figure 8.19 and Figure 8.20) allows you to login to the system. The Database Setup screen (Figure 8.21) can be accessed from the Login screen.

Figure 8.19 New User Login




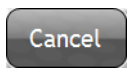
Figure 8.20 Switch User from User Setup Menu




**User name** — Use to enter login name.

**Password** — Use to enter the password.

 — Use to accept username and password.

 — Use to exit the login window without logging in

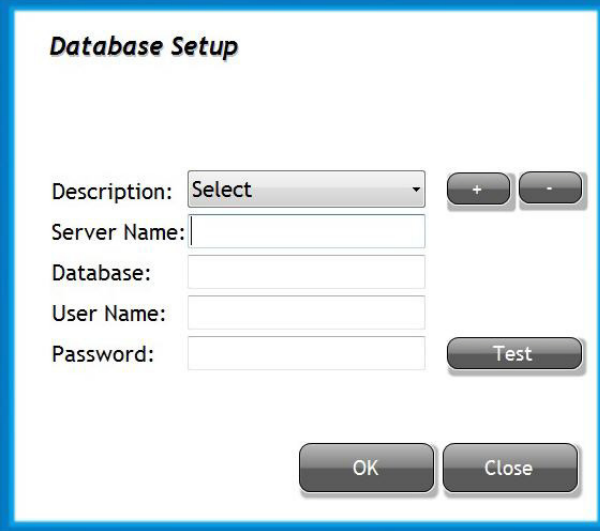
 — Use to access and edit the database setup

**NOTE** Only a system administrator can change the database setup. The AQUIOS system stores Test Requests, Results, and User information in an SQL server database. Databases are created outside of the AQUIOS system software. You can use this window to disconnect from your current database and connect to a different database.

**NOTE** Test requests are purged by the system after 30 days.

**IMPORTANT** Connecting to a different database will change your user names and passwords to those in the new database. Ensure that you have the login information for the new database before connecting to it.

**Figure 8.21** Database Setup Screen



**Database Setup**

Description:  + -

Server Name:


Database:


User Name:

Password:  Test

OK Close

**Description** — Use drop-down menu to select the appropriate database name

 — Use to add an existing database to the list

 — Use to remove a database from the list; the database is not deleted

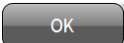
**Server name** — Use to enter the name for the server


**Database** — Use to enter the name for the database

**User name** — Use to enter login name for the database; this differs from the user name in the AQUIOS System software

**Password** — Use to enter the password for the database; this differs from the password in the AQUIOS System software

 — Select this to connect to the database; the system will alert you if it is unable to connect.

 — Use to accept the changes

 — Use to exit database setup screen



## Overview

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This chapter contains information about:

- Safety Precautions
- EMC Information
- Laser Related Hazards
- Hazard Labels and Locations
- Disposal of Electrical Instrumentation
- RoHS Notice
- Powering Up / Powering Down
- Troubleshooting Procedures
- General Troubleshooting
- System Error Messages
- Analysis Error Messages
- System Warning Messages
- Incomplete Request Causes

## Safety Precautions

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### Operational

 **WARNING**

Risk of personal injury if instrument cover is removed or a door is left open due to possible exposure to high voltages, laser radiation, and/or moving parts. Never operate the instrument without a cover or with a door opened.

 **WARNING**

Risk of personal injury from door hinges. Do not close any door while your fingers are grasping the side of the door. Instrument doors that are mishandled can fail, leading to personal injury. Handle the doors with care and always follow the written instructions for opening and closing the doors. Never remove and reinstall the doors.

 **CAUTION**

Risk of flow cell clog if the recommended number of pierces are exceeded. Specimen tubes can be pierced a maximum of eight (8) times with the following exceptions:

- Sarstedt Monovette tubes can be pierced a maximum of five (5) times.
- The 2 mL Covidien 10.25mmX50mm Kendall Monoject tubes should be run in Single-tube Loader as open vial only.

When using the Sarstedt Monovette tubes Beckman Coulter recommends that you remove the cap when using the Single-tube Loader.

 **CAUTION**

Risk of erroneous results. For AQUIOS whole blood control material, each cap should have no more than 15 piercings. Cap-piercing beyond the allotted number may clog the instrument.

 **CAUTION**

Risk of Flow Cell clog or instrument line blockage if Extended Shutdown is not performed when storing the instrument for more than seven days. Follow the [Extended Shutdown](#) in [CHAPTER 7, Shutdown](#) when turning off the instrument for more than seven days.



 **CAUTION**

Risk of probe damage if antibody carousel is mis-positioned in the carousel platform. Make sure that the antibody carousel is locked by the carousel platform when attempting to turn the carousel.

 **CAUTION**

Risk of probe damage if plate is mis-positioned in the plate platform. Make sure that plate is locked in by the edges of the plate platform.

 **CAUTION**

Risk of incorrect flagging if patient reference ranges are not validated before running samples. Follow your laboratory's procedure for establishing patient reference ranges.

## Electronic

 **WARNING**

Risk of personal injury from electrical shock. Electronic components can cause shock and or injury. To prevent possible injury or shock, do not tamper with the instrument and do not remove any components (covers, doors, panels, and so forth) unless otherwise instructed in this document.

 **WARNING**

Risk of personal injury if electronic equipment is used near fumes or flammable gases. Avoid this risk by never operating electronic equipment near fumes or flammable gases.

## Biological

Use universal precautions when working with pathogenic materials. Methods must be available to decontaminate the instrument and to dispose of biohazardous waste.

 **WARNING**

**Risk of personal injury or contamination:**

- To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection.
- Operating the instrument while the waste level sensor is disconnected can cause biological contamination. Do not operate the instrument while the waste level sensor is disconnected.

 **WARNING**

**Risk of possible biohazardous contamination. All blood specimens should be treated as potentially infectious. Adequate precautions and safety attire should be used when handling a blood sample. For details on handling potentially infectious samples, refer to document “CLSI M29 Protection of Laboratory Workers From Occupational Acquired Infections”.**

 **WARNING**

**Risk of biohazard spill and invalid results if using the same plate on two or more non-networked instruments. Never share plates between instruments, as the plate wells will be reused by the second instrument and the out-of-well condition bypassed.**

 **WARNING**

**Risk of biohazardous contamination. Clean up any blood spill as quickly as possible. Dispose of all contaminated disposable cleaning materials in accordance with your local regulations and acceptable laboratory practices.**

 **WARNING**

**Risk of personal injury or contamination if you have skin contact with the waste container, its contents, and its associated tubing. The waste container and its associated tubing can contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the contents of the waste container in accordance with your local regulations and acceptable laboratory procedures.**

## Moving Parts

### **WARNING**

Risk of personal injury:

- Operating the instrument with doors or covers open can cause personal injury. Ensure that all covers and doors are closed.
- Operating the instrument with a loose or bent probe can cause personal injury. If the probe is loose or bent, do not run the instrument. Contact your local Beckman Coulter Representative.

## EMC Information

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This *in vitro diagnostic* (IVD) equipment complies with the emission and immunity requirement described in IEC 61326-2-6.

### **CAUTION**

This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment, it could cause radio interference, in which case, you may need to take measures to mitigate the interference.

It is advised that prior to operation of the device, the electromagnetic environment should be evaluated. Do not use this device in close proximity to sources of strong electromagnetic radiation (for example, unshielded intentional RF sources), as these could interfere with the proper operation.

## Laser Related Hazards

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Beckman Coulter design and manufacture of the instrument complies with the requirements governing the use and application of a laser specified in regulatory documents issued by the:

- U.S. Department of Health and Human Services and
- Center for Devices and Radiological Health (CDRH).

In compliance with these regulatory documents, every measure has been taken to ensure the health and safety of users and laboratory personnel from the possible dangers of laser use.

Use the instrument according to the information in the manuals.

Use controls or adjustments or performance of procedures other than those specified herein might result in hazardous radiation exposure.

To ensure your safety, the Cytometer lasers are covered with protective shields. Do not remove these shields.

No user-serviceable assemblies are accessible. Do not attempt to remove the laser or open it. The instrument has components that are dangerous to the operator. If any attempt has been made to defeat a safety feature, or if the instrument fails to perform as described in its manuals, disconnect the power and contact your Beckman Coulter Representative.

## Laser Beam Hazards

The AQUIOS CL flow cytometer contains a 488 nm 25 mW solid-state diode laser.

A laser beam is a unique light source that shows characteristics different from conventional light sources. The safe use of the laser depends upon familiarity with the instrument and the properties of coherent, intense beams of light.



**Risk of personal injury. The laser beam can cause eye damage if viewed either directly or indirectly from reflective surfaces (such as a mirror or shiny metallic surfaces). To prevent eye damage, avoid direct exposure to the laser beam. Do not view it directly or with optical instruments.**

Indirect contact with the laser beam from reflective surfaces (such as jewelry or a screwdriver) is called specular reflection and might also cause damage.

For these reasons, it is important to:

- Limit access to the Cytometer to trained and experienced personnel.
- Never attempt to remove a shield housing a laser.
- Never remove a warning label.
- Contact your Beckman Coulter Representative if a label is missing or unclear.

## Laser Warning Labels



**Risk of personal injury from radiation exposure. Never remove the shield surrounding a laser. Never remove covers.**

CDRH-approved labels are also placed near or on those covers that when removed might expose laser radiation. If necessary, a cover with a CDRH-approved label must be removed by a qualified Beckman Coulter Representative only.

CDRH-required warning labels are located:

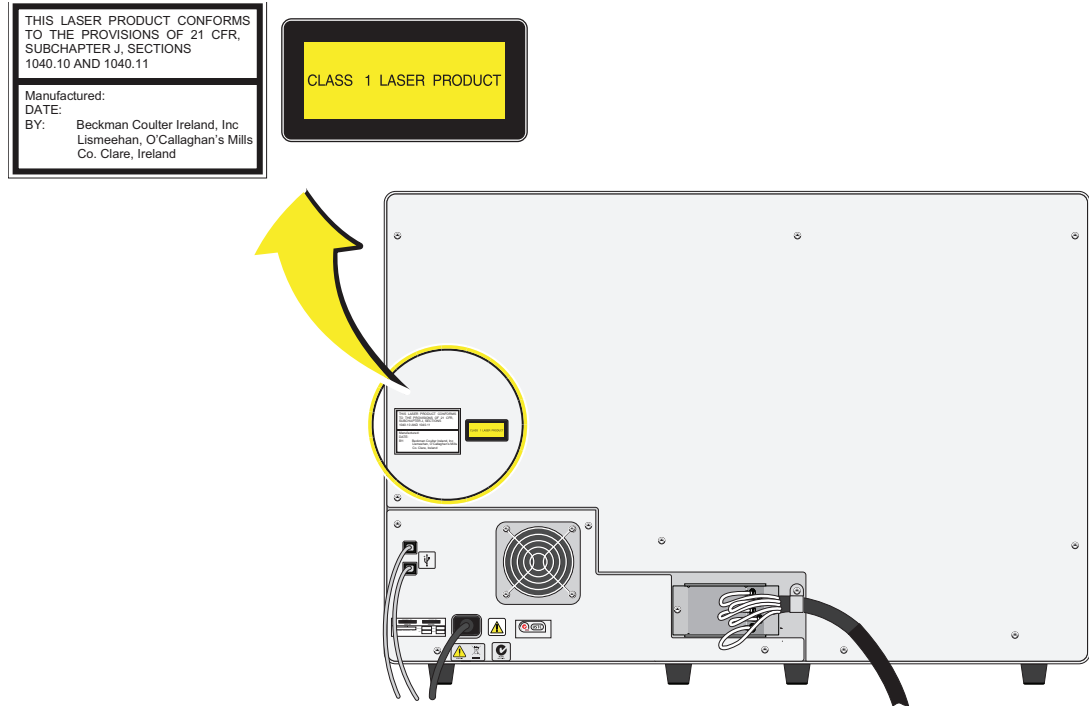
See [Figure 9.1](#) for the Laser Warning Label on the Cytometer Lower Rear Cover.

See [Figure 9.2](#) for the Laser with Protective Housing and Warning Label (Located Inside the Cytometer).

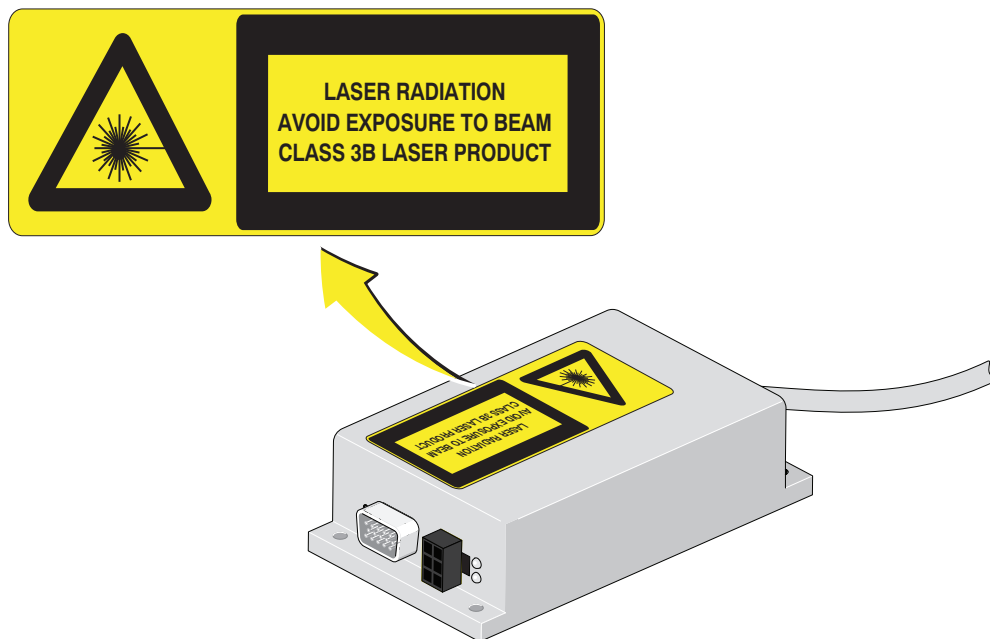
See [Figure 9.3](#) for the Laser Warning Label Where the Laser Fiber Connects to the Flow Cell (Inside Cytometer)

The laser is classified as Class I when it is in the system with the protective housing in place. This product complies with 21 CFR Parts 1040.10 and 1040.11 as well as EN60825-1. See [Figure 9.1](#).

**Figure 9.1** Laser Warning Label on the Cytometer Lower Rear Cover

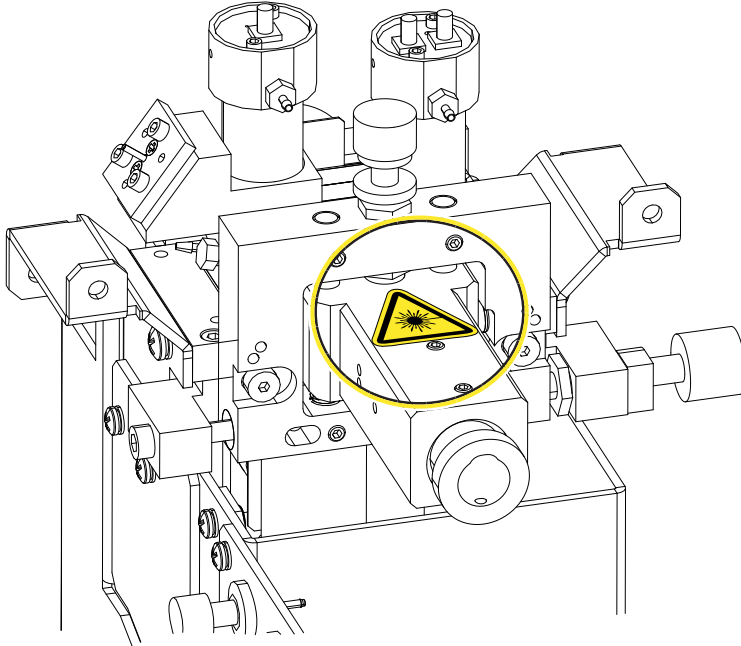


**Figure 9.2** Laser with Protective Housing and Warning Label (Located Inside the Cytometer)



A laser warning label is also provided at the point where the laser fiber connects to the flow cell as shown in [Figure 9.3](#).

**Figure 9.3** Laser Warning Label Where the Laser Fiber Connects to the Flow Cell (Inside Cytometer)



## Hazard Labels and Locations

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Carefully read the hazard warning labels on the instrument. The hazard labels are located on the instrument as indicated.

**NOTE** If a label is missing or unclear, contact your Beckman Coulter Representative.

## Caution/Warning Label and Locations

Figure 9.4 Caution/Warning Label on the Back Panel of the Cytometer

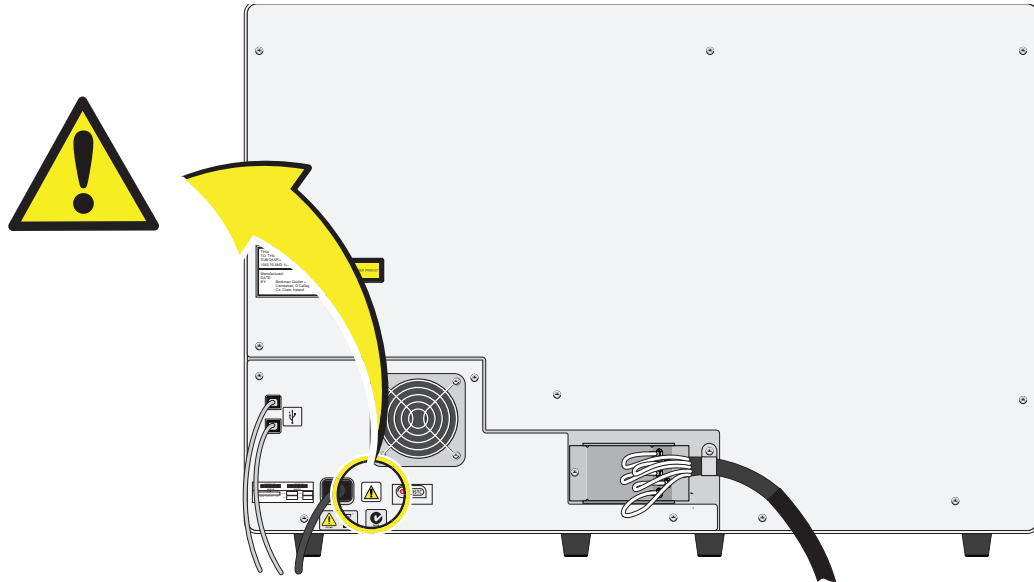


Figure 9.5 Caution/Warning Label Inside the Reagent Compartment

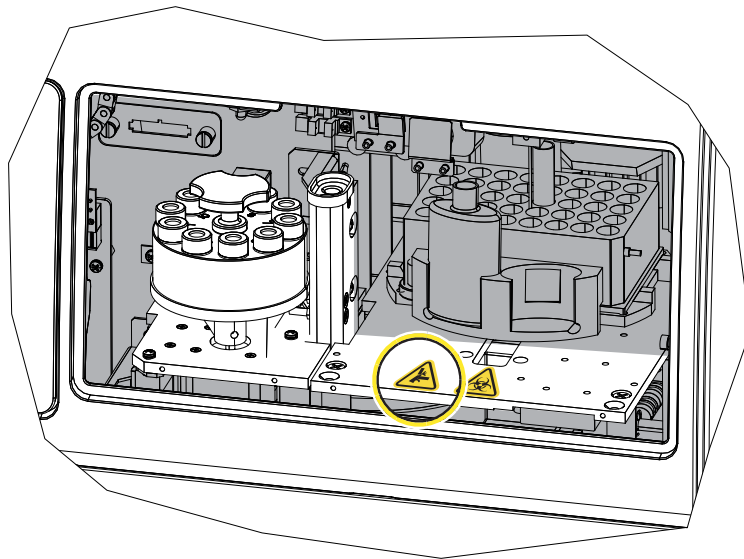
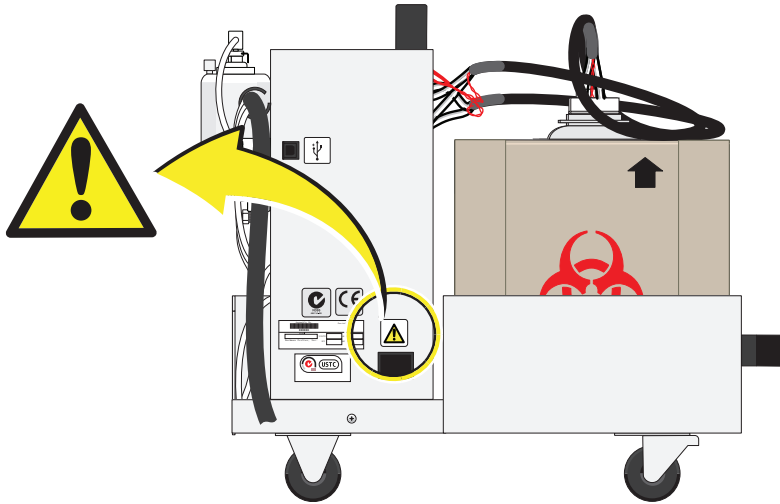


Figure 9.6 Caution/Warning Label on the Supply Cart (Left View)



## Biohazard Label and Locations

Figure 9.7 Biohazard Label Inside the Reagent Compartment

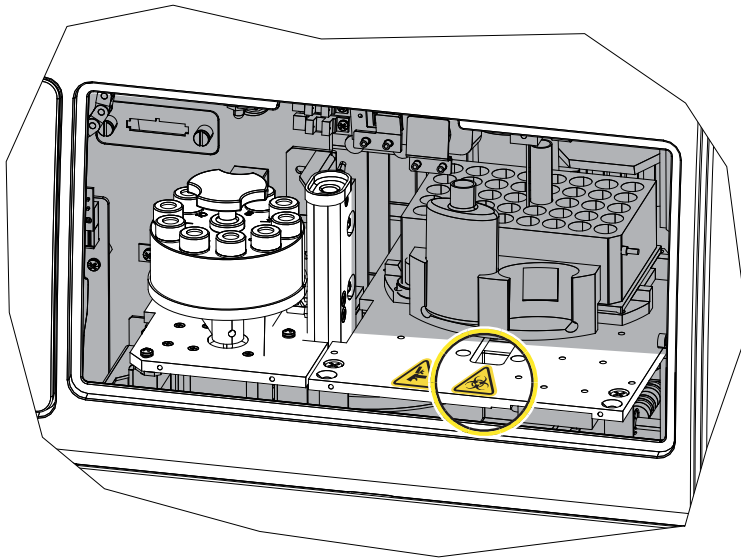




Figure 9.8 Location of Biohazard Label on the Single-Tube Loader

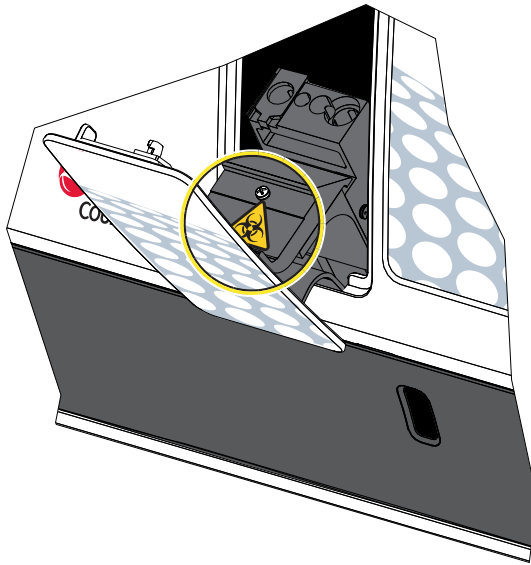


Figure 9.9 Vacuum Reservoir and Supply Cart (Back View)

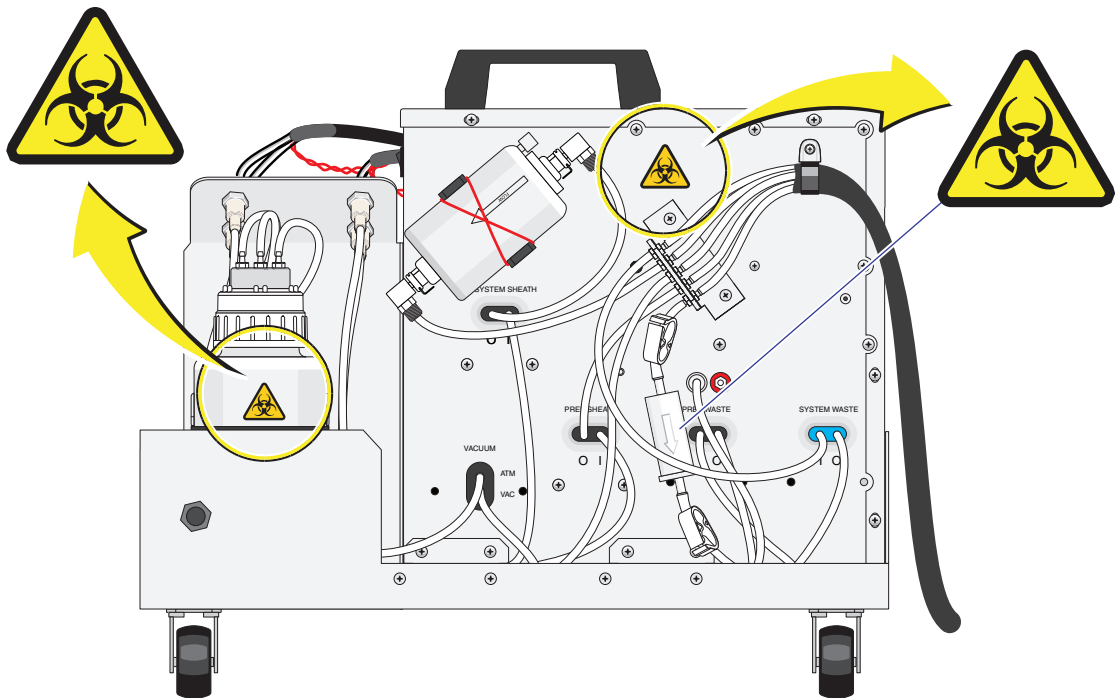
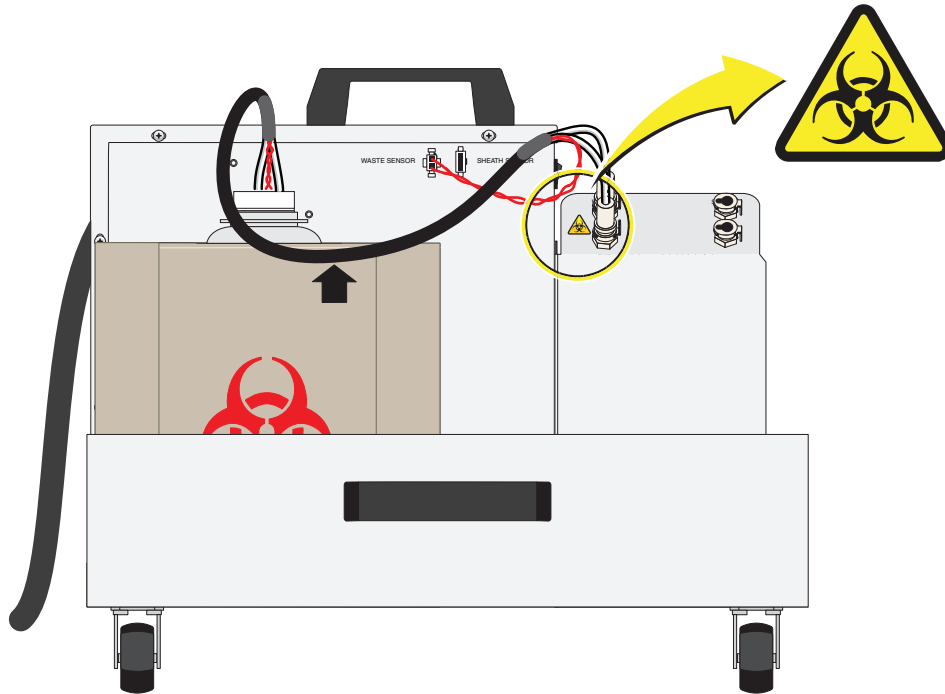


Figure 9.10 Biohazard Label on the Supply Cart (Front View)



## Pinch-Point Warning Label and Location

Figure 9.11 Pinch-Point Warning Label on the Autoloader



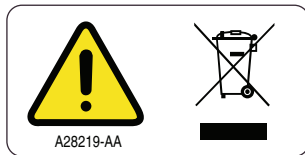
## Disposal of Electrical Instrumentation

It is very important that customers understand and follow all laws regarding the safe and proper disposal of electrical instrumentation.

The symbol of a crossed-out wheeled bin on the product is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this marking on the product indicates:

1. that the device was put on the European Market after August 13, 2005 and

- that the device is not to be disposed via the municipal waste collection system of any member state of the European Union.



For products under the requirement of WEEE directive, please contact your dealer or local Beckman Coulter office for the proper decontamination information and take-back program which will facilitate the proper collection, treatment, recovery, recycling, and safe disposal of device.

## RoHS Notice

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These labels and materials declaration table (the Table of Hazardous Substance's Name and Concentration) are to meet People's Republic of China Electronic Industry Standard SJ/T11364-2006 "Marking for Control of Pollution Caused by Electronic Information Products" requirements.

### RoHS Caution Label



This label indicates that the electronic information product contains certain toxic or hazardous substances. The center number is the Environmentally Friendly Use Period (EFUP) date, and indicates the number of calendar years the product can be in operation. Upon the expiration of the EFUP, the product must be immediately recycled. The circling arrows indicate the product is recyclable. The date code on the label or product indicates the date of manufacture.

## Powering Up / Powering Down

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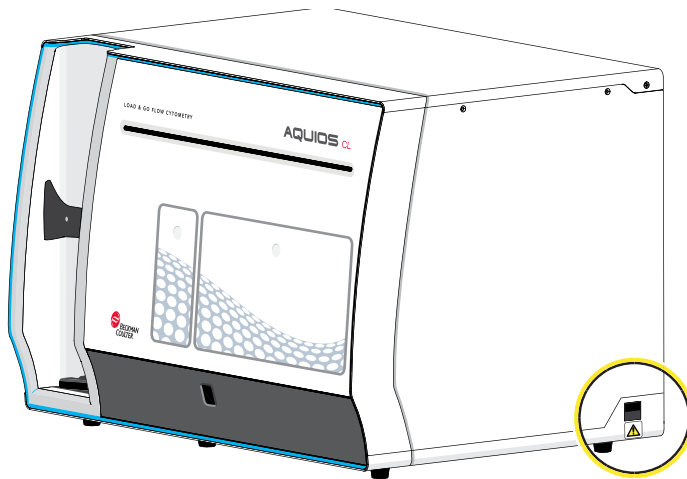
When performing maintenance or troubleshooting your AQUIOS CL Flow Cytometer, it may be necessary to turn off the power. When the task is completed, the power to major components must be restored and the Cytometer properly prepared for sample analysis.

## Power Up the System

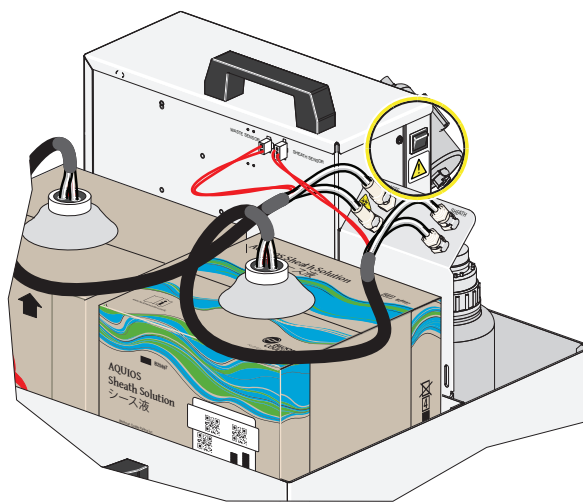


Risk of damage to the Cytometer. Do not attempt to manually open the reagent door or Single-tube Loader door while the Cytometer is powering up.



- 1 Turn **ON** the Cytometer by pressing the power switch on the right side of the Cytometer.



- 2 Turn **ON** the Supply Cart by pressing the power switch on the right side of the Supply Cart (as viewed from the right side).



- 3 Turn **ON** the Workstation by pressing the power switch on the Workstation computer.

- 4 Plug the Uninterruptible Power Manager (UPM) into the wall outlet.
- 5 Press the ON/OFF button on the UPM for more than 3 seconds to turn the UPM on.
- 6 When the Login screen appears, enter your **User name** and **Password** then select .
- 7 Once Login is complete, select .

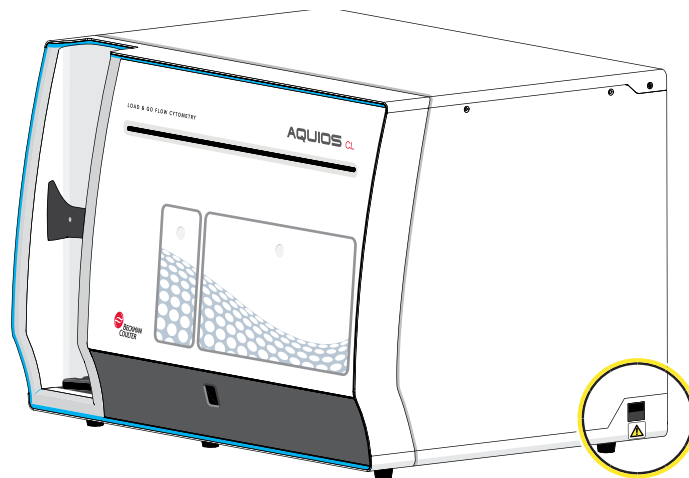
## Power Down the System

**IMPORTANT** Always perform a shutdown cycle before powering down the unit. See [Shutdown](#) in [CHAPTER 7, Shutdown](#).

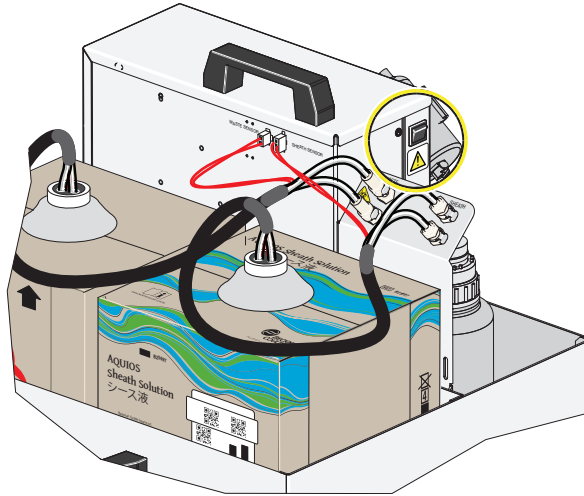
### CAUTION

**Risk of erroneous results. Do not power off the instrument while it is cycling to prevent samples from being interrupted and lost.**

- 1 Turn **OFF** the Cytometer by pressing the power switch on the right side of the Cytometer.



- 2 Turn **OFF** the Supply Cart by pressing the power switch on the right side of the Supply Cart (as viewed from the front).



- 3 Turn **OFF** the Workstation by pressing the power switch on the Workstation computer.
- 4 Press the ON/OFF button on the UPM for more than 3 seconds to turn the UPM off.

## Troubleshooting Procedures

The troubleshooting topics in this chapter include:

- [General Troubleshooting](#)
- [System Error Messages](#)
- [Analysis Error Messages](#)
- [System Warning Messages](#)
- [Incomplete Request Causes](#)


Before following the suggested actions in these sections, review handling procedures, warning labels, and Beckman Coulter Material Safety Data Sheets (MSDS). For further assistance and/or repairs, contact your Beckman Coulter Representative.

## General Troubleshooting

**IMPORTANT** Sipper, Probe, and Needle may be used interchangeably when referring to the sample prep probe, and the analyzer probe.

Table 9.1 describes suggested actions for troubleshooting an AQUIOS system.

**Table 9.1** Troubleshooting Tips

Situation	Probable Cause	Corrective Action
Screen “freezes up”	System software is frozen and cannot complete the last routine.	<ol style="list-style-type: none"> <li>1. Exit/close the software.</li> <li>2. Restart the software.</li> <li>3. If the problem persists, exit/close the software; turn off the Workstation and then turn it back on again.</li> </ol>
Printer does not print.	Interruption of power or communication	<ol style="list-style-type: none"> <li>1. Verify that the power and communication cables are properly connected.</li> <li>2. Exit the AQUIOS System software and verify that the printer driver is properly installed on the computer.</li> <li>3. If problem persists, consult the printer’s manual for additional printer troubleshooting details.</li> </ol>
Failure to Connect to the LIS	LIS Connection	<ol style="list-style-type: none"> <li>1. Select  under the Status bar.</li> <li>2. Turn on the LIS connection.</li> <li>3. If the problem persists, consult the LIS professional who is responsible for the LIS connection</li> </ol>
System Alarm (ON)	See Error Messages	<ol style="list-style-type: none"> <li>1. Read the error message.</li> <li>2. Perform the corrective action(s) associated with the error message.</li> </ol>

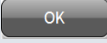


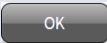
**Table 9.1** Troubleshooting Tips (Continued)

Situation	Probable Cause	Corrective Action
No events observed when running multiple consecutive samples.	Partial or fully clogged Flowcell	<ol style="list-style-type: none"> <li>1. <a href="#">Run Bleach Cycle.</a></li> <li>2. <a href="#">Run Flush Cycle.</a></li> </ol>
When using the autoloader, in the case of no reagents onboard, the elevator and sample prep indicator LED's will be green but the new cassette will not be loaded into the system. Check the status bar for reagent information.	The system does not have reagents on board	<p>Load necessary reagents. See <a href="#">Replacing Reagents and Consumables.</a></p>

## System Error Messages














System Error Messages are messages that appear in dialog windows and do not appear in the Maintenance Log. See [Table 9.2](#) for such messages.

**Table 9.2** AQUIOS System Error Messages

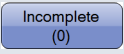




Error Message Displayed	Cause	Software Response	Possible Solution
Please close the reagent door to start the system.	<ol style="list-style-type: none"> <li>1. The Reagent Door is open.</li> <li>2. There is a sensor malfunction.</li> </ol>	System will not start.	<ol style="list-style-type: none"> <li>1. Close the Reagent door and press the top, center so the latch engages.</li> <li>2. If the problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p>The system is out of Cleaning Agent. Please replace with a fresh bottle and select <a href="#">Shutdown</a> again.</p> <p>Remember to scan the barcode on the bottle into the system first.</p>	The AQUIOS Cleaning Agent bottle is empty.	<ol style="list-style-type: none"> <li>1. Select  to bring you back to the main screen.</li> <li>2. Select  to bring you to the next message.</li> </ol>	<ol style="list-style-type: none"> <li>1. Select . The message <i>out of cleanse</i> appears.</li> <li>2. Replace the Cleaning Agent. See <a href="#">Replacing the AQUIOS Cleaning Agent Bottle in CHAPTER 11, Replacement Procedures</a> for the AQUIOS Cleaning Agent replacement procedure.</li> <li>3. Select .</li> <li>4. Reinitiate shutdown.</li> </ol>







**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
<p>The system is still out of Cleaning Agent.</p> <p>Would you like to cancel the shutdown?</p>	<ol style="list-style-type: none"> <li>The AQUIOS Cleaning Agent bottle is empty.</li> <li>The AQUIOS Cleaning Agent bottle is not put in correctly.</li> <li>A sensor has malfunctioned.</li> </ol>	<p>The system will prompt  or .</p>	<ol style="list-style-type: none"> <li>Select  to cancel the shutdown. See <a href="#">Replacing the AQUIOS Cleaning Agent Bottle</a> in <a href="#">CHAPTER 11, Replacement Procedures</a> for the AQUIOS Cleaning Agent replacement procedure. Reinitiate shutdown. OR Select  to continue shutdown without Cleaning Agent.</li> <li>If the problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p>The system needs an available well to transfer cleaner to the probe for shutdown.</p> <p>Do you want to shut down without cleaner (not recommended)?</p>	<p>There is no empty well to deposit the cleaner into.</p>	<ul style="list-style-type: none"> <li>Select  to initiate the shutdown process.</li> <li>Select  to cancel shutdown and replace the Deep Well Plate.</li> </ul>	<ol style="list-style-type: none"> <li>If a new plate is available: <ul style="list-style-type: none"> <li>Select  to initiate shutdown.</li> <li>Replace the Deep Well Plate, see <a href="#">Replacing the AQUIOS Deep Well Plate</a> in <a href="#">CHAPTER 11, Replacement Procedures</a>.</li> <li>Select  to reinitiate shutdown.</li> </ul> </li> <li>If a new plate is not available: <ul style="list-style-type: none"> <li>Cancel, or</li> <li>Shutdown without cleaning.</li> </ul> </li> </ol>
<p>Samples are running. Do you want to shut down when they are finished?</p>	<p>User has selected .</p>	<ul style="list-style-type: none"> <li>Select  to allow the system to continue prepping samples and will initiate the stop cycle once samples are finished running.</li> <li>Select  to cancel system shutdown.</li> </ul>	<ol style="list-style-type: none"> <li>Select  to shutdown the system.  <b>NOTE</b> The system will not shutdown until the prepping samples have processed.  OR</li> <li>Select  to cancel the system shutdown.</li> </ol>

**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
<i>The system stopped because of multiple instrument related flags.</i>	Instrument stopped due to multiple errors.  <b>NOTE</b> Multiple errors is set to Stop in the System Setup screen.	The system stops after 3 consecutive errors.	Review your flags. See <a href="#">Flags And Notifications</a> in <a href="#">CHAPTER 9, Troubleshooting</a> .
<i>Warning! The system has encountered multiple instrument related flags.</i>	Instrument stopped due to multiple errors.  <b>NOTE</b> Multiple errors is set to Stop in the System Setup screen.	The system provides a notification after 3 consecutive errors.  <b>NOTE</b> Depending on the option selected in System Setup, the system will provide a notification by email or text.	Review your flags. See <a href="#">Flags And Notifications</a> in <a href="#">CHAPTER 9, Troubleshooting</a> .
<i>The necessary reagents are not onboard!</i>  <i>The sample cannot be run.</i>  This message only occurs with the Single Tube Loader.	Insufficient reagents	If sample processing has started sample requests will be moved to the  tab.	Load necessary reagents.  See <a href="#">Replacing Reagents and Consumables</a> in <a href="#">CHAPTER 11, Replacement Procedures</a> .
<i>No valid Sample ID was entered!</i>  <i>The sample cannot be run</i>	<ol style="list-style-type: none"> <li>1. Sample ID has not been properly scanned from the specimen tube in Single-Tube mode.</li> <li>2. Sample ID has not been manually provided in Single-Tube mode.</li> <li>3. Invalid Sample ID.</li> </ol>	Notification	Provide Sample ID either manually or via the barcode scanner, see <a href="#">Add Test Request for a Patient Sample</a> in <a href="#">CHAPTER 5, Sample Processing</a> .
<i>The system must first be running.</i>	<ol style="list-style-type: none"> <li>1.  or  was selected and the instrument is not running.</li> <li>2.  or  was selected and the instrument may have lost communications.</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. Ensure all cables are connected properly.</li> <li>2. Turn power off.</li> <li>3. Turn power on and restart the instrument and software.</li> <li>4. Perform the startup, see <a href="#">Startup</a> in <a href="#">CHAPTER 3, Daily Startup</a>.</li> <li>5. If the problem persists, contact your Beckman Coulter Representative.</li> </ol>

**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
<i>You cannot perform a Bleach while the system is processing samples.</i>	 was selected while samples were being processed.	Notification	Select  when all samples have been processed if necessary.
<i>No Test was selected! The sample cannot be run.</i>	The test has not been selected in Single-Tube mode.	Notification	Select a test.
<i>The System has stopped because there were not enough reagents or wells to run a test.</i>	<ol style="list-style-type: none"> <li>1. The system is out of reagents.</li> <li>2. There are no available wells on the plate to run the test.</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. If the system is out of reagents, see <a href="#">Replacing the AQUIOS Panel Reagents</a> in <a href="#">CHAPTER 11, Replacement Procedures</a>.</li> <li>2. Replace the Deep Well Plate, see <a href="#">Replacing the AQUIOS Deep Well Plate</a> in <a href="#">CHAPTER 11, Replacement Procedures</a>.</li> </ol>
Error! The system was stopped. Instrument Communication Error.	Communication malfunction.	Notification	<ol style="list-style-type: none"> <li>1. Power down the system and computer.</li> <li>2. Power up the system and computer.</li> <li>3. Select  to review the maintenance log for details. See <a href="#">Maintenance Screen</a> in <a href="#">CHAPTER 8, Setup</a>.</li> <li>4. If the problem persists, contact your Beckman Coulter Representative.</li> </ol>
<i>The System has stopped! Motion or Communications failure! Power down the system and computer. Please check the maintenance log for details.</i>	<ol style="list-style-type: none"> <li>1. Communication malfunction</li> <li>2. Motion malfunction</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. Power down the system and computer.</li> <li>2. Power up the system and computer.</li> <li>3. Select  to review the maintenance log for details. See <a href="#">Maintenance Screen</a> in <a href="#">CHAPTER 8, Setup</a>.</li> <li>4. If the problem persists, contact your Beckman Coulter Representative.</li> </ol>











**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
<p><i>The System stopped due to a prep wash station failure.</i></p> <p><i>Please power down, and check the system!</i></p>	<ol style="list-style-type: none"> <li>1. Failure to connect the red Waste connector on the Supply Cart.</li> <li>2. The Prep Waste Pump in the Supply Cart failed.</li> <li>3. Tubing on the back of the instrument is pinched.</li> <li>4. Sensor malfunction</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. Power down the system and computer.</li> <li>2. Check that the red Waste connector is properly connected.</li> <li>3. Check that the tubing on the back of the instrument is not pinched.</li> <li>4. Power up the system and computer.</li> <li>5. If the problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p><i>Waste warning!</i></p> <p><i>The waste is full! Please wait until the system is idle to change.</i></p>	<ol style="list-style-type: none"> <li>1. Waste is almost full during startup or shutdown</li> <li>2. A sensor cable is disconnected</li> <li>3. Sensor malfunction</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. Wait until the system has completed the Startup/Shutdown procedure.</li> <li>2. Replace the Waste Container, see <a href="#">Replacing the Waste Container in CHAPTER 11, Replacement Procedures</a>.</li> <li>3. Check the sensor cable connection.</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p>Startup failed because of the following reasons: The waste is full.</p>	<p>The internal waste bottle is full at the start of analysis due to:</p> <ul style="list-style-type: none"> <li>• Broken pump</li> <li>• Kinked tubing, or</li> <li>• Sensor malfunction</li> </ul>	Notification	Contact your Beckman Coulter Representative.
<p><i>Waste warning!</i></p> <p><i>Please wait for loaded samples to finish!</i></p>	<ol style="list-style-type: none"> <li>1. Waste is almost full while running samples.</li> <li>2. A sensor cable is disconnected.</li> <li>3. Sensor malfunction</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. Wait for the loaded samples to finish running.</li> <li>2. Replace the Waste Container, see <a href="#">Replacing the Waste Container in CHAPTER 11, Replacement Procedures</a>.</li> <li>3. Check the sensor cable connection.</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>



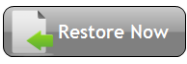









**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
<p><i>Waste Full!</i> <i>Please change the waste now!</i> <i>Open/close the reagent door to restart the system.</i></p>	<ol style="list-style-type: none"> <li>1. Waste is full</li> <li>2. A sensor cable is disconnected.</li> <li>3. Sensor malfunction</li> </ol>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Replace the Waste Container, see <a href="#">Replacing the Waste Container</a> in CHAPTER 11, Replacement Procedures.</li> <li>2. Check the sensor cable connection.</li> <li>3. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p><i>Sheath warning!</i> <i>The sheath is empty! Please wait until the system is idle to change.</i></p>	<ol style="list-style-type: none"> <li>1. Sheath is running low during startup or shutdown.</li> <li>2. A sensor cable is disconnected.</li> <li>3. Sensor malfunction</li> </ol>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Wait until the system has completed the Startup/Shutdown procedure.</li> <li>2. Replace the AQUIOS Sheath Solution cubitainer, see <a href="#">Replacing the AQUIOS Sheath Solution Cubitainer</a> in CHAPTER 11, Replacement Procedures.</li> <li>3. Check the sensor cable connection.</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p><i>Sheath warning!</i> <i>Please wait for loaded samples to finish!</i> <i>Remember to scan the barcode into the system first.</i></p>	<ol style="list-style-type: none"> <li>1. Sheath is running low while running samples.</li> <li>2. A sensor cable is disconnected.</li> <li>3. Sensor failure.</li> </ol>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Wait for the loaded samples to finish running.</li> <li>2. Replace the AQUIOS Sheath Solution cubitainer, see <a href="#">Replacing the AQUIOS Sheath Solution Cubitainer</a> in CHAPTER 11, Replacement Procedures.</li> <li>3. Check the sensor cable connection.</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>







**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
<p><i>Sheath Empty!</i></p> <p><i>Please change the sheath now!</i></p> <p><i>Open/close the reagent door to restart the system.</i></p> <p><i>Remember to scan the barcode into the system first.</i></p>	<ol style="list-style-type: none"> <li>1. Sheath is empty.</li> <li>2. A sensor cable is disconnected.</li> <li>3. Sensor malfunction</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. Replace the AQUIOS Sheath Solution cubitainer, see <a href="#">Replacing the AQUIOS Sheath Solution Cubitainer in CHAPTER 11, Replacement Procedures.</a></li> <li>2. Check the sensor cable connection.</li> <li>3. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p><i>There is a cassette onboard!</i></p> <p><i>The reagent door cannot be opened with cassettes onboard.</i></p> <p><i>Do you want to cancel running the cassette?</i></p>	<p>Selected  when there is a cassette in the rocker.</p>	<ol style="list-style-type: none"> <li>1. Selecting  cancels running the cassette and will display the next message.</li> <li>2. Selecting  allows the cassette to continue running.</li> </ol>	<ol style="list-style-type: none"> <li>1. Select  to cancel running the cassette.</li> <li>2. Select  to continue running the cassette.</li> </ol>
<p><i>To open the reagent door, wait until the cassette is unloaded.</i></p> <p><i>Then press this button again.</i></p>	<p>Selected  to the prompt: <i>There is a cassette onboard!</i></p> <p><i>The reagent door cannot be opened with cassettes onboard.</i></p> <p><i>Do you want to cancel running the cassette?</i></p>	Notification	<p>Select  once the cassette is unloaded.</p>
<p><i>The reagent door cannot be opened at this time!</i></p>	<p>Startup or Shutdown is in progress and  has been selected.</p>	Notification	<ol style="list-style-type: none"> <li>1. Wait for Startup/Shutdown process to be completed.</li> <li>2. Select .</li> </ol>
<p>Ensure that non-pierceable reagent caps have been removed or replaced as instructed.</p>	<p>Reagents have been replaced and the non-pierceable cap has been left on at least one reagent.</p>	Notification	<ol style="list-style-type: none"> <li>1. Select .</li> <li>2. Remove any non-pierceable caps, and replace with pierceable caps where appropriate.</li> <li>3. Close the reagent door.</li> </ol>

**Table 9.2** AQUIOS System Error Messages (Continued)


Error Message Displayed	Cause	Software Response	Possible Solution
<i>The run cannot be canceled as it is scheduled. Please wait to cancel the job.</i>	A sample run is already scheduled and was selected. 	Notification	<ol style="list-style-type: none"> <li>1. Wait for the sample to change/transition from the scheduled state.</li> <li>2. Select .</li> </ol>
<i>Are you sure you want to lose all your data and restore the current file?</i>	The user selected  .	<ol style="list-style-type: none"> <li>1. Selecting  will cause the message: <i>All data will be lost, proceed?</i> to appear.</li> <li>2. Selecting  will cancel restore now.</li> </ol>	<ol style="list-style-type: none"> <li>1. Select  to continue with restore now.</li> <li>2. Select  to cancel restore now.</li> </ol>
<i>All data will be lost, proceed?</i>	Selected  to the prompt: <i>Are you sure you want to lose all your data and restore the current file?</i>	<ol style="list-style-type: none"> <li>1. Selecting  will replace all existing data with restored data.</li> <li>2. Selecting  will cancel restore now.</li> </ol>	<ol style="list-style-type: none"> <li>1. Select  to proceed with restore now.</li> <li>2. Select  to cancel.</li> </ol>
Control result failed! Please check control runs, as a blood control has failed QC!	Control Failed and QC Pause is not enabled. Control or reagent is expired.	Notification	<ol style="list-style-type: none"> <li>1. Review control results.</li> <li>2. Check reagents.</li> <li>3. If controls are expired, use new lot of controls. If reagents are expired, replace with new reagents.</li> <li>4. Rerun controls.</li> <li>5. If patient samples were run, review the patient results and rerun the patient specimens if necessary.</li> <li>6. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
Control result failed! Please check control runs, as a blood control has failed QC! The system will resume when you exit!	Control Failed and the QC Pause is enabled.	Notification	<ol style="list-style-type: none"> <li>1. Check the results for control runs.</li> <li>2. Re-request the QC.</li> <li>3. If problem persists, contact your Beckman Coulter Representative.</li> </ol>

**Table 9.2** AQUIOS System Error Messages (Continued)




Error Message Displayed	Cause	Software Response	Possible Solution
Laser Power error! Samples may not run correctly! Please check maintenance log.	Laser power is very low	Notification	 <ol style="list-style-type: none"> <li>1. Select  to review the maintenance log for details. See <a href="#">Maintenance Screen</a> in <a href="#">CHAPTER 8, Setup</a>.</li> <li>2. Turn the power off.</li> <li>3. Turn the power on.</li> <li>4. If the problem persists, contact your Beckman Coulter Representative.</li> </ol>
Error! The system was stopped! Analysis was Canceled because: Vacuum was low.	Vacuum low	Notification	 <ol style="list-style-type: none"> <li>1. Select  to review the maintenance log for details. See <a href="#">Maintenance Screen</a> in <a href="#">CHAPTER 8, Setup</a>.</li> <li>2. Turn the power off.</li> <li>3. Turn the power on.</li> <li>4. If the problem persists, contact your Beckman Coulter Representative.</li> </ol>
Error! The system was stopped! Analysis was Canceled because: Sipper stalled	Pump Inject Handle Sipper stalled	Notification	 <ol style="list-style-type: none"> <li>1. Select  to review the maintenance log for details. See <a href="#">Maintenance Screen</a> in <a href="#">CHAPTER 8, Setup</a>.</li> <li>2. Turn the power off.</li> <li>3. Turn the power on.</li> <li>4. If the problem persists, contact your Beckman Coulter Representative.</li> </ol>
Error! The system was stopped! Analysis was Canceled because: The plate failed to position properly.	The Pump Inject Handle plate position is not proper.	Notification	<ol style="list-style-type: none"> <li>1. Turn power off.</li> <li>2. Select  to visually inspect the area for obstructions and potential spillage.</li> <li>3. Close reagent door.</li> <li>4. Turn power on.</li> <li>5. If problem persists, contact your Beckman Coulter Representative.</li> </ol>





**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
<p>Error! The system was stopped! Analysis was Canceled because: The Sheath bottle could not be filled! Please check the Sheath tank!</p>	<ol style="list-style-type: none"> <li>1. Sheath is Empty</li> <li>2. Kinked Tubing</li> <li>3. Tubing is disconnected</li> <li>4. Pump is not working properly</li> </ol>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Check the sheath cubitainer. See <a href="#">Replacing the AQUIOS Sheath Solution Cubitainer</a> in CHAPTER 11, Replacement Procedures.</li> <li>2. Ensure the tubing is not kinked or disconnected.</li> <li>3. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p>Error! The system was stopped! Analysis was Canceled because: Sipper Crash: The Sipper Hit an object going down.</p>	<p>Analyzer Probe struck the Deep Well Plate.</p>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Turn power off.</li> <li>2. Open the reagent door by pressing the top middle part of the door in one single, solid motion to visually inspect the probe.</li> <li>3. Check the deep well plate, check the plate positioning. See <a href="#">Replacing the AQUIOS Deep Well Plate</a> in CHAPTER 11, Replacement Procedures.</li> <li>4. Turn power on.</li> <li>5. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p>Error! The system was stopped! Analysis was Canceled because: Analyzer needle could not be raised!</p>	<p>The Pump Inject Handle Analyzer needle could not be raised. Bent probe Communication Malfunction Hardware Malfunction</p>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Turn power off.</li> <li>2. Select  to visually inspect the probe. If probe is bent, contact your Beckman Coulter Representative. If probe is not bent, close the reagent door.</li> <li>3. Turn power on.</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p><i>Error! The system was stopped! Analysis was Canceled because: Internal Sheath bottle overflow.</i></p>	<p>Analysis was canceled because the internal sheath bottle overflow sensor detected a sheath overflow.</p>	<p>Notification</p>	<p>Contact your Beckman Coulter Representative</p>

**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
<p><i>Error! The system was stopped! Analysis was Canceled because the internal Waste Bottle is full! The sample could not be processed.</i></p>	<p>The internal waste bottle is full.</p>	<p>Notification</p>	<p>Contact your Beckman Coulter Representative</p>
<p>Auto-Loader crashed loading a cassette. Please remove the cassette. Next open the reagent door (with button press). Then close the reagent door to restart the system</p>	<p>Cassette misaligned</p>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Remove the cassette and reposition the cassette.</li> <li>2. Select  to visually inspect the area for obstructions and potential spillage.</li> <li>3. Close reagent door.</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p>Auto-Loader crashed unloading the cassette. Please remove the cassette. Next open the reagent door (with button press). Then close the reagent door to restart the system</p>	<p>Cassette misaligned</p>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Remove the cassette and reposition the cassette.</li> <li>2. Select  to visually inspect the area for obstructions and potential spillage.</li> <li>3. Close reagent door.</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p>Auto-Loader crashed moving up. Please remove the cassette. Next open the reagent door (with button press). Then close the reagent door to restart the system</p>	<ol style="list-style-type: none"> <li>1. Cassette misaligned</li> <li>2. The Auto-Loader crashed while moving the cassette up to unload.</li> </ol>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Inspect the autoloader area for any obstructions and remove the cassette and reposition the cassette.</li> <li>2. Select  to visually inspect the area for obstructions and potential spillage.</li> <li>3. Close reagent door.</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>



**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
<p>Auto-Loader crashed moving down. Please remove the cassette. Next open the reagent door (with button press). Then close the reagent door to restart the system</p>	<ol style="list-style-type: none"> <li>1. The Auto-Loader crashed while moving down for a new cassette.</li> <li>2. The Auto-Loader crashed while moving down to unload a cassette.</li> </ol>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Remove the cassette and reposition the cassette.</li> <li>2. Select  to visually inspect the area for obstructions and potential spillage.</li> <li>3. Close reagent door.</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p>Database Connection failed.</p>	<ol style="list-style-type: none"> <li>1. Test Connection failed on the database setup screen.</li> <li>2. Network cables may be disconnected or the network may be down.</li> <li>3. The connection failed on the login screen.</li> <li>4. The database is down.</li> </ol>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Check each parameter that you have entered. (Username, password, database name, server)</li> <li>2. Check all computer connections.</li> <li>3. Check that the host system has a firewall exception for SQL Server and SQL Browser.</li> <li>4. Ensure SQL Server Browser service is running on host workstation.</li> <li>5. Check your username and password are correct. If that does not work, select  and check each parameter that you have entered.</li> <li>6. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p>No data selected. Please verify</p>	<p>The search filters you have selected did not yield any data when exporting a .crd file from the QC area.</p>	<p>Notification</p>	<p>Check your search filter. Select search.</p>
<p>No data selected. Please verify</p>	<p>The search filters you have selected did not yield any data when exporting a .csv file from the QC area.</p>	<p>Notification</p>	<p>Check your search filters. Select search.</p>

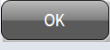
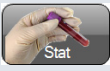
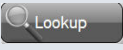
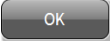
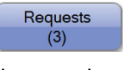
**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
No records found.	Applied criteria is not applicable because there is no data for the criteria selected. (This applies to all export file types.)	Notification	Review search criteria. Select valid criteria and refresh.
This request cannot be edited as it is already running!	The user attempted to edit a request that is already running.	Notification	Wait for the system to finish running and create a new request.
You must have a valid Sample ID!	<ol style="list-style-type: none"> <li>1. Sample ID was not entered.</li> <li>2. Invalid characters were used in the Sample ID.</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. Enter a valid Sample ID.</li> <li>2. Ensure that the Sample ID entered is correct.</li> </ol>
Request failed. Please verify.	Add Request Save Failed	Notification	<ol style="list-style-type: none"> <li>1. Try saving again.</li> <li>2. Verify database connections.</li> <li>3. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
Cannot append to different test. Please verify	Tried to append additional query results to the previous query results and the new query had a different test.	Notification	Ensure that the test selected is the same as that of the previous query. If not, perform a new query.
Import Complete. Total run(s) succeeded: <Files Count> Total run(s) failed:<Failed Count>	The import operation has completed.	Notification	<ol style="list-style-type: none"> <li>1. If any of the runs have failed, go to the source. Export it again. Then, try to import again.</li> <li>2. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
Archive failed.	<ol style="list-style-type: none"> <li>1. Not able to get a database connection.</li> <li>2. Save path was invalid or unavailable.</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. Check your database connections.</li> <li>2. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
Settings not saved.	In the LIS setup screen, when save is selected.	Notification	<ol style="list-style-type: none"> <li>1. Save again.</li> <li>2. If problem persists, contact your Beckman Coulter Service Representative.</li> </ol>
Unable to create new user.	Create new user failed because of database failure	Notification	<ol style="list-style-type: none"> <li>1. Try to create a new user again.</li> <li>2. If problem persists, contact your Beckman Coulter Representative.</li> </ol>

**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
Lot not added, please revise information	Database connection failure when entering the Lot manually.	Notification	<ol style="list-style-type: none"> <li>1. Try again.</li> <li>2. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
Duplicate Sample ID with different Patient information exists. Do you want to proceed?	Same Sample ID, with different Specimen Type, Collect Date, or Patient Information when adding a request manually.	Notification	<p>Select  to add the request. Or;</p> <p>Select  to cancel the action and return to the Add Request Screen.</p>
This change is not allowed for the currently logged in user.	<ol style="list-style-type: none"> <li>1. The user attempts to delete the current user.</li> <li>2. The user attempts to deactivate the current user.</li> </ol>	Notification	Log off and login as a different user. Repeat the process to delete or deactivate the user.
Invalid Messaging Configuration	On the system setup screen (setting up email and text config.), the user selected Test and there are invalid parameters.	Notification	<ol style="list-style-type: none"> <li>1. Check parameters on the system setup screen.</li> <li>2. Check parameters on the system setup screen.</li> <li>3. Contact your local IT representative for correct parameter values.</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
Unable to perform the backup.	<ol style="list-style-type: none"> <li>1. Database connection issue</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. Check your database connections.</li> <li>2. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
Restore Failed	<ol style="list-style-type: none"> <li>1. Problem with the Restore file</li> <li>2. Database connection issue</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. Recreate the backup and attempt to restore.</li> <li>2. Check your database connections.</li> <li>3. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
Invalid Settings	The user has entered an invalid setting in the database setup dialog.	Notification	Check your settings that you have entered.

**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
Backup cannot be performed because the database is not local.	The user has attempted to create a backup or restore of a remote database and this can only be performed on local databases.	Notification	<ol style="list-style-type: none"> <li>1. You must backup on the workstation that is running the database.</li> <li>2. If you are running the database on a network server, contact your local IT representative.</li> </ol>
The Sample could not be run as there is already a request for this sample ID. Please press the lookup button to use this request!	The user has attempted, through the single loader, to create a duplicate request with the same sample ID and different information.	Notification	<ol style="list-style-type: none"> <li>1. Select  to close the message and the sample is not run.</li> <li>2. Select  and enter the Sample ID.</li> <li>3. Select  to add a test request.</li> <li>4. Close the door.</li> </ol>
Duplicate Sample ID with different Patient information exists.	Trying to rerequest a test that has been placed in the incomplete tab or run that is being rejected and rerequested.	Notification	<ol style="list-style-type: none"> <li>1. Select  to close the message. No new test requests will be created.</li> <li>2. Select  to display the test requests.</li> <li>3. Edit the test request if necessary and run the sample.</li> </ol>
The locale must be US English.	The user attempted to start the software with a locale other than US "English."	Notification	<ol style="list-style-type: none"> <li>1. Check the locale settings in the Windows setup to ensure that it is US English.</li> <li>2. Contact your local IT Representative.</li> </ol>
The internal Waste Bottle is full! The sample could not be processed.	The internal waste bottle is full at the start of analysis due to: <ul style="list-style-type: none"> <li>• Broken pump</li> <li>• Kinked tubing, or</li> <li>• Sensor malfunction</li> </ul>	Notification	Contact your Beckman Coulter Representative.
Run rejected, however a request could not be created as the run has already been reviewed or rejected.	The user has selected <b>Reject, Re-request</b> for a run that has previously been reviewed or rejected.	Notification	Create a new Add Request.

**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
<p>The system could not communicate with the hardware. Please reboot the computer and try again.</p>	<p>The instrument is present, but an error occurred while trying to communicate with the instrument.</p>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Check that all your USB cables are connected.</li> <li>2. Ensure the instrument is on.</li> <li>3. Disconnect and reconnect the USB cables between the instrument and the workstation</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p>The vacuum module could not be connected to. Please check the power and USB cables.</p>	<p>An error occurred during startup while trying to connect to the vacuum module.</p>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Check that all your USB cables are connected.</li> <li>2. Ensure the supply cart is on.</li> <li>3. Disconnect and reconnect the USB cables between the instrument and the workstation</li> <li>4. Insure the power cord is connected to the supply cart.</li> <li>5. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p>The instrument could not be connected to. Please check the power and USB cables.</p>	<p>An error occurred during startup while trying to connect to the instrument.</p>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Check your USB cables are connected.</li> <li>2. Ensure the instrument is on.</li> <li>3. Disconnect and reconnect the USB cables between the instrument and the workstation</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p>Error! The system was stopped! Analysis was Canceled because: Analyzer Syringe error!</p>	<p>Analyzer Syringe reported an error in the analysis cycle.</p>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Turn power off.</li> <li>2. Turn power on.</li> <li>3. Restart the system.</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<p>Startup Failed: Motors failed to initialize.</p>	<p>Startup was canceled because the IMS stepping motors did not home properly or the home and zero check failed.</p>	<p>Notification</p>	<ol style="list-style-type: none"> <li>1. Turn power off.</li> <li>2. Turn power on.</li> <li>3. Restart the system.</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>

**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
Startup Failed: Sheath not filled.	Startup was canceled because the system could not fill the internal sheath bottle.	Notification	<ol style="list-style-type: none"> <li>1. Replace the AQUIOS Sheath Solution cubitainer, see <a href="#">Replacing the AQUIOS Sheath Solution Cubitainer in CHAPTER 11, Replacement Procedures</a>.</li> </ol> <p><b>NOTE</b> The bar code scanner is not active until a START cycle has completed. Connect the new sheath cubitainer, run and complete the START cycle, then scan the sheath bar code label.</p> <ol style="list-style-type: none"> <li>2. Check the sensor cable connection.</li> <li>3. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
Startup Failed: Waste not emptied.	<p>The internal waste bottle is full at the start of analysis due to:</p> <ul style="list-style-type: none"> <li>• Broken pump</li> <li>• Kinked tubing, or</li> <li>• Sensor malfunction</li> </ul>	Notification	Contact your Beckman Coulter Representative.
Startup Failed: Vacuum level not reached.	Startup was canceled because the system could not achieve necessary vacuum due to a loose bottle cap, pump malfunction, or vacuum sensor failure.	Notification	<ol style="list-style-type: none"> <li>1. Check that the vacuum reservoir cap in the Supply Cart is tightened then rerun system startup. See <a href="#">CHAPTER 3, Daily Startup</a>.</li> <li>2. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
Instrument settings error. Startup aborted.	Startup was canceled because the instrument settings could not be properly read from the electronics.	Notification	<ol style="list-style-type: none"> <li>1. Perform System Shutdown. Then, perform System Startup again. See <a href="#">CHAPTER 3, Daily Startup</a>.</li> <li>2. If problem persists, contact your Beckman Coulter Representative.</li> </ol>



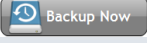
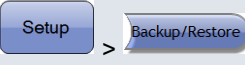
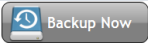
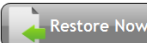
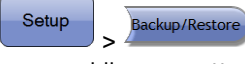

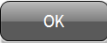


**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
Startup Failed: Sheath overflow.	Startup was canceled because the sheath overflow sensor detected a sheath overflow. The sensor on the top of the Sheath tank has failed and allowed an overflow to the bottom tank.	Notification	Contact your Beckman Coulter Representative.
<i>Aquios.exe is not responding.</i>	<ol style="list-style-type: none"> <li>1. The system is busy.</li> <li>2. The system is attempting to connect to an instrument which is not powered on.</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. Allow the software to continue processing until it becomes available.</li> <li>2. Close the software, turn the instrument on and Select 'Connect' to connect to the instrument.</li> </ol>
<i>Shutdown Failed! Analyzer needle couldn't be raised during bleaching.</i>	The system could not raise the analyzer needle during its bleaching operation.	Notification	<ol style="list-style-type: none"> <li>1. Turn power off.</li> <li>2. Turn power on.</li> <li>3. Restart the system.</li> <li>4. If problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<i>Incompatible Hardware!</i>	User is attempting to connect to a system whose hardware is not compatible with the version of software.	Notification	<ol style="list-style-type: none"> <li>1. Turn power off.</li> <li>2. Disconnect and reconnect the USB cables between the workstation and the instrument.</li> <li>3. Turn power on.</li> <li>4. If problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<i>Startup Failed: System crashed! Syringe Error.</i>	Syringe error during startup.	Notification	<ol style="list-style-type: none"> <li>1. Turn power off.</li> <li>2. Turn power on.</li> <li>3. Restart the system.</li> <li>4. If problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<i>Startup Failed: System crashed! Lowering needle.</i>	Error lowering prep needle during startup.	Notification	<ol style="list-style-type: none"> <li>1. Turn power off.</li> <li>2. Turn power on.</li> <li>3. Restart the system.</li> <li>4. If problem persists, contact your local Beckman Coulter Representative.</li> </ol>





**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
<i>Startup Failed: System crashed! Needle could not be raised.</i>	Error raising prep needle during startup.	Notification	<ol style="list-style-type: none"> <li>1. Turn power off.</li> <li>2. Turn power on.</li> <li>3. Restart the system.</li> <li>4. If problem persists, contact your local Beckman Coulter Representative.</li> </ol>
<i>AQUIOS Software Cannot Be running.</i>	The user launched a second instance of the AQUIOS Software.	Notification	Close the second instance of the AQUIOS software.
<i>Restore cannot be performed because the database is not local.</i>	The user has attempted to restore a backup on to a remote database and this can only be performed on local database.	Notification	<ol style="list-style-type: none"> <li>1. Restore from the local computer that contains the database.</li> <li>2. Perform Restore Database, see <a href="#">CHAPTER 8, Restore Database</a>.</li> </ol>
<i>Incorrect database version.</i>	The user has clicked on login button and the database is not compatible with the current version software.	Notification	<ol style="list-style-type: none"> <li>1. Select the correct database.</li> <li>2. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<i>The request is already being run by another instrument. The sample cannot be run.</i>	The user has looked up a request through the Stat door and the request is already started running on a different or same instrument.	Notification	<ol style="list-style-type: none"> <li>1. Wait for the original request to complete.</li> <li>2. Create a new request on another instrument.</li> </ol>
<i>Cannot Backup to or Restore from a network drive.</i>	If the user selects a network drive, or a folder on shared drive during a Backup or Restore.	Notification	<ol style="list-style-type: none"> <li>1. Restore from the local computer that contains the database.</li> <li>2. Perform Restore Database, see <a href="#">CHAPTER 8, Restore Database</a>.</li> </ol>
<i>Restore Failed. You must exit the software.</i>	<ul style="list-style-type: none"> <li>• The restore function exceeded the allowed time.</li> <li>• Problem with the Restore file.</li> <li>• Database connection issue.</li> </ul>	Notification	<ol style="list-style-type: none"> <li>1. Select  to close the software.</li> <li>2. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<i>You cannot perform a Bleach while a cassette is onboard.</i>	 was selected on the Maintenance screen while a cassette was processing.	Notification	<ol style="list-style-type: none"> <li>1. Wait for the system to unload the cassette to unload.</li> <li>2. Select .</li> </ol>

**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
<i>There is a cassette onboard. Backup database could not proceed.</i>	 was selected on the  screen while a cassette was processing.	Notification	<ol style="list-style-type: none"> <li>1. Wait for the system to unload the cassette to unload.</li> <li>2. Select .</li> </ol>
<i>There is a cassette onboard. Restore database could not proceed.</i>	 was selected on the  screen while a cassette was processing.	Notification	<ol style="list-style-type: none"> <li>1. Wait for the system to unload the cassette to unload.</li> <li>2. Select .</li> </ol>
<i>AQUIOS Cleaning Agent Open Vial expired.</i>	The AQUIOS Cleaning Agent was expired upon startup.	Notification	<ol style="list-style-type: none"> <li>1. Replace the Cleaning Agent. See <a href="#">Replacing the AQUIOS Cleaning Agent Bottle in CHAPTER 11, Replacement Procedures</a> for the AQUIOS Cleaning Agent replacement procedure.</li> <li>2. Select .</li> </ol>
<i>AQUIOS Cleaning Agent expired.</i>	The open vial time for the AQUIOS Cleaning Agent was expired upon startup.	Notification	<ol style="list-style-type: none"> <li>1. Replace the Cleaning Agent. See <a href="#">Replacing the AQUIOS Cleaning Agent Bottle in CHAPTER 11, Replacement Procedures</a> for the AQUIOS Cleaning Agent replacement procedure.</li> <li>2. Select .</li> </ol>
<i>You cannot perform a Flush while a cassette is onboard.</i>	 was selected on the Maintenance screen while a cassette was processing.	Notification	<ol style="list-style-type: none"> <li>1. Wait for the system to unload the cassette to unload.</li> <li>2. Select .</li> </ol>

**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
<i>Unable to perform Flush. The system must first be running.</i>	<p>1.  or  was selected and the instrument is not running.</p> <p>2.  or  was selected and the instrument may have lost communications.</p>	Notification	<ol style="list-style-type: none"> <li>1. Ensure all cables are connected properly.</li> <li>2. Turn power off.</li> <li>3. Turn power on and restart the instrument and software.</li> <li>4. Perform the startup, see <a href="#">Startup</a> in <a href="#">CHAPTER 3, Daily Startup</a>.</li> <li>5. If the problem persists, contact your Beckman Coulter Representative.</li> </ol>
<i>Not enough wells to run the test. The sample cannot be run.</i>	There were no available wells on the plate to run the test.	Notification	<ol style="list-style-type: none"> <li>1. Replace the Deep Well Plate, see <a href="#">Replacing the AQUIOS Deep Well Plate</a> in <a href="#">CHAPTER 11, Replacement Procedures</a>.</li> <li>2. Re-request the sample run.</li> </ol>
<i>The sheath is empty! Please wait until the system is idle to change. The sample cannot run.</i>	<p>A request was submitted through the Single-tube loader and one of the following occurred:</p> <ol style="list-style-type: none"> <li>1. Sheath is empty</li> <li>2. A sensor cable is disconnected</li> <li>3. Sensor malfunction</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. Wait until the system is idle and replace the AQUIOS Sheath Solution cubitainer, see <a href="#">Replacing the AQUIOS Sheath Solution Cubitainer</a> in <a href="#">CHAPTER 11, Replacement Procedures</a>.</li> <li>2. Check the sensor cable connection.</li> <li>3. Re-request the sample run.</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>
<i>The waste is full! Please wait until the system is idle to change. The sample cannot be run.</i>	<p>A request was submitted through the Single-tube loader and one of the following occurred:</p> <ol style="list-style-type: none"> <li>1. Waste is full</li> <li>2. A sensor cable is disconnected</li> <li>3. Sensor malfunction</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. Wait until the system is idle and replace the Waste Container, see <a href="#">Replacing the Waste Container</a> in <a href="#">CHAPTER 11, Replacement Procedures</a>.</li> <li>2. Check the sensor cable connection.</li> <li>3. Re-request the sample run.</li> <li>4. If problem persists, contact your Beckman Coulter Representative.</li> </ol>

**Table 9.2** AQUIOS System Error Messages (Continued)

Error Message Displayed	Cause	Software Response	Possible Solution
<i>The system stopped because of a cassette ID mismatch.</i>	The onboard cassette ID does not match the expected cassette ID of the next scheduled tube. The following will occur: <ol style="list-style-type: none"> <li>1. The system will stop.</li> <li>2. The Autoloader light will change from green to red.</li> </ol>	Notification	<ol style="list-style-type: none"> <li>1. Exit the AQUIOS software.</li> <li>2. Restart and Log in to the AQUIOS software.</li> <li>3. Perform the startup, see <a href="#">Startup</a> in <a href="#">CHAPTER 3, Daily Startup</a>, steps 13 - 16.</li> <li>4. If the problem persists, contact your Beckman Coulter Representative.</li> </ol>
<i>Incorrect instrument configuration. Startup aborted.</i>	Instrument settings are outside of the acceptable ranges.	Notification	<ol style="list-style-type: none"> <li>1. Exit the AQUIOS software.</li> <li>2. Restart and Log in to the AQUIOS software.</li> <li>3. Perform the startup, see <a href="#">Startup</a> in <a href="#">CHAPTER 3, Daily Startup</a>, steps 13 - 16.</li> <li>4. If the problem persists, contact your Beckman Coulter Representative.</li> </ol>

## Analysis Error Messages

Table 9.3 describes some analysis error messages.






**Table 9.3** Analysis Error Messages

Message Type	Possible Causes	Corrective Actions
Notification	<p>The system has detected a condition that could affect the results, such as:</p> <ul style="list-style-type: none"> <li>• Insufficient blood in specimen tube.</li> <li>• A problem aspirating the sample.</li> <li>• The characteristic of blood sample, including an aged specimen.</li> <li>• Insufficient region or total cells being counted.</li> <li>• Inability to find a whole blood cell population.</li> </ul>	<ol style="list-style-type: none"> <li>1. Review the sample results from the Review screen. If the minor condition affects the results, then select <b>Reject, Re-Request</b> for the sample from the Review Options menu. For more information on generic notifications, see <a href="#">Flags And Notifications</a> in <a href="#">CHAPTER 6</a>.</li> <li>2. Before loading the sample, verify that the blood level in the specimen tube is sufficient. See information in the applicable System Guide.</li> </ol>
Flags	<p>Major error due to:</p> <ul style="list-style-type: none"> <li>• Insufficient blood in sample tube.</li> <li>• A problem aspirating the sample.</li> <li>• The characteristic of blood sample, including an aged specimen.</li> <li>• Insufficient region or total cells being counted.</li> <li>• Inability to find a whole blood cell population</li> </ul>	<ol style="list-style-type: none"> <li>1. Review the sample results from the Review screen. If the condition affects the results, then select <b>Reject, Re-Request</b> for the sample from the Review Options menu. For more information on generic flags, see <a href="#">Flags And Notifications</a> in <a href="#">CHAPTER 6</a>.</li> <li>2. Before loading the sample, verify that the blood level in the specimen tube is sufficient. See information in the applicable System Guide.</li> </ol>
QC Flags	<p>Control result not within the:</p> <ul style="list-style-type: none"> <li>• Range</li> <li>• Resolution</li> <li>• Compensation</li> </ul>	<ol style="list-style-type: none"> <li>1. Check the controls expiration date.</li> <li>2. Check if the controls' blood level is sufficient.</li> <li>3. Repeat Quality Control. See <a href="#">Run QC Samples</a> in <a href="#">CHAPTER 4</a> for details.</li> </ol>







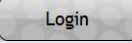


## System Warning Messages

See [Table 9.4](#).

**Table 9.4** System Warnings and Status Messages


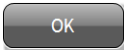
Message	General Category	Corrective Action
<p><i>Failed</i></p>	Database Setup Screen	<ol style="list-style-type: none"> <li>1. Log into the database using SQL server to ensure that the database has been properly created and that you have the correct information.</li> <li>2. If the information is incorrect, re-enter the information.</li> <li>3. Select .</li> <li>4. If the problem persists, contact your database administrator.</li> </ol>
<p><i>Insufficient reagents</i></p> 	Located on the status bar at the bottom of the screen.	<ol style="list-style-type: none"> <li>1. Allow the samples on the Running screen to complete analysis before adding the reagents.</li> <li>2. Replace the reagents as needed before loading the new sample. See <a href="#">Replacing Reagents and Consumables in CHAPTER 11, Replacement Procedures</a>.</li> <li>3. Proceed to add the instant request.</li> </ol>
<p><i>No Sample ID</i></p> 	Add Request Screen through Stat button.	Enter or scan the sample ID.
<p><i>No Test</i></p> 	Add Request Screen through Stat button.	Select the test.
<p><i>No Request Found</i></p> 	Add Request Screen through Stat button.	<p>No advance request was found for the scanned sample ID.</p> <ol style="list-style-type: none"> <li>1. Type in Sample ID and Test to create a request. A request will be added.</li> <li>2. Load the mixed sample on the Single-tube Loader.</li> <li>3. Close the door.</li> </ol>

**Table 9.4** System Warnings and Status Messages (Continued)

Message	General Category	Corrective Action
<i>You must select a test</i>	Add Test Request Screen	Select  to add request. See <a href="#">Add Test Request for a Patient Sample</a> in <a href="#">APPENDIX A, Software Screens</a> .
<i>You must have a Valid Sample ID.</i>	Add Test Request Screen	Enter or scan sample ID.
<i>Reagent Levels: Empty</i> 	Status Bar	<ol style="list-style-type: none"> <li>1. Allow samples on the Running screen to complete analysis.</li> <li>2. Replace the reagents as needed. See <a href="#">Replacing Reagents and Consumables</a> in <a href="#">CHAPTER 11, Replacement Procedures</a>.</li> </ol>
<i>Reagent Levels: Low</i> 	Status Bar	<ol style="list-style-type: none"> <li>1. Allows samples on the Running screen to complete analysis.</li> <li>2. Replace the reagents as needed. See <a href="#">Replacing Reagents and Consumables</a> in <a href="#">CHAPTER 11, Replacement Procedures</a>.</li> </ol>
<i>Plate Low</i> 	Status Bar	<ol style="list-style-type: none"> <li>1. Allow samples on the Running screen to complete analysis.</li> <li>2. Replace the microplate. See <a href="#">Replacing Reagents and Consumables</a> in <a href="#">CHAPTER 11, Replacement Procedures</a>.</li> </ol>
<i>No Plate</i> 	Status Bar	<ol style="list-style-type: none"> <li>1. See <a href="#">Replacing Reagents and Consumables</a> in <a href="#">CHAPTER 11, Replacement Procedures</a>.</li> </ol>
<i>AQUIOS Alert</i> 	Status Bar	<ol style="list-style-type: none"> <li>1. Exit the software.</li> <li>2. Power the system on.</li> <li>3. Double-click on the AQUIOS icon. The Login screen (<a href="#">Figure 8.19</a>) appears.</li> <li>4. Enter the Username and Password and select . The Main screen (<a href="#">Figure A.1</a>) appears.</li> </ol>
	Status Bar	<p>Instrument is not ready to run.</p> <p>To run samples, select  to begin system Startup.</p>



**Table 9.4** System Warnings and Status Messages (*Continued*)

Message	General Category	Corrective Action
<p><i>LIS Not Connected</i></p> 	Status Bar	<ol style="list-style-type: none"> <li>1. If you want to connect to the LIS, turn on the LIS and configure its settings. See <a href="#">LIS Setup Screen</a> in <a href="#">CHAPTER 8, Setup</a>.</li> <li>2. If the problem persists, contact your LIS administrator.</li> </ol>
<i>Flag</i>	Review and Results screens	See <a href="#">Figure A.4</a> .
<i>Notification</i>	Review and Results screens	See <a href="#">Figure A.4</a> .
<i>Please select a date range</i>	Setup Screen, Archive Setup	Enter dates next to <b>From</b> and <b>To</b> .
<i>In Edit Mode</i>	Setup Screen, Reagent Info and Test Settings	<ol style="list-style-type: none"> <li>1. Make the necessary changes.</li> <li>2. Save the changes.</li> </ol>
<i>Please remove all reagents from the system as per labeling instructions.</i>	Shutdown Procedure	<ol style="list-style-type: none"> <li>1. Open the reagent door.</li> <li>2. Remove the antibodies and controls and place them in the refrigerator. All other reagents can be left at room temperature.</li> <li>3. Place the respective caps on the AQUIOS Lysing Kit Reagents.</li> <li>4. Close the door.</li> <li>5. Select .</li> </ol>

## Incomplete Request Causes

See [Table 9.5](#) for the causes of Incomplete Requests.

**Table 9.5** Causes for Incomplete Requests

General Category	Probable Cause	Corrective Action
No barcode (autoloader samples only)	<ul style="list-style-type: none"> <li>Defective barcode.</li> <li>Barcoded tube not properly aligned in cassette for barcode scanning.</li> <li>No barcode on tube. See <a href="#">Barcode Labels</a> for details.</li> <li>No barcode on cassette.</li> <li>Misalignment of autoloader barcode reader.</li> </ul>	<ol style="list-style-type: none"> <li>Replace the barcode and create a new request. See <a href="#">Request Screen</a> in <a href="#">APPENDIX A, Software Screens</a> for details.</li> <li>Ensure that the cassette has a barcode and that the barcodes are facing the front in the cassette. OR</li> <li>Run the sample on the Single-tube Loader without a barcode. See <a href="#">Running a Sample Using the Single-tube Loader</a> in <a href="#">CHAPTER 5, Sample Processing</a> for details.</li> <li>If problem persists, contact your Beckman Coulter Representative.</li> </ol>
No Request (autoloader samples only)	No LIS or User Request was created for the autoloader sample and the Default Test setup is "OFF".	<ol style="list-style-type: none"> <li>Create a request for this sample. See <a href="#">Request Screen</a> in <a href="#">APPENDIX A, Software Screens</a> for details.</li> <li>Set up a default test and run the sample (autoloader only).</li> <li>Run the sample on the Single-tube Loader without a Request. See <a href="#">Running a Sample Using the Single-tube Loader</a> in <a href="#">CHAPTER 5, Sample Processing</a> for details.</li> </ol>
Insufficient Reagents	The system has insufficient reagents for the run requested.	Ensure that there are a sufficient amount of reagents onboard the instrument to run the selected test. Refer to <a href="#">CHAPTER 11, Replacement Procedures</a> for reagent replacement procedures.
System Stopped	The system stopped due to an error.	<ol style="list-style-type: none"> <li>View the error log for the cause of the system stop.</li> <li>Restart the instrument.</li> <li>Restart the software.</li> <li>Create a new request and rerun the sample.</li> <li>If problem persists, contact your Beckman Coulter Representative.</li> </ol>
Duplicate Sample ID	An LIS test request with a duplicate sample ID, but different patient information was received.	Verify patient information and sample IDs are accurate.

## Overview

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In addition to the procedures below, you can trigger a 5-minute cleaning routine involving AQUIOS Sodium Hypochlorite Solution. See [Run Bleach Cycle](#) in [CHAPTER 8, Setup](#).

**NOTE** When you request this panel, the system completes the current action in progress, halts further actions, and begins the cleaning procedure.

This chapter contains information on the following:


- [Cleaning the Wash Station](#)
- [Cleaning the Barcode Reader on the Front of the Instrument](#)
- [Cleaning Blood Spills](#)
- [Cleaning the System](#)

## Cleaning the Wash Station

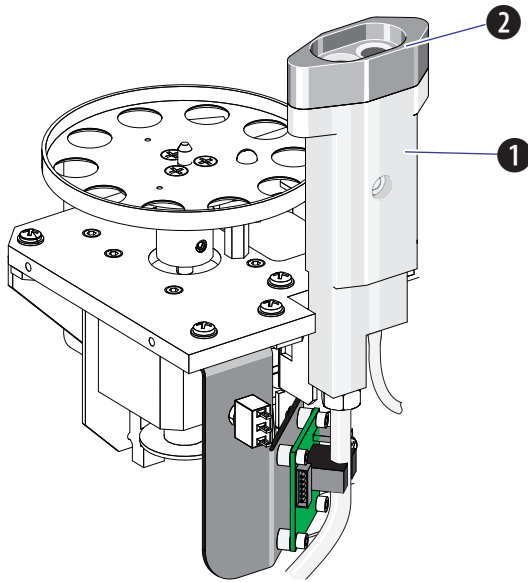
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**Risk of personal injury or contamination. To prevent possible injury or biohazardous exposure, always wear proper laboratory attire, including gloves, a laboratory coat, and eye protection.**

- 1 Select **Open Reagent Door** from the status bar before trying to open the reagent door. Open the reagent door by selecting  **Open Reagent Door** from the menu bar. When prompted open the reagent door by pressing the top middle part of the door in one single, solid motion. See [CHAPTER 1, Doors](#).
- 2 Using a cotton swab, dispense enough AQUIOS Sodium Hypochlorite solution to wet the swab without saturating it.

- 
- 3** Wipe the stainless steel opened portion of the wash station, including the well and rim, with the swab.



1. Wash Station

2. Wash Station well and rim

- 
- 4** Use a clean cotton swab to remove any excess AQUIOS Sodium Hypochlorite.

- 
- 5** Close the reagent door.
-

## Cleaning the Barcode Reader on the Front of the Instrument

---

Built-up dust or un-cleaned fluid spills can interfere with the barcode scanning process. If the barcode reader at the front of the instrument fails to read unaltered barcode labels, clean the barcode reader and attempt to scan the barcode label again.

### WARNING

**Risk of possible biohazardous contamination. Adequate precautions and safety attire should be used when cleaning possible biohazard spills from the barcode reader. For details, refer to document “CLSI M29, Protection of Laboratory Workers from Occupational Infections.”**

### WARNING

**Use barrier protection, including protective eyewear, gloves, and suitable laboratory attire. Refer to the Safety Data Sheet for details about chemical exposure before using the chemical.**

### CAUTION

**Risk of damaging the barcode reader window when using abrasive or corrosive cleaners such as bleach. Only use the suggested products in this procedure to ensure that the sensitive barcode reader window is not damaged.**

- 1 Carefully wipe the barcode reader window, [Figure 1.6](#), with a soft, lint-free tissue containing isopropyl alcohol.
- 2 Verify that the barcode reader is able to scan the reagent information.

## Cleaning Blood Spills

---

### WARNING

**Risk of injury and biohazardous contamination if blood is spilled and not immediately and properly cleaned up. In the event of a blood spill, clean the area according to your laboratory protocol and follow all safety precautions.**

- 1 Disinfect the area using a disinfectant solution according to your laboratory’s procedures.

- 2 Dispose of all materials in your laboratory's biohazard waste containers.
- 3 Refer to CLSI/CCCLS document GP17 - Clinical Laboratory Safety for additional information.

## Cleaning the System

**WARNING**

**Risk of chemical injury from bleach. To avoid contact with the bleach, use barrier protection, including protective eyewear, gloves, and suitable laboratory attire. Refer to the Safety Data Sheet for details about chemical exposure before using the chemical.**

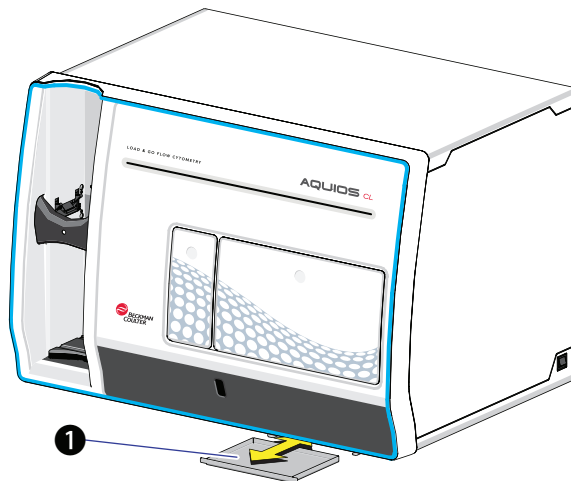
Using wipes soaked with 10% bleach or sporicidin, clean the external surfaces of the instrument surfaces weekly.

If build up of dried blood is noticed in the probe wash station to the right of the reagent carousel, use a cotton swab soaked with 10% bleach or sporicidin to clean it.

**WARNING**

**Risk of biohazard spill. Check the wash station overflow tray for spills during routine maintenance and after a wash station overflow and clean if necessary, to prevent any biohazardous contamination.**

Figure 10.1 Wash Station Overflow Tray



1 Wash station overflow tray

# CHAPTER 11

## Replacement Procedures

### Overview

---

This chapter contains information on the following:

- Replacing Reagents and Consumables
- Replacing the AQUIOS Deep Well Plate
- Replacing the AQUIOS Lysing Reagent
- Replacing the AQUIOS Panel Reagents
- Starting a New Lot of Controls
- Logging In Reagents
- Replacing the AQUIOS Sheath Solution Cubitainer
- Replacing the AQUIOS Sodium Hypochlorite Solution Tube
- Replacing the AQUIOS Cleaning Agent Bottle
- Replacing the Waste Container
- Replacing the Inline Waste Filter

## Replacing Reagents and Consumables

---

### CAUTION

Risk of erroneous results. The AQUIOS CL Flow Cytometer system tracks all onboard reagents for remaining tests, and expiration dates. If your laboratory has more than one AQUIOS CL Flow Cytometer and the systems are networked, the networked databases are sharing information so that, for example, the reagents from system #1 can be loaded onto system #2 without a problem. However, if the systems are not networked, and reagents are moved from one system to another, the systems will not be able to accurately track the reagent.

As an example, if a monoclonal antibody vial has 10 tests remaining and is moved to another system (that is not networked and sharing databases), the system will think the vial is full (50 tests remaining in the vial) and continue to aspirate from that vial even though it is empty. Therefore, Beckman Coulter strongly recommends that multiple systems in a laboratory always be networked and sharing the same database.

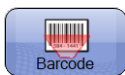
### CAUTION

Risk of incomplete analysis. The AQUIOS CL Flow Cytometer may not be able to analyze the onboard samples if reagents are replaced while samples are being analyzed. Before starting a large run, verify sufficient reagent to complete the run. Replace reagents as needed.

**IMPORTANT** When replacing reagents, the software looks for specific barcodes to ensure the correct reagent is loaded and tracked.

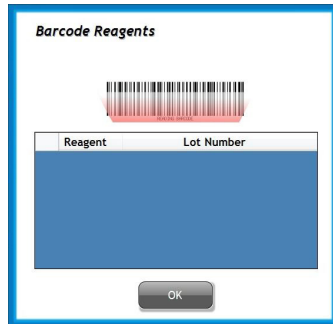
## Barcode Reagents

**NOTE** The reagent bar code scanner is activated as part of the START cycle, and available for use once the START cycle is completed.



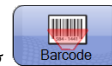
Selecting  activates the barcode scanner located on the front of the instrument.

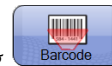


**Figure 11.1** Barcode Reagents Dialog

**OK** - Use to accept scanned reagent name and lot number that appeared on the dialog window.

### Scan Reagent Information From Barcode



The following reagents need to be scanned by selecting  upon loading a new reagent:

- AQUIOS Sheath Solution (barcode on removable sticker on the cubitainer)
- AQUIOS Cleaning Agent (barcode on bottle)
- AQUIOS whole blood controls (barcode on assay sheet)

**NOTE** Be sure to scan the reagent barcode before using the reagents listed above.

**NOTE** AQUIOS Sodium Hypochlorite Solution is the only reagent that does not carry a barcode.

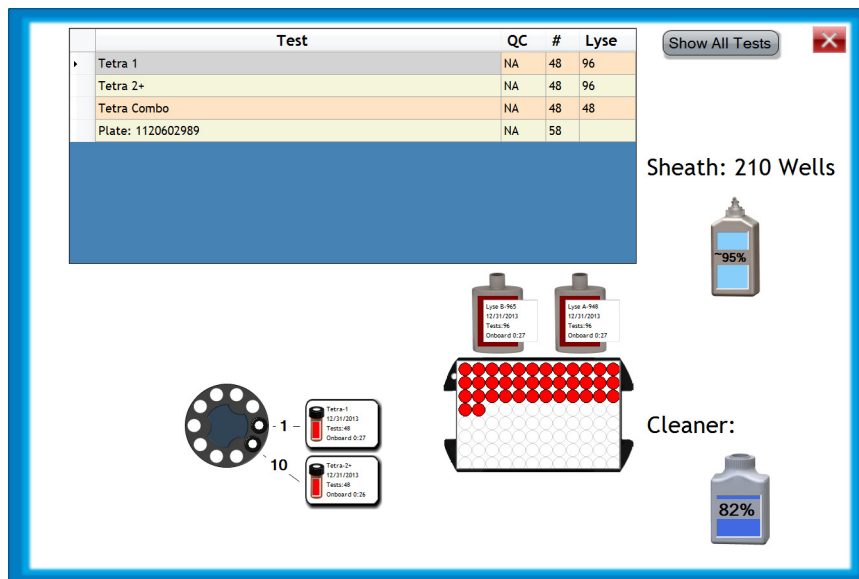
The application specific reagents are automatically scanned by the system once they are loaded in the respective holder:

- AQUIOS Monoclonal Antibody Panel vials (on carousel).
- AQUIOS Lysing Reagent (plate platform reagent holders)
- AQUIOS Deep Well Plate (plate platform)
- Any additional application specific reagents

## Reagent Levels Screens

The Reagent Levels Test Summary screen (Figure 11.2) provides a dialog to monitor reagent and deep well plate usage, status, and location. This example shows the Tetra application, your screen may differ depending on the application being used. The screen displays the total number of tests remaining based on the current reagent and well availability. Every time the reagent door is opened and closed, the reagents and deep well plate are scanned and the dialog provides the current reagent/plate usage summary.

Figure 11.2 Reagent Levels Screen [Tetra Application]



**Show All Tests** — Use to display all the imported tests available on the instrument

**Reagent Levels table** — Use to track the number of tests remaining based on the current reagent/plate usage.

- **Test** - Reagent tracked for the number of tests.
- **QC** - Indicates if QC has been run successfully for this test. NA indicates that QC is not applicable for this reagent.
- **#** - Number of tests remaining for antibodies.
- **Lyse** - Number of tests remaining for the lysing reagents. If a sample is running, the Lyse column displays the number of tests scheduled to be lysed in brackets.

**NOTE** Any other application specific reagents will be displayed in the Reagents Levels table.

**Reagent Illustrations** — Visually displays an estimated percentage remaining or the number of tests remaining per reagent. It also displays the plate usage where red represents a used well and white represents available wells. Monoclonal antibody vials will display white if it is within stability standards and red if the expiration date has been reached.

**NOTE** The indication of the % of sheath available is an approximation. You will be notified with a message when the sensor detects that the sheath cubitainer is empty. In some cases, the system may indicate 0% available when there is still sheath remaining. The system may also indicate there is still some sheath available when there is not any remaining in the cubitainer because this number is an approximation. You will be notified with a message when the level sensor detects that the sheath cubitainer is empty.



**Risk of erroneous results. Non-networked systems will not detect an out-of-reagent condition if the reagent is used on two different instruments that are not networked. Only a networked system can track the number of times that the reagent has been used across systems. Do not use the same bottle of reagents on two different instruments that are not networked.**


## Replacing the AQUIOS Deep Well Plate

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 **WARNING**

Risk of personal injury if instrument cover is removed or a door is left open due to possible exposure to high voltages, laser radiation, and/or moving parts. Never operate the instrument without a cover or with a door opened.

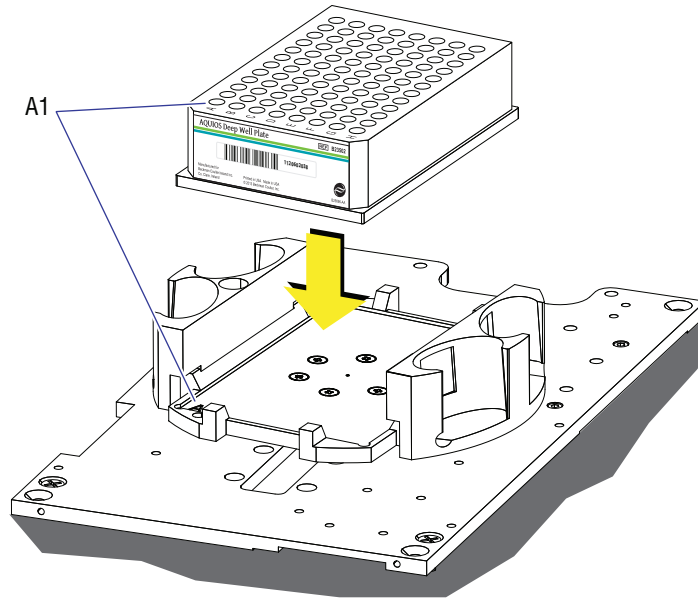
---

- 1 If the system is on, select the  **Open Reagent Door** in the status bar. Wait until given the prompt, then open the reagent door by pressing the top middle part of the door in one single, solid motion. See [CHAPTER 1, Doors](#).

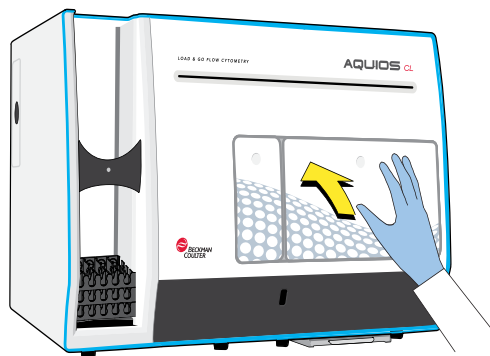


- 2 Remove the used plate.

- 3 Place the new plate on the module so that the A1 corner of the plate falls on the A1 engraved location on the plate platform.




- 4 Close the reagent door. The system scans the reagents and plate, then the Reagent Levels screen appears.



- 5 Close the screen and the Main screen (Figure A.1) appears.

## Replacing the AQUIOS Lysing Reagent

---

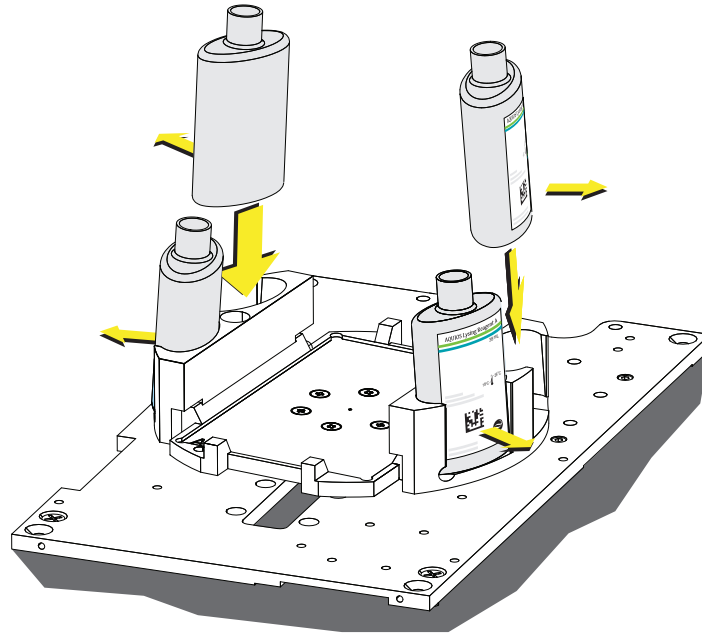
- 1 Select  **Open Reagent Door** on the status bar. When prompted, open the reagent door by pressing the top middle part of the door in one single, solid motion.



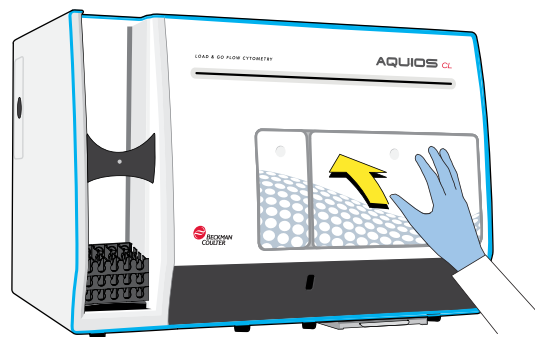
- 2 Remove the empty AQUIOS Lysing Reagent bottles.
- 3 Remove the caps on the new AQUIOS Lysing Reagent bottles before loading.

**NOTE** These caps are not cap-pierceable.

- 4 Place the new bottles in the appropriate holders with the barcodes facing outwards. The AQUIOS Lysing Reagent bottles are interchangeable and can be placed in any of the four available positions.




- 5 Close the reagent door. The reagents and plate are scanned, then the Reagent Levels screen appears.



- 6 Close the Reagent Levels screen and the Main screen (Figure A.1) appears.

## Replacing the AQUIOS Panel Reagents

---

- 1 Select  Open Reagent Door from the menu bar before trying to open the reagent door, then press the top center door when instructed.



 **WARNING**

**Risk of biohazardous contamination. Empty Monoclonal Antibody vials should be considered as contaminated containers. Dispose of all empty Monoclonal Antibody vials in accordance with your local regulations and acceptable laboratory practices.**

- 2 Remove the empty Monoclonal Antibody vials.

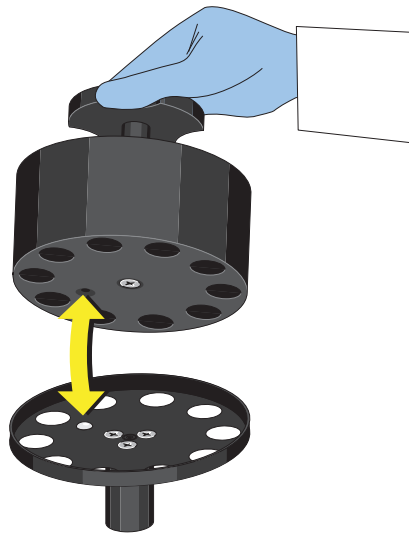


**CAUTION**

Ensure the shipping cap has been replaced with the pierceable caps provided with the reagent packaging, otherwise the probe can be damaged. The pierceable caps should be handled with care to avoid contamination.

- 3 Place the new antibodies in any of the ten available positions on the carousel.

**NOTE** When loading the carousel into the instrument, be sure to place it on the wheel and gently turn it until it locks into position on the wheel.



- 4 Close the reagent door. The system scans the reagents and plate, then the Reagent Levels screen appears.



- 5 Close the screen. The Main screen (Figure A.1) appears.



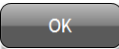
## Starting a New Lot of Controls

---

See also, [Quality Control](#) in [CHAPTER 4, Quality Control](#).



**Risk of biohazardous contamination. Empty control bottles should be considered as contaminated containers. Dispose of all empty control bottles in accordance with your local regulations and acceptable laboratory practices.**

-  Select . The barcode reader next to the Single-tube Loader door activates.
  - 2 Scan the barcode on the control assay sheet. The barcode reader beeps as the control is displayed on the Barcode Reagent screen.
  - 3 Select .
- NOTE** The new control assay values have been registered in the system. To request and load the control, see [Request Screen](#) in [APPENDIX A, Software Screens](#).
- 4 Verify that control values and expiration date have been scanned in correctly.

## Logging In Reagents

---

Prior to running either controls or samples on the system, the reagents to be used with the particular system should be logged into the database. For instructions on using the barcode scanner to load new reagent information in the Reagent Info screen, see [Barcode Reagents](#). For instructions manually entering barcode information, see [Add New Controls Lot Manually](#) in [CHAPTER 8, Setup](#).

## Replacing the AQUIOS Sheath Solution Cubitainer

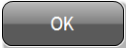
---

**NOTE** To reduce workflow interruptions, it is recommended that you change the waste container every time you replace the Sheath cubitainer. To change cubitainers independently, just follow the software prompts for Sheath or Waste Warnings.

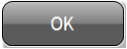
**NOTE** The bar code scanner is not active until a START cycle has completed successfully.

- 1 The message *Sheath Warning Please wait for loaded samples to finish* appears. Allow all loaded samples to complete processing and do not load any new samples in the system. Wait for the next message before replacing the AQUIOS Sheath Solution cubitainer.

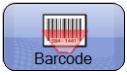
---

- 2 Select . The message *Sheath Empty! Please change the sheath now! Open/close the reagent door to restart the system. Remember to scan the barcode into the system first.* appears.

---

- 3 Select .

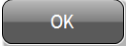
---

- 4 Select  to activate the barcode reader next to the Single-tube Loader.

---

- 5 Peel off the sticker with the 2D barcode on the new AQUIOS Sheath Solution and scan the barcode. The barcode reader beeps as the reagent lot information is displayed on the barcode Reagent screen.

---

- 6 Select .

---

- 7 Cut out the paper protection on the new AQUIOS Sheath Solution cubitainer.

---

- 8 Remove the cap and the foil seal on the new cubitainer's spout.

---

- 9 Remove the cap with the sensor from the empty AQUIOS Sheath Solution cubitainer.

---

- 10 Put the cap from the new cubitainer on the empty cubitainer to prevent spillage when moving the cubitainers.

---

- 11 Carefully and without forcing the tubing lines, unload the empty AQUIOS Sheath Solution cubitainer from the Supply Cart.

---

- 12 Carefully transfer the tube assembly from the used AQUIOS Sheath Solution cubitainer to the new AQUIOS Sheath Solution cubitainer before moving it into place on the supply cart to prevent spillage.

- 
- 13** Lift the neck of the cubitainer while you tighten the cap without crimping or pinching any of the tubes.

**NOTE** If replacing the Sheath cubitainer and Waste container at the same time. Proceed to [Replacing the Waste Container](#).

- 
- 14** Open/close the reagent door to reset the system, and the Reagent Levels screen appears and updates with the information for the new cubitainer of Sheath.


- 
- 15** Close the Reagent Levels screen. The Main screen ([Figure A.1](#)) appears.

- 
- 16** Verify that the tubes are not crimped or pinched after the AQUIOS Sheath Solution cubitainer replacement. If necessary, readjust the tubing or containers to prevent tubing damage. If you see tubing damage, contact your Beckman Coulter Representative.
- 

## Replacing the AQUIOS Sodium Hypochlorite Solution Tube

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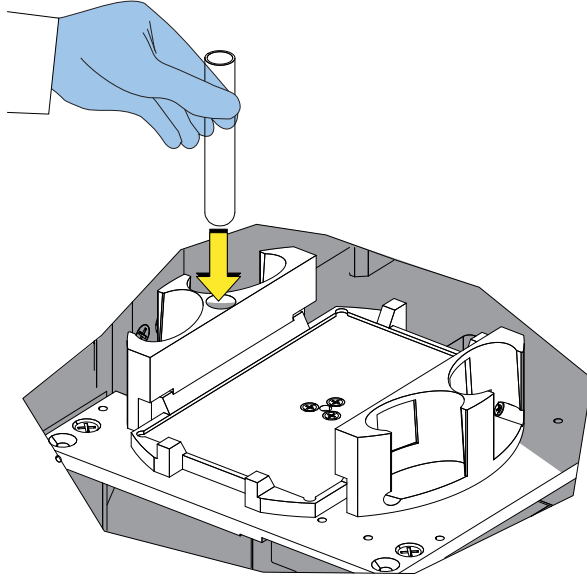
**NOTE** The AQUIOS Sodium Hypochlorite Solution is not a disinfectant. To disinfect the instrument, refer to [Cleaning the System](#) and [Cleaning Blood Spills](#).

- 
- 1** Dispense 2 mL of AQUIOS Sodium Hypochlorite Solution into the 12 x 75 mm tube.
- 
- 2** Open the reagent door by selecting  from the menu bar, then press the top middle part of the door in one single motion.

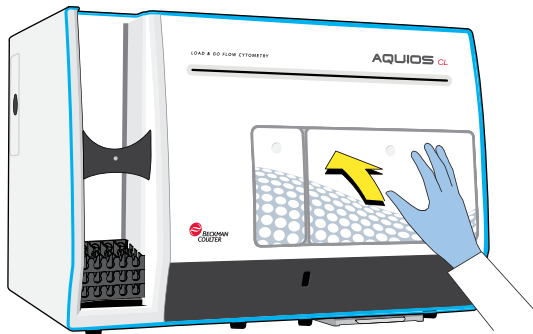


- 3 Place the 12 x 75 mm tube in the tube holder shown in [Figure 11.3](#).

**Figure 11.3** AQUIOS Sodium Hypochlorite Solution: Placement in Holder




- 4 Close the reagent door. The system scans the reagents and plate, then the Reagent Levels screen appears.



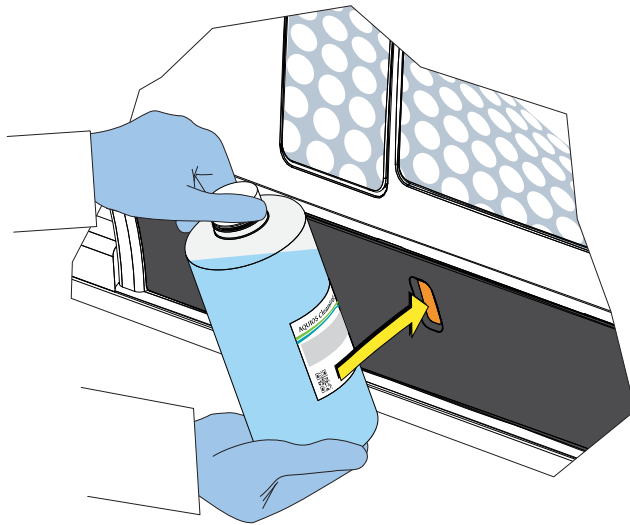
- 5 Close the Reagent Levels screen and the Main screen ([Figure A.1](#)) appears.

## Replacing the AQUIOS Cleaning Agent Bottle

---

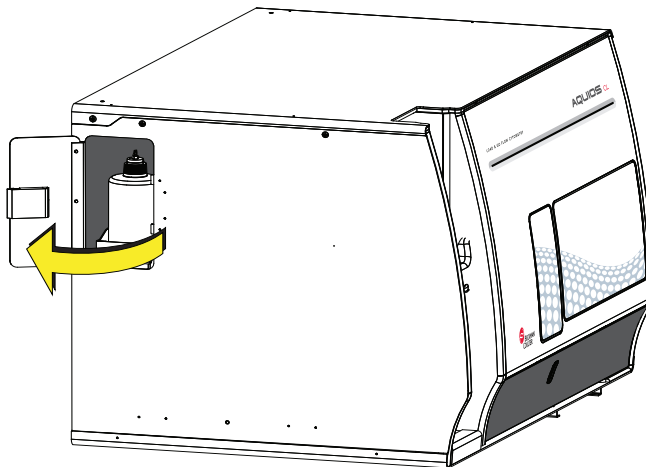
- 1 Select . The barcode reader next to the Single-tube Loader door activates.

- 2 Scan the barcode on the new AQUIOS Cleaning Agent bottle. The barcode reader beeps as the reagent is displayed on the barcode Reagent screen.



- 3 Select .

- 4 Open the cleaning reagent door on the Cytometer left-side cover.



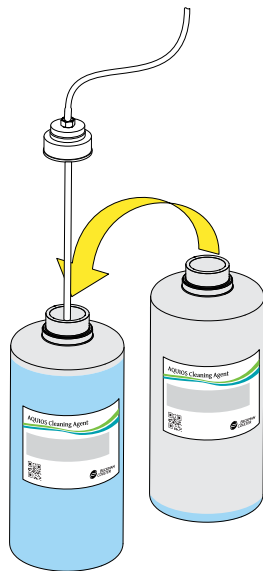
- 
- 5 Carefully and without forcing the tubing lines, unload the used container from the instrument and place it adjacent to the new container.

---

  - 6 Remove the cap and the foil seal on the spout of the new container.

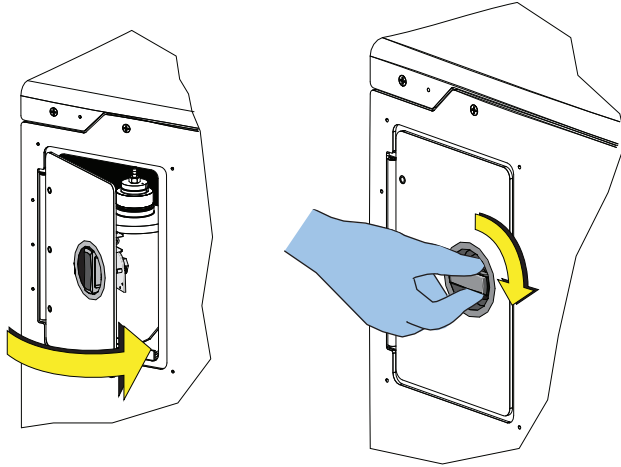
---


  - 7 Carefully transfer the tube assembly from the used container to the new container. Then tighten the cap without crimping or pinching any of the tubes.

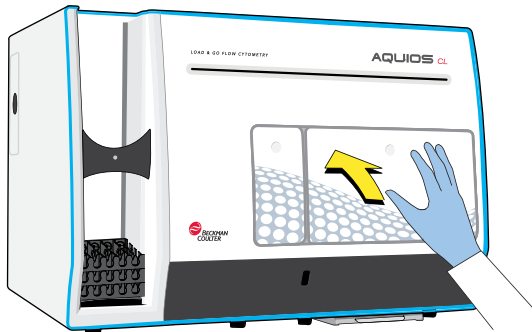


- 
- 8 Load the new container on the instrument.

- 
- 9** Close the cleaning agent door.



- 
- 10** Select  **Open Reagent Door** from the status bar to open and close the reagent door to allow the system to fully update with the new reagent levels.





## Replacing the Waste Container

---

** WARNING**

Risk of possible biohazardous contamination. Wear the appropriate protective attire and avoid contact with the waste container contents. Always dispose of waste in accordance to all applicable local regulations.

** WARNING**

Risk of biohazard spill, if the waste container is not changed when prompted by the software. To reduce workflow interruptions, it is recommended that you change the waste container every time you replace the AQUIOS Sheath Solution cubitainer.

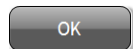
** WARNING**

Risk of biohazardous contamination if waste is replaced while the instrument is processing samples. Wait for the instrument computer to display a message instructing to change the waste.


** WARNING**

Risk of personal injury or contamination if you have skin contact with the waste container, its contents, and its associated tubing. The waste container and its associated tubing can contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the contents of the waste container in accordance with your local regulations and acceptable laboratory procedures.

- 1 When the message *Waste Warning! Please wait for loaded samples to finish!* appears, select



- 2 Allow all loaded samples to complete processing and do not load any new samples in the system. Wait for the next message *Waste Full! Please change the waste now!*

- 3 Open the reagent door by selecting  Open Reagent Door from the status bar to open and close the reagent door to allow the system to restart.



- 4 Select .


- 5 Unload the full waste container from the Supply Cart. Place the full and empty waste containers adjacent to each other.

- 6 Verify that both waste containers have biohazard labels.

 **WARNING**

**Risk of chemical injury from bleach. To avoid contact with the bleach, use barrier protection, including protective eyewear, gloves, and suitable laboratory attire. Refer to the Safety Data Sheet for details about chemical exposure before using the chemical.**

- 7 Add 1 L of household bleach to the empty 10 L waste container.
- 8 Remove the lid from the empty container, and save the lid to cap the used container.
- 9 Carefully transfer the tube assembly from the used waste container to the empty waste container. Then tighten the cap without crimping or pinching any of the tubes.
- 10 Put the cap on the full container.

- 
- 11** Lift the neck of the container while you tighten the cap of the used waste container before moving it anywhere.
- 
- 12** If replacing the AQUIOS Sheath Solution cubitainer and waste containers at the same time, proceed to [Replacing the AQUIOS Sheath Solution Cubitainer](#).
- 
- 13** Select  Open Reagent Door from the status bar to open and close the reagent door to restart the system (see [CHAPTER 1, Doors](#)), and the Reagent Levels screen appears.
- 
- 14** Close the Reagent Levels screen. The Main screen ([Figure A.1](#)) displays.
- NOTE** Verify that the tubing is not crimped or pinched after the waste container replacement. If necessary readjust the tubing or containers to prevent tubing damage. If you see tubing damage, please contact your Beckman Coulter Representative.
- 
- 15** Empty the used waste container according to your laboratory's procedures and local regulations. Save the empty container for future reuse.
-

## Replacing the Inline Waste Filter

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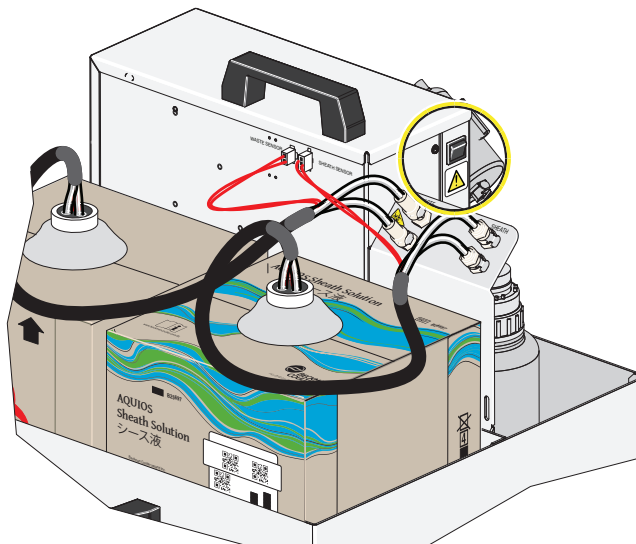
**WARNING**

Risk of possible biohazardous contamination. Wear the appropriate protective attire and avoid contact with the waste container contents. Always dispose of waste in accordance to all applicable local regulations.

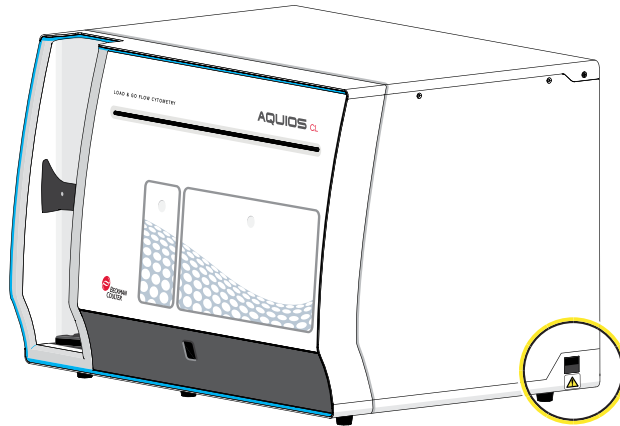
**WARNING**

Risk of personal injury or contamination if you have skin contact with the inline waste filter. The inline waste filter and its associated tubing can contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the contents of the waste container in accordance with your local regulations and acceptable laboratory procedures.

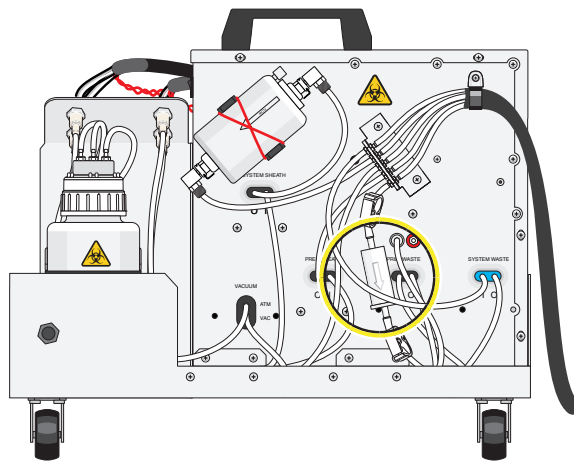
- 1 Turn off the power to the Supply Cart.



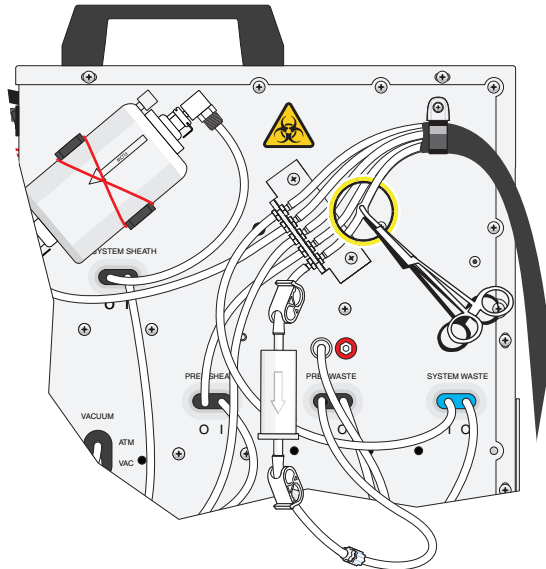
- 2 Turn off the Cytometer power.



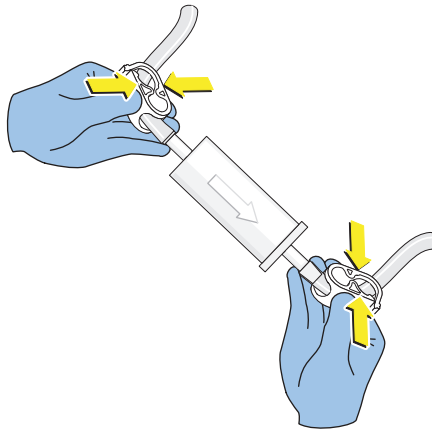
- 3 Locate the Inline Waste Filter.



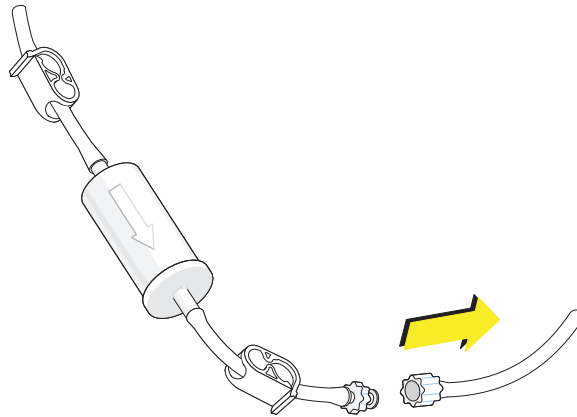
- 4** Using a hemostat, pinch waste line tubing.



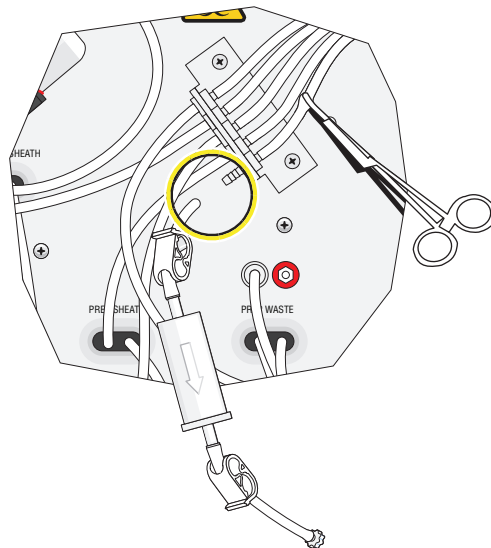
- 5** Close both clamps.



- 
- 6** Unscrew the bottom Luer fitting.



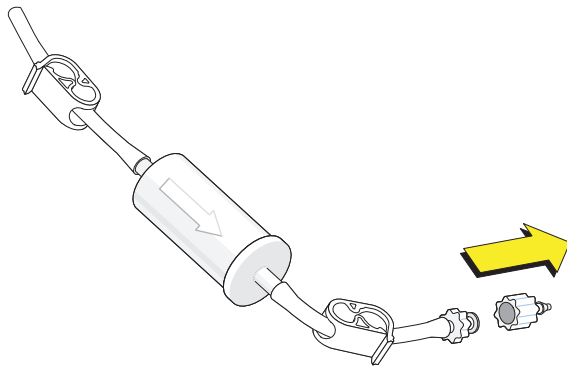
- 
- 7** Detach the silicon tubing from the barbed Quick Disconnect fitting.



- 
- 8** Dispose entire assembly in a sanctioned biological waste container and according to local regulations.

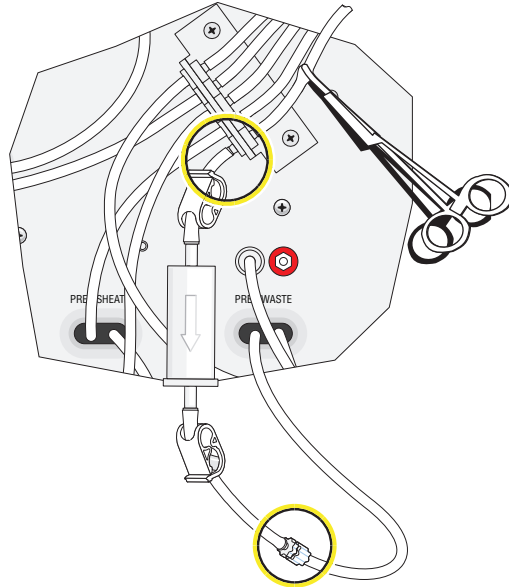


- 
- 9** Remove and discard part of the Luer fitting from the new assembly.

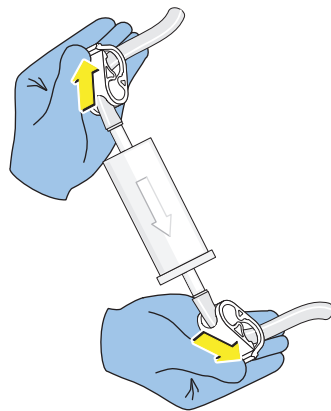




**10** Screw in the Luer fitting to the new assembly and attach to the barb Quick Disconnect fitting.

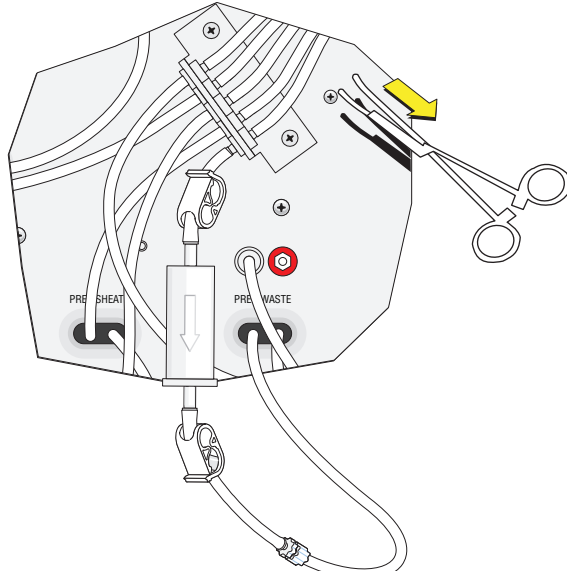


**11** Open both clamps.



---

**12** Remove hemostat.



---

**13** Run [Startup](#) in [CHAPTER 3, Daily Startup](#).

---

**14** Run [QC Samples](#) in [CHAPTER 11, Replacement Procedures](#).

---

## Main Screen

The Main screen (Figure A.1) displays all the basic processes necessary to operate the AQUIOS system. The instrument status bar and the Main screen buttons are permanently located and accessible from any other software window. For details, see Table A.1.

**Figure A.1** Main Screen



**Table A.1** Main Screen: Definitions


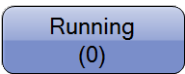
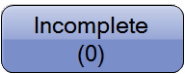


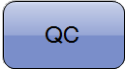
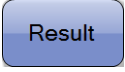


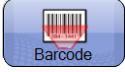
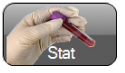
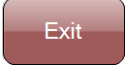













Item	Description
	Use to access the Request tab for the creation of test requests and to oversee the current number of pending test orders. The Request tab keeps track of pending test requests that are either received from the LIS or manually entered by the user.
	Use to access the running tab and to see the current number of requests that are presently processing on board. The running tab tracks samples that are being prepared, incubated, lysed, or analyzed by the system.
	Use to access the Incomplete Tab and to oversee the current number of requests that have encountered a processing problem. The Incomplete Tab displays samples in progress that have failed or have been interrupted while preparing, incubating, lysing, or analyzing a sample.
	Use to access the Review Tab and to oversee the samples pending for review. The Review Tab displays all the analyzed samples previously scheduled for review that you have not yet reviewed.

Table A.1 Main Screen: Definitions (Continued)

Item	Description
	Use to access the Main screen, as needed.
	Use to access the QC screen. The QC screen tracks the result of completed QC samples.
	Use to access the Result screen. The Result screen provides a search menu to navigate through the results database. Both reviewed and unreviewed results can be searched through this database.
	Use to access the Setup screen. The Setup screen can be used to set the system preferences such as: system setup, test settings, reagent info, LIS setup, archive setup, backup/restore, and user setup.
	Use to access the Maintenance screen. The Maintenance screen provides a log for tracking the routine maintenance performed by you and the system events, warnings, and error messages.
	Use to access the barcode reagent dialog window. This window allows you to scan the following AQUIOS reagents upon their first use: AQUIOS Cleaning Agent, AQUIOS Sheath Solution, and assay values on the package insert for the AQUIOS whole blood controls.
	Use to access the Single-tube Loader. Tubes loaded on the Single-tube Loader are given a higher priority than tubes loaded on the autoloader.
	Use to close the software.
 or 	Use to startup, reconnect, or shut down the instrument. This item displays the instrument status: connecting, startup percent to completion, shut down percent to completion.
	Use to access the LIS status dialog window. The LIS connectivity status is indicated by the color. If the LIS is connected the dot turns green. If the LIS is disconnected the dot turns red.
 or  or 	<p><b>WINDOWS 7 ONLY</b></p> <p>Use to open the RMS Setup screen.</p> <p><b>NOTE</b></p> <ul style="list-style-type: none"> <li>• Red indicates that there is an RMS connection problem or the instrument is not enrolled.</li> <li>• Green indicates that the RMS is functioning correctly.</li> <li>• Orange indicates that there are maintenance log messages that have not been transmitted to RMS.</li> </ul>

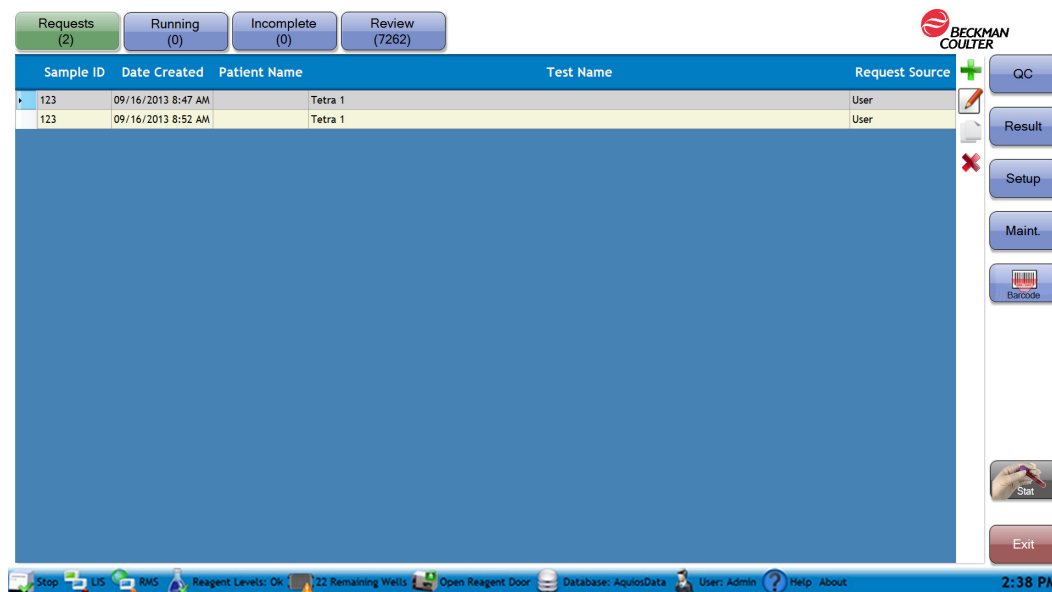
**Table A.1** Main Screen: Definitions (Continued)

Item	Description
 Reagent Levels:	Use to access the reagent levels dialog window. The displays shows the number of tests left based on the reagents and plate usage.
 48 Remaining Wells	The display shows the number of unused wells remaining on the onboard plate.
 Open Reagent Door	Communicates to the system that the user want to open the door. When this is selected and it safe to do so, the system prompts you to press the door in order to open it
 Database: NewDBW11	Shows the name of the database that is currently being used for test requests and results.
 User: Admin	Use as a link to user setup. The message area displays the name of the user currently operating the instrument according to the user name entered on the log in screen.
 Help	Use to direct the user to the location of the PDF of this Instructions for Use document.
 About	Use to obtain information about the system software and operating version.

## Request Screen

The Request screen (Figure A.2) tracks pending test requests that are either received from the LIS or manually entered by the operator. You can add new requests, copy an existing request, and edit or delete existing test requests.

**Figure A.2** Request Screen [Tetra Application]



**Request details list headings** — Use these headings to re-order the existing entries on the request detail list in ascending or descending order.

**Sample ID:** The identifier on the barcode for each specimen tube.

**Date created:** The date and time in which the request was generated.

**Patient name:** The blood donor name.

**Test name:** The type of test requested for the sample, for example, Tetra-Combo.

**Request Source:** The entity generating the test order, either LIS or User.

**Requests details list** — Use this list to track unprocessed requests and relevant information particular to the test orders.



— Use to access the create request dialog box and to enter a new test request for a patient or QC sample in advance. See [Add Test Request for a QC Sample](#) or [Add Test Request for a Patient Sample](#) in [APPENDIX A, Software Screens](#).



— Use to access the edit request dialog box in order to edit a selected existing entry of a patient or QC sample. The dialog box displays the information from the original entry with the capability of editing all fields.





— Use to create a duplicate of the selected test request.





— Use to remove a selected request from the request details list.

## Edit a Request




- 1 Select  as shown in [Figure A.2](#).
- 2 Select a request from the Request Details List.
- 3 Select . The Add Request Screen appears with the information available for that request. See [Add Test Request for a QC Sample](#) in [APPENDIX A, Software Screens](#).
- 4 Manually modify or enter additional information for the existing request.

**NOTE** Sample ID and Test are required fields for any type of request (patient or QC).

## Copy a Request

- 1 Select  as shown in [Figure A.2](#).
- 2 Select a request from the Request Details List.
- 3 Select .
- 4 The copied request will be displayed at the bottom of the list of requests.

## Delete a Request

- 1 Select  as shown in [Figure A.2](#).
- 2 Select a Request from the Request Details List.
- 3 Select . The dialog “Are you sure you want to delete these records?” appears.
- 4 Select .

## Running Screen

The Running screen tracks any samples currently processing on board. The sample workflow is displayed on the screen as the specimen progresses from one stage to the next from prepping to analysis.

The running sample stages are defined in your application specific AQUIOS System Guide. The running detail list can be organized in ascending or descending order by the following categories: sample ID, name, type, test name, run status, start date/time or details. You can interrupt the processing samples at any stage by cancelling the run.

Figure A.3 Running Screen: Populated (Example) [Tetra Application]

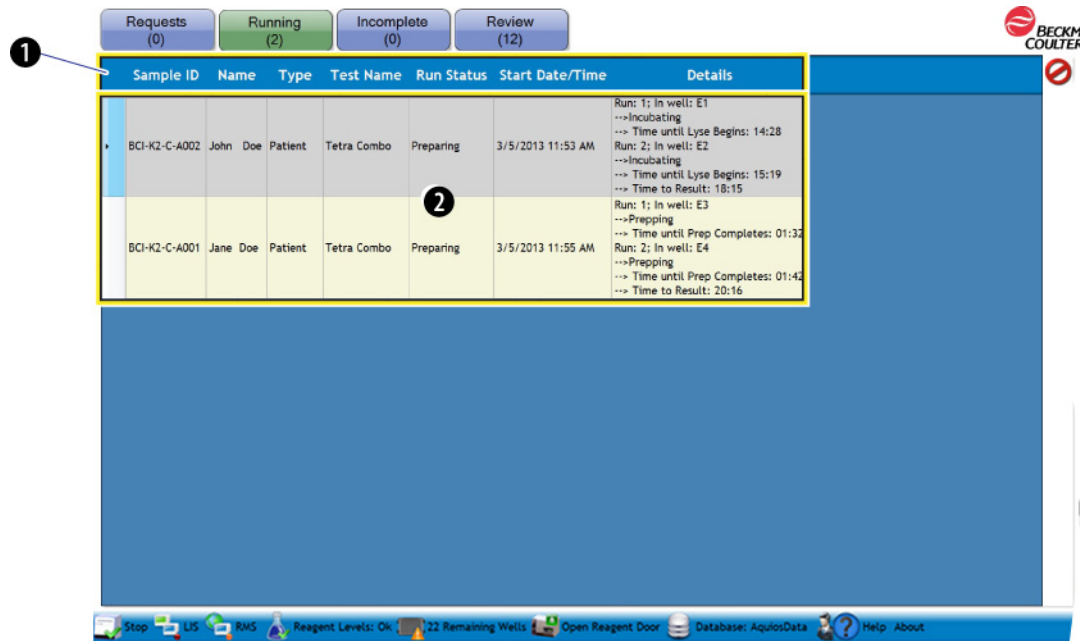



Table A.2 Running Screen: Defined

Item	Definition
1	<p><b>Running details list headings</b> - Use these headings to re-order the existing entries on the running detail list in ascending or descending order.</p> <ul style="list-style-type: none"> <li>• <b>Sample ID</b> - The identifier number on the barcode for each specimen tube.</li> <li>• <b>Name</b> - The blood donor name.</li> <li>• <b>Type</b> - The sample type, For example: whole blood.</li> <li>• <b>Test Name</b> - The type of test requested for the running sample.</li> <li>• <b>Run Status</b> - Stage of the sample, that is Running, Preparing.</li> <li>• <b>Start Date/Time</b> - Time in which the sample entered prepping.</li> <li>• <b>Details</b> - The stages of the sample in progress, that is prepping, incubating, lysing, analyzing; and its estimated time to completion.</li> </ul>
2	<p><b>Running details list</b> - Use this list to track relevant information of requests that are currently processing on board.</p>
3	<p> - Use to stop the selected request on the running details list.</p> <p><b>NOTE</b> The sample appears on the incomplete screen as a User Interruption.</p>

## Cancel a Running Request (User Interruption)


- 1 Select . Figure A.3 appears.



---

2 Select a running Request from the Running Details List.

---

3 Select . The dialog *Are you sure you want to cancel the selected run?* appears.

---

4 Select .

---

**NOTE** The canceled running Request will be listed on the Incomplete Screen as a User Interruption. The user can re-request the canceled Request from the Incomplete Screen. See [Re-request an Incomplete Sample Due to a User Interruption](#).

## Incomplete Screen

---

The Incomplete screen ([Figure A.4](#)) tracks samples that have encountered problems while processing on board. You can erase incomplete requests or rerequest incomplete test orders due to user interruptions or insufficient reagents. The incomplete details list can be organized by the following categories: cassette ID, location, sample ID, patient name, test name, date/time and reason. The samples can appear on the incomplete screen for the following reasons: user interruption, insufficient reagents, no barcode, or no request.



- **User interruption** - A sample was cancelled on the running screen. See [Cancel a Running Request \(User Interruption\)](#)
- **No barcode** - A tube with missing, misplaced, or damaged barcode was detected in a cassette. See [Table 9.5](#).
- **No request** - A barcoded tube with no request was detected in a cassette while the Default Test setting is OFF. See [Table 9.5](#).
- **Insufficient reagents** - A sample that was unable to run due to short supply of reagents. See [Table 9.2](#).
- **System Stopped** - The System was stopped as a result of an error. See [Table 9.2](#).
- **Duplicate Sample ID** - An LIS test request with a duplicate Sample ID (but different patient information) is received. See [Table 9.2](#).

**NOTE** In case of power failure, specimen tubes that were being processed may also appear on the Incomplete Screen.

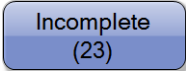
Figure A.4 Incomplete Screen




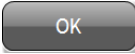
Table A.3 Incomplete Screen: Defined

Item	Definition
1	<p><b>Incomplete details list headings</b> - Use these headings to re-order the existing entries on the incomplete details list in ascending or descending order.</p> <ul style="list-style-type: none"> <li>• <b>Cassette ID</b> - For autoloader samples, this is the cassette number holding the bar-coded tube with an incomplete request</li> <li>• <b>Location</b> - For autoloader samples, this is the position of the bar-coded tube with the incomplete request within the cassette</li> <li>• <b>Sample ID</b> - The identifier number on the barcode for the specimen tube</li> <li>• <b>Patient Name</b> - The blood donor name</li> <li>• <b>Test name</b> - The type of assay requested for the incomplete sample</li> <li>• <b>Date/Time</b> - Date and time in which sample became incomplete</li> <li>• <b>Reason</b> - The cause of the incomplete request, that is no barcode, no request, user interruption or insufficient reagents</li> </ul>
2	<p><b>Incomplete details list</b> - Use this list to track relevant information of any request that has encountered a problem between prepping and analyzing.</p>
3	<p> - Use to make a new request out of the selected user interruption or insufficient reagents sample. Select this to submit the new test order to the Request screen.</p> <p><b>NOTE</b> Samples with no request or no barcode Insufficient Reagent or System Stopped cannot be rerequested.</p>
4	<p> - Use to delete a request under the incomplete details list.</p>

## Recover Specimen Tube with an Incomplete Request

- 1 Select  as shown in [Figure A.4](#).
- 2 Find the Incomplete Request of interest under the Incomplete Request Details List.

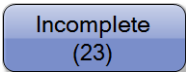
- 3 If the specimen tube was placed in the Single-tube Loader:

- a. At the Main Screen, select  to open the single-tube door. If the system is available, the message *Please press on the single tube door, and then wait for the system to release it* appears. Open the door by pressing the top-middle part of the door in one single, solid motion. If the system is busy, the message *The system is busy! Press on the single-tube door, and then wait for the system to release it* is displayed. Open the door by pressing the top-middle part of the door in one single, solid motion, when the system is no longer busy, the door automatically opens. If there is a tube in the Single-tube Loader, the message *Please remove any tubes from the Single-tube loader* is displayed. Remove the tube and select . The Sample Information screen is displayed. See [Figure 4.1](#).
- b. Close the Single-tube Loader door.

- 4 If the specimen tube was placed on the autoloader:

- a. Review the Cassette ID and Location headings. The Cassette ID is the number for the cassette containing the sample. The Location refers to the position of the specimen tube within the cassette. There are five possible cassette locations starting from left to right.
- b. Collect the cassette of interest from the processed cassette pile at the bottom part of the autoloader.
- c. Remove the specimen tube of interest from the cassette.

## Re-request an Incomplete Sample Due to a User Interruption

- 1 Select  as shown in [Figure A.4](#).
- 2 Recover the specimen tube. See [Recover Specimen Tube with an Incomplete Request](#).
- 3 Select the sample to rerequest from the Incomplete Details List.

---

4 Select .

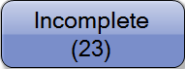
---

5 Load the specimen tube.

---

## Delete Incomplete Request


---

1 Select  as shown in [Figure A.4](#).

---

2 Select an incomplete Request from the Incomplete Details List.

---

3 Select . The message *Are you sure you want to delete the selected job* appears.

---

4 Select .

---

## Add Test Request for a QC Sample

A test request can be scheduled before the tubes are ready to be loaded into the system. Once the Sample ID is scanned, the request will appear on the Request Details List and it will remain there up to a maximum of 30 days, until the tubes are ready to be loaded on the Single-tube Loader or on the autoloader.

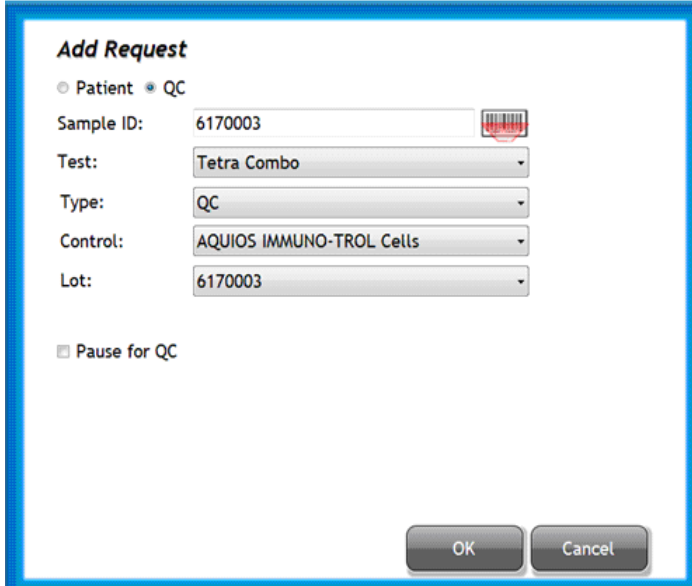
### CAUTION

**Risk of misleading results if the control package insert guidelines are not followed thoroughly. Before using the controls, read and follow the package insert directions; then confirm that the assay values for the specific control lot have been registered in the instrument.**

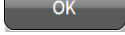
### Add Test Request for a QC Sample Screen

The Add Request Screen for a QC Sample is shown below. Coordinating descriptions are listed below in [Figure A.5](#).

**Figure A.5** Add Request for a QC Sample Screen [Tetra Application]



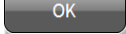
**Sample ID** — Use to automatically or manually enter the specimen ID on the barcode. Maximum of 50 characters. Minimum of 1 character since this is a required data field.

**NOTE** If no characters are entered in this field prior selecting , the message “You must have a valid Sample ID” appears.



— Use to activate the barcode reader for sample barcode scanning. The information scanned from the barcode is placed in the Sample ID field.

**Test** — Use drop-down menu to select the test to be requested for that specimen.

**NOTE** If no test is selected from the drop-down menu prior selecting , the message “You must select a Test” appears.

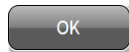
**Type** — Use to select a type of QC test from the drop-down.

**NOTE** QC is displayed by default.

**Control** — This field is automatically populated when the bar code is scanned.

**Lot** — This field is automatically populated when the bar code is scanned.

**Pause for QC** — Once QC samples have completed analysis, the autoloader remains paused if QC fails so that the problem can be corrected before running subsequent samples. If QC passes, the autoloader continues processing additional cassettes in the autoloader.



— Use to accept changes made on the dialog window.



— Use to reject changes and close the dialog window.

## Add Test Request for a Patient Sample

The test request can be scheduled before the tubes are ready to be loaded into the system; this allows for faster, more efficient operation of the AQUIOS System. Once the test request is created, the request will appear on the Request Details List and it will remain there up to a maximum of 30 days, until the tubes are ready to be loaded on the Single-tube Loader or on the autoloader.


### Add Test Request for a Patient Sample Screen

The Add Request Screen for a Patient Sample is shown below. Select the Patient radial to create the Patient test request. Coordinating descriptions are listed below [Figure A.6](#).

**Figure A.6** Add Request for a Patient Sample Screen

**Add Request**

Patient  QC

Sample ID:  

Test:

Specimen Type:  Collect Date:

Patient Name:

Patient ID:  Gov ID:

Status:

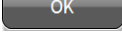
Location:

Gender:  Date of Birth:

Physician Name:

Physician Code:

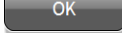
**Sample ID** — Use to automatically or manually enter the specimen number on the barcode. Maximum of 25 characters. Minimum of 1 character since this is a required data field.

**NOTE** If no characters are entered in this field prior selecting , the message *You must have a valid Sample ID* appears.



— use to activate the barcode reader for sample barcode scanning.

**Test** — Use drop-down menu to select the type of assay requested for that patient.

**NOTE** If no test is selected from the drop-down menu prior selecting , the message *You must select a Test* appears.

**Specimen Type** — Use to enter the type of sample to be run.

**Collection Date** — Use to enter the date in which the blood was drawn. A dialog window will activate when selecting the field for easy data entering. This is not a required data field.

**Patient Name** — Use to enter the first name, middle initial, and last name.

**Patient ID** — Use to enter an identifier number.

**Gov. ID** — Use to enter an additional ID or number.

**Status** — Use to enter information about the sample.

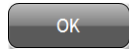
**Location** — Use to enter the blood collection location.

**Gender** — Use drop-down menu to select the sex.

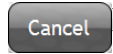
**Date of Birth** — Use to enter the date of birth. A dialog window will activate when selecting the field for easy data entering. This is not a required data field.

**Physician Name** — Use to enter the physician's first name, middle initial, and last name.

**Physician Code** — Use to enter the code for the physician.



— Use to accept changes made on the dialog window.



— Use to reject changes made on the dialog window.

**NOTE** When using the touch screen, a small keyboard icon will appear if alpha or numeric information needs to be entered. Touch the keyboard icon and a keyboard will appear on screen to enter demographics.



## Delivery Inspection

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The AQUIOS CL Flow Cytometer is tested before shipping. International symbols and special handling instructions are printed on the shipping cartons to inform the carrier of the precautions and care applicable to electronic instruments.



**Possible damage could occur if you uncrate, install, or setup system components prior to the arrival of your Beckman Coulter Representative. Keep system components in their original packaging until your Beckman Coulter Representative uncrates the components for installation and setup.**

When you receive your AQUIOS CL Flow Cytometer system components, carefully inspect all cartons. If you see signs of mishandling or damage, file a claim with the carrier immediately. If separately insured, file the claim with the insurance company.

## Special Requirements

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Before your Beckman Coulter Representative arrives to install the AQUIOS CL Flow Cytometer, you must determine where you want the system placed and the overall layout. Consider the factors described in the following paragraphs.

### Location

A bench or table, preferably with wheels, must be available for installation. Ideally, Uninterruptible Power Manager (UPM), the Cytometer and Workstation are placed on the bench or table with the Supply Cart positioned on the floor underneath the bench or table supporting the Cytometer and Workstation. Install the system in a location free of vibration. Ensure that the location chosen does not allow sunlight to shine into the cassette elevator area as direct sunlight in the elevator area could cause the system to recognize a cassette even if one is not loaded. Ensure that the instrument is not located under an air conditioning vent or in the path of a cool air flow which can decrease the operating temperature of the system.

Allow room to interconnect all system components. Also, arrange for

- Comfortable working height
- Space for ventilation
- Access for maintenance and service

Table B.1 contains specifications for determining the footprint for an AQUIOS CL Flow Cytometer and the necessary operating clearances.

**NOTE** If there is not enough space to set the Workstation next to the Cytometer, the Workstation may be placed on top of the Cytometer.

**Table B.1** Required Operating Clearances for Main Components

Specifications	Cytometer	Supply Cart	Workstation
<b>Height</b>	56 cm (22 in.)	41 cm (16 in.)	42 cm (16.6 in.)
Additional clearance above for servicing	30 cm (12 in.)	30 cm (12 in.)	30 cm (12 in.)
Total height needed	86 cm (34 in.)	71 cm (28 in.)	72 cm (28.6 in.)
<b>Width</b>	82 cm (32 in.)	53 cm (21 in.)	65 cm (25.7 in.)
Additional clearance on right for servicing	30 cm (12 in.)		
Additional clearance on left for servicing	30 cm (12 in.)		
Total width needed	142 cm (56 in.)	53 cm (21 in.)	65 cm (25.7 in.)
<b>Depth</b>	56 cm (22 in.)	46 cm (18 in.)	16 cm (6.4 in.)
Additional clearance behind instrument for sufficient cooling and room for servicing	30 cm (12 in.)	30 cm (12 in.)	30 cm (12 in.)
Total depth needed	86 cm (34 in.)	76 cm (30 in.)	46 cm (18.4 in.)

## Electrical Input



**System components must be installed in a position that provides adequate access to the power cord for disconnection in the event that an emergency power down is required. Possible equipment damage could occur if you use an extension cord or a power strip to connect the Cytometer or Supply Cart. Always plug the Cytometer and Supply Cart into the Uninterruptible Power Manager (UPM) provided with your system and then plug the Uninterruptible Power Manager (UPM) into a dedicated outlet with an isolated ground.**

The UPM provided with the instrument is used to power the Cytometer and the supply Cart.

- The primary power cord on the rear of the Cytometer must be plugged directly into a receptacle on the UPM provided with the system.
- The primary power cord on the rear of the Supply Cart must be plugged directly into a receptacle on the UPM provided with the system
- The UPM must be plugged directly into an independent and protected circuit. Do not use an extension cord.
  - Receptacle furnishing single-phase input power. For Countries that have 96-151 Vac service, use a minimum 10A outlet with a NEMA 5-15R connector. For Countries that have a 181-290 Vac service, use a minimum 5A outlet with an IEC 320/C14 connector.
  - A ground path cable capable of carrying the full current of the circuit (confirmed third-wire earth ground required).

The Workstation must be plugged directly into a receptacle on the UPM provided with the system.

Table B.2 shows the ac input specifications and voltage rating for the Cytometer, Supply Cart, and Workstation.

**Table B.2** Electrical Specifications

Input Specifications	Cytometer	Supply Cart	Workstation	UPM
Voltage Rating	100/115/230 Vac	100/115/230 Vac	100-240 Vac	96-151/181 - 290 Vac
Current Rating	3.0/3.0/2.0 A	1.5/1.5/1 A	1.5A	7.9/3.9 A
Frequency Rating	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz
Connection Type	IEC 320/C14	IEC 320/C14	IEC 320/C5	NEMA5-15R/IEC 320/C14

For Europe, a Continental Europe line cord that meets the following requirements is required:

- Cord: H05VV-F, 3 x 1.0 mm, Unshielded, CEE Color Cord, Temperature rating 60°C, Rating 250 V 10 A, Jacket color: black
- Plug: IEC 884/CEE7-VII
- Connector: IEC 60320 C13

## After the Installation Is Complete

Your AQUIOS CL Flow Cytometer must be installed by a Beckman Coulter Representative. Once the system is installed, verify that the computer's date and time are correct. If correct, install the printer and perform the printer diagnostics.

**NOTE** Use the US date format in the system computer. (Example: mm/dd/yyyy)

**NOTE** Once installation is complete, have your IT department install and validate your network connection.

## Lifting or Carrying System Components



**Risk of possible operator injury. A minimum of two people is necessary to lift or carry the Cytometer. The AQUIOS CL Cytometer weighs up to 59 kg (130 lbs).**

AQUIOS CL Flow Cytometer component weights are listed in Table B.3.

**Table B.3** AQUIOS CL Flow Cytometer Component Weights

Cytometer	59 kg (130 lbs)
Supply Cart	11 kg (25 lbs) (excluding reagents)
Workstation	12 kg (27 lbs)
Uninterruptible Power Manager (UPM) (North America)	8 kg(18 lbs)
Uninterruptible Power Manager (UPM) (International)	4 kg(9 lbs)

## System Connections

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### Power and Signal Cable Connections

 **WARNING**

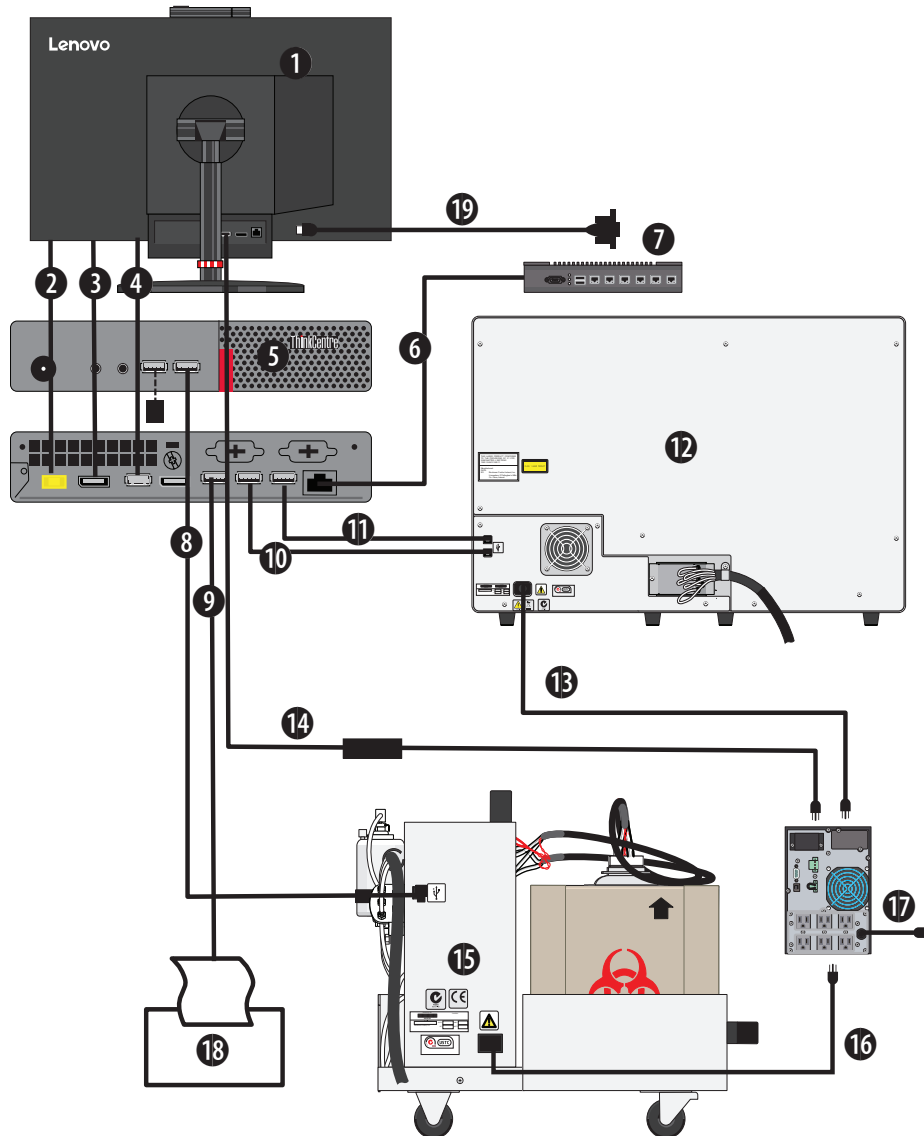
**Risk of personal injury if instrument cover is removed or a door is left open due to possible exposure to high voltages, laser radiation, and/or moving parts. Never operate the instrument without a cover or with a door opened.**

 **WARNING**

**Risk of personal injury. The laser beam can cause eye damage if viewed either directly or indirectly from reflective surfaces (such as a mirror or shiny metallic surfaces). To prevent eye damage, avoid direct exposure to the laser beam. Do not view it directly or with optical instruments.**

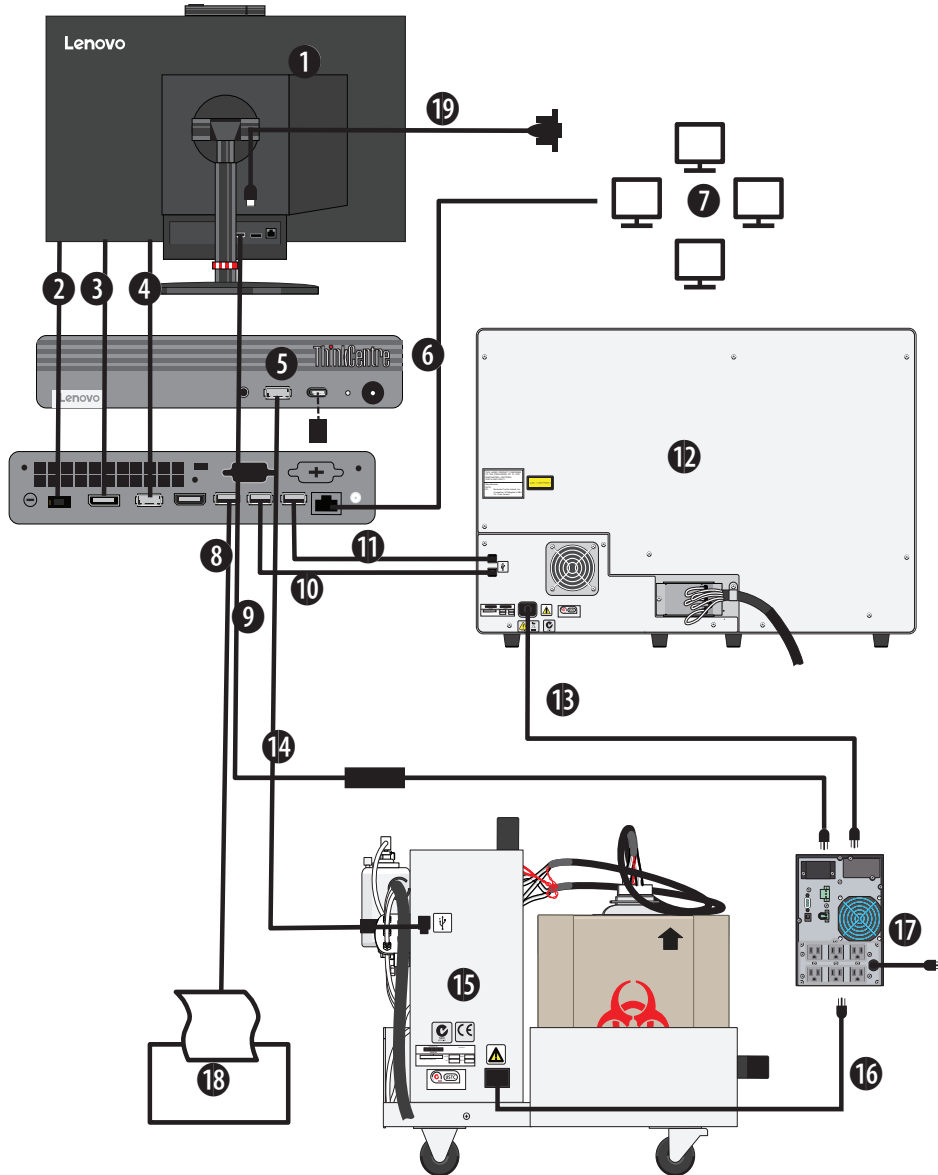
Figure B.1 shows the inter-unit connections of the power and signal cables.

**Figure B.1** Overview of Power and Signal Cables Connections (Windows 7 or 10)



- |   |  |
|---|--|
| <ol style="list-style-type: none"> <li>1. Tiny-In-One Monitor</li> <li>2. Power Connection - workstation to monitor when docked</li> <li>3. Video connection - workstation to monitor when docked</li> <li>4. USB - workstation to monitor when docked</li> <li>5. Tiny-In-One Workstation</li> <li>6. RJ45 Ethernet Cable to Rapbox (Windows 7) / RJ45 Ethernet Cable to Lab network (Windows 10)</li> <li>7. RAP Box for Windows 7 only. Laboratory network for Windows 10.</li> <li>8. USB A 2.0 Cable to Reagent/Pneumatic Cart</li> <li>9. USB A 2.0 Cable to printer</li> </ol> | <ol style="list-style-type: none"> <li>10. USB A 2.0 Cable to instrument</li> <li>11. USB A 2.0 Cable to instrument</li> <li>12. Cytometer</li> <li>13. Power Cable from instrument to UPS</li> <li>14. Power Adapter from Tiny-in-One monitor to UPS</li> <li>15. Instrument Reagent/Pneumatic Cart</li> <li>16. Power Cable from Reagent/Pneumatic Cart to UPS</li> <li>17. UPS</li> <li>18. Printer</li> <li>19. USB A for optional USB to Serial Adapter for LIS Connection</li> </ol> |
|---|--|

**Figure B.2** Overview of Power and Signal Cables Connections (Windows 10)

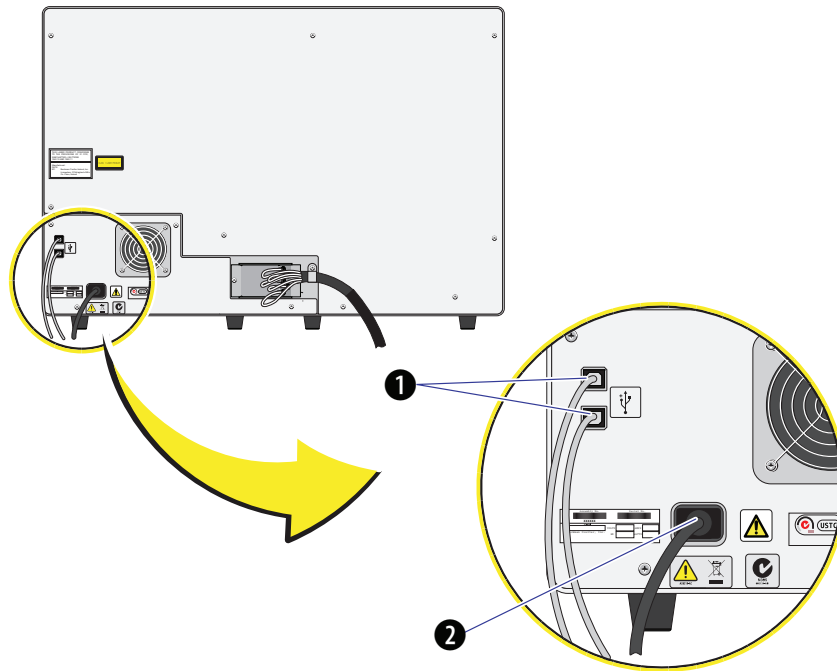


- |  |   |
|--|---|
| 1. Tiny-In-One Monitor                                   | 11. USB A 2.0 Cable to instrument                               |
| 2. Power Connection - workstation to monitor when docked | 12. Cytometer   |
| 3. Video connection - workstation to monitor when docked | 13. Power Cable from instrument to UPS                          |
| 4. USB - workstation to monitor when docked              | 14. Power Adapter from Tiny-in-One monitor to UPS               |
| 5. Tiny-In-One Workstation                               | 15. Instrument Reagent/Pneumatic Cart                           |
| 6. RJ45 Ethernet Cable to Lab network                    | 16. Power Cable from Reagent/Pneumatic Cart to UPS              |
| 7. Laboratory Network                                    | 17. UPS   |
| 8. USB A 2.0 Cable to Reagent/Pneumatic Cart             | 18. Printer   |
| 9. USB A 2.0 Cable to printer                            | 19. USB A for optional USB to Serial Adapter for LIS Connection |
| 10. USB A 2.0 Cable to instrument                        |   |

**NOTE** Computer configurations may vary.

## Cytometer

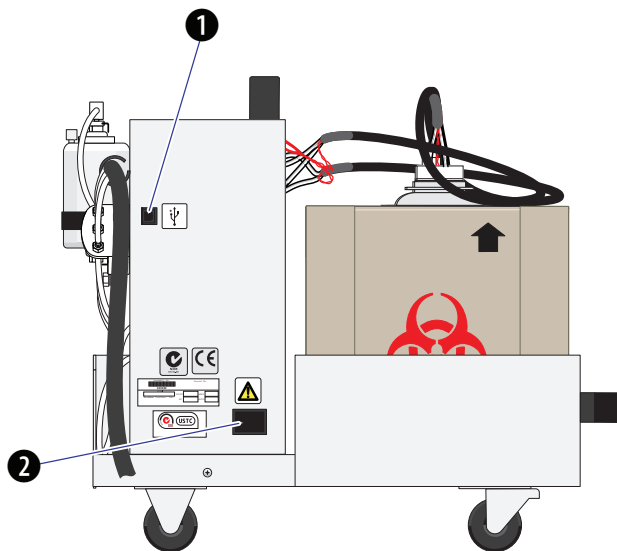
**Figure B.3** USB and Power Connections on the Rear of Cytometer



1. USB ports that connect to the Workstation
2. Power receptacle plugs into the UPM

## Supply Cart

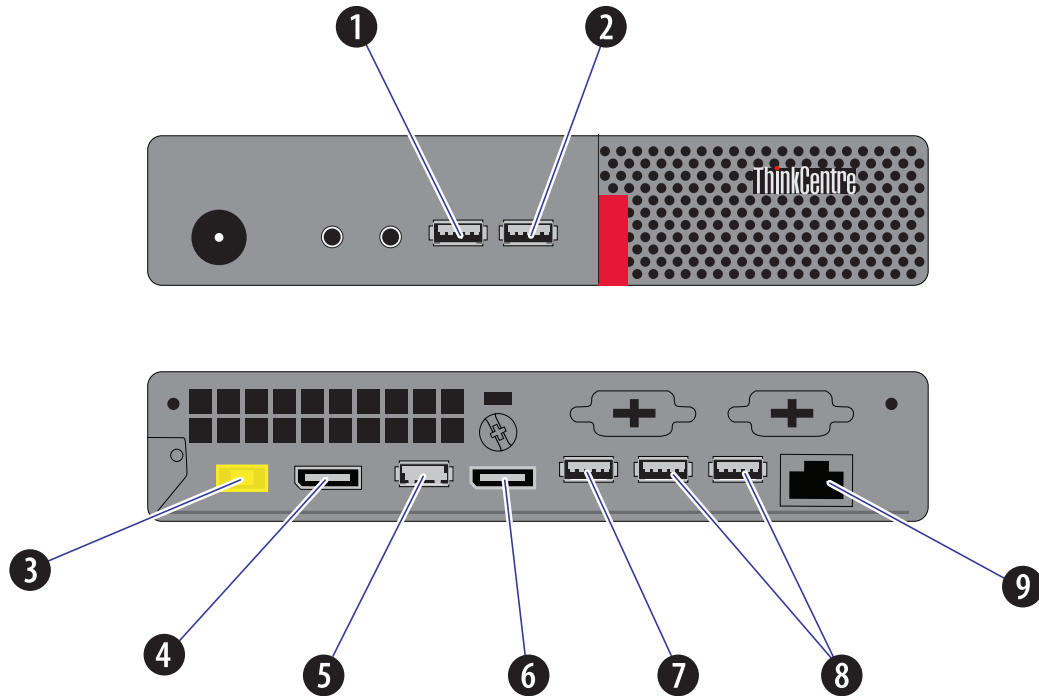
**Figure B.4** USB Connector and Power Receptacle Locations on the Supply Cart (Left View)



1. USB port connects to the Workstation
2. Power receptacle to be plugged into the UPM which is plugged into a dedicated at wall outlet with an isolated ground

## Workstation

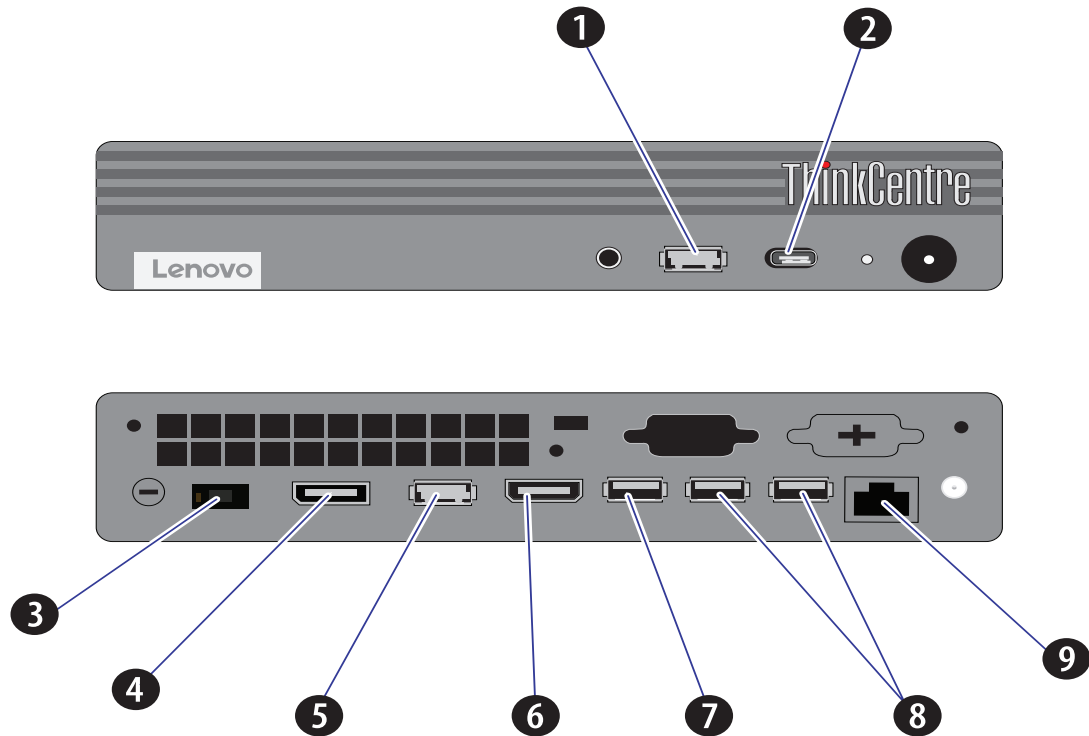
Figure B.5 LAN and USB Connections: Back of Workstation (Windows 7 or 10)



- |  |   |
|--|---|
| 1. USB, Wireless Keyboard/Mouse Receiver   | 6. Video (HDMI)   |
| 2. USB, Instrument Reagent/Pneumatic Cart  | 7. USB, Printer   |
| 3. Power, docks with monitor               | 8. USB, Instrument  |
| 4. Video (DisplayPort), docks with monitor | 9. RJ45, RAP Box (Windows 7) or Laboratory network (Windows 10) |
| 5. USB, docks with monitor                 |   |



**Figure B.6** LAN and USB Connections: Back of Workstation (Windows 10)



- |  |                             |
|--|-----------------------------|
| 1. USB, Instrument Reagent/Pneumatic Cart                            | 6. Video (HDMI)             |
| 2. USB, Wireless Keyboard/Mouse Receiver with USB A to USB C adapter | 7. USB, Printer             |
| 3. Power, docks with monitor   | 8. USB, Instrument          |
| 4. Video (DisplayPort), docks with monitor                           | 9. RJ45, Laboratory network |
| 5. USB, docks with monitor   |                             |

**NOTE** Computer configurations may vary.

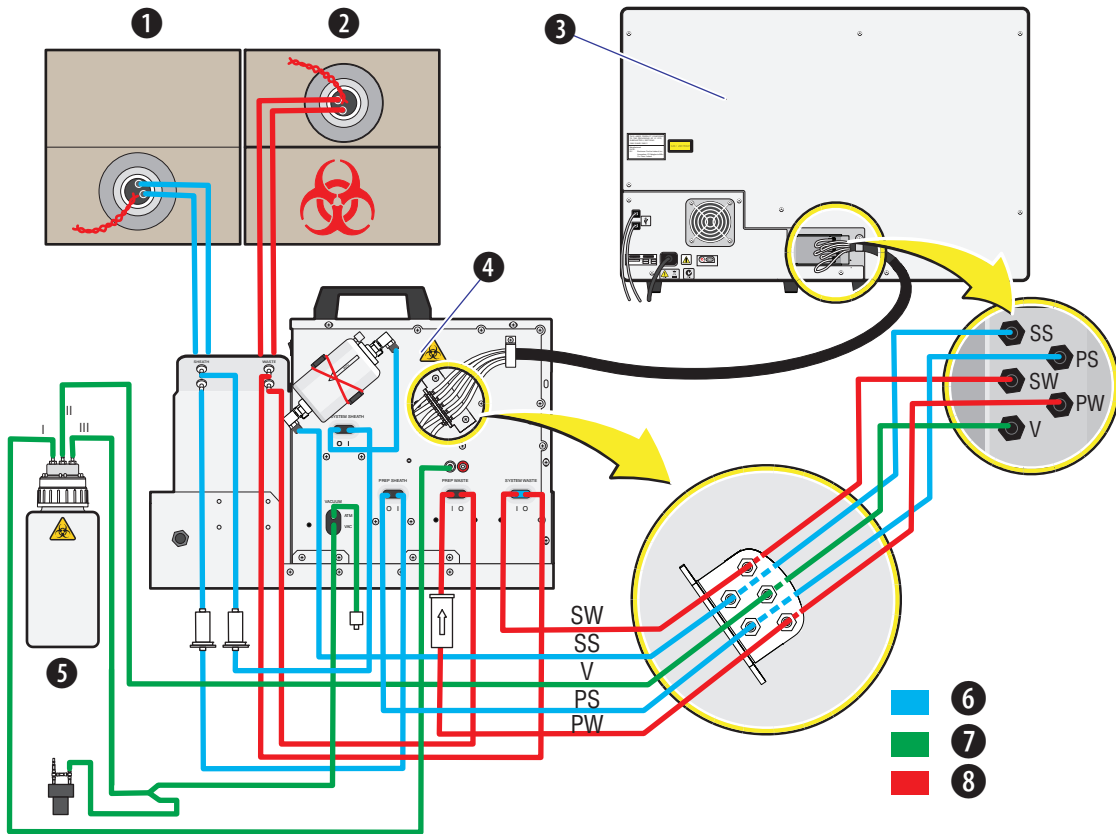
## Fluidic and Pneumatic Tubing

Figure B.7 shows the fluidic and pneumatic signal cables inter-unit connections.

**⚠ WARNING**

**Risk of biohazardous contamination. Do not disconnect the tubing from the back of the instrument or the supply cart. If you need to disconnect the tubing in order to move the instrument, contact your local Beckman Coulter representative.**

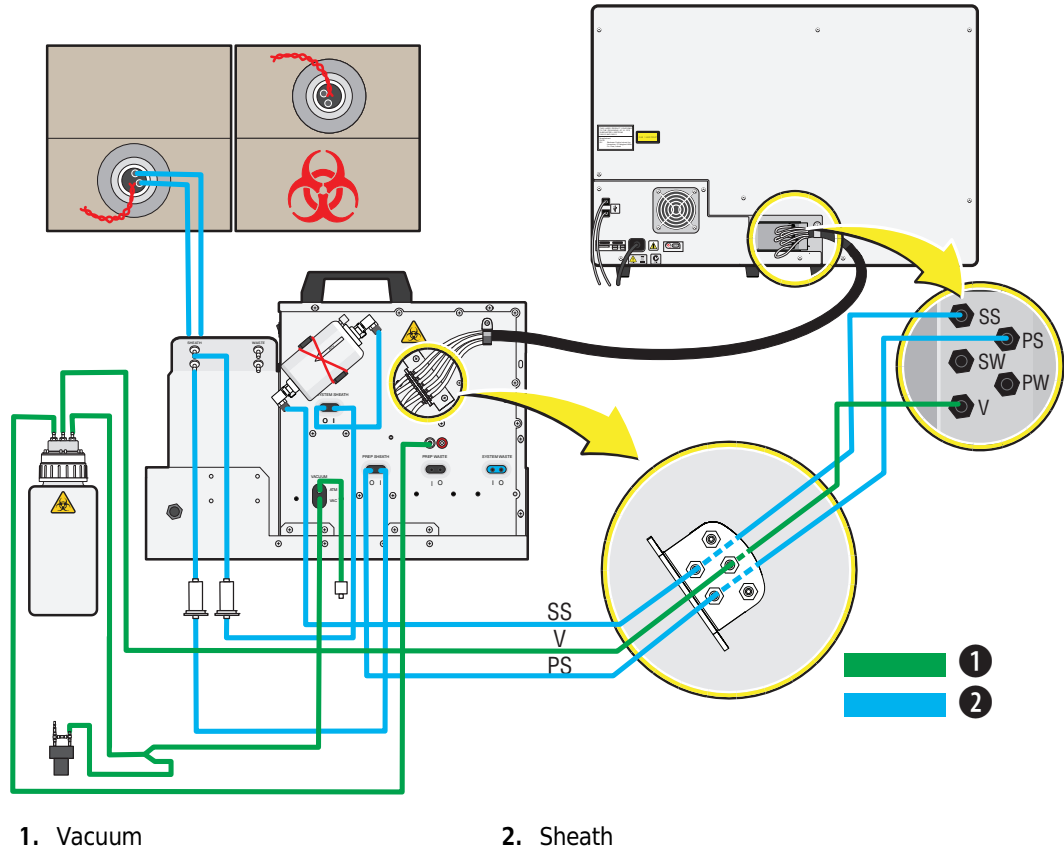
Figure B.7 Pneumatic, Reagent, and Waste Interconnectors



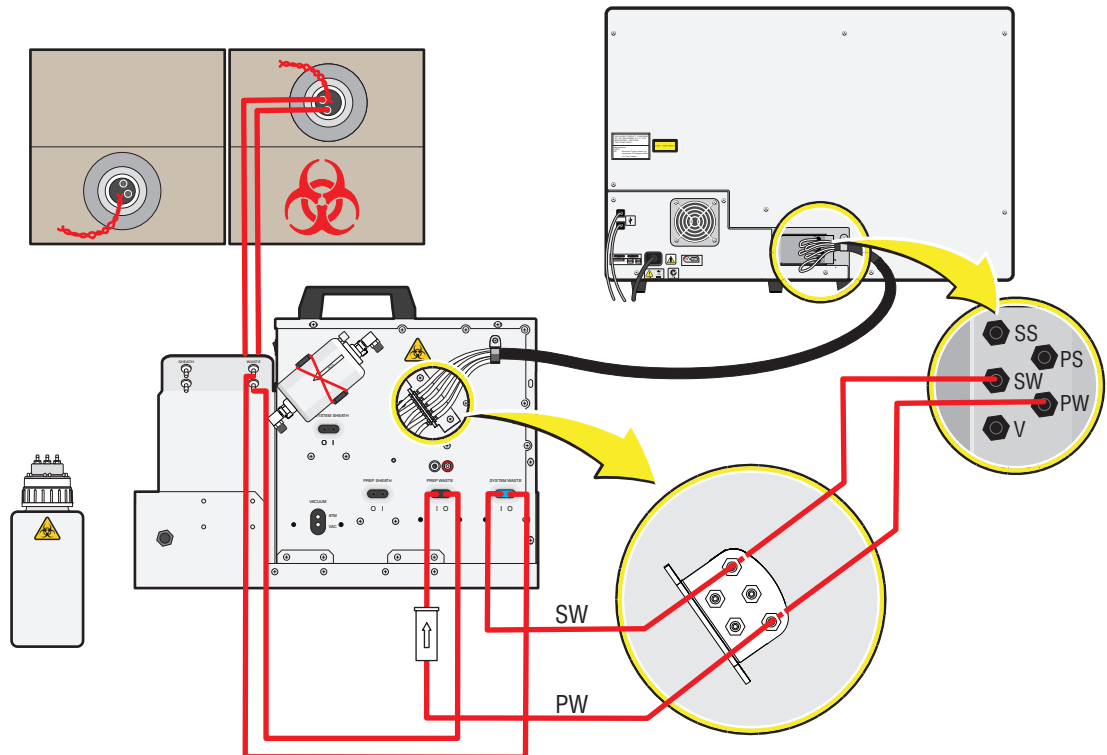
- 1. Sheath Solution Supply
- 2. Waste Container
- 3. Analyzer
- 4. Supply Cart

- 5. Vacuum reservoir
- 6. Sheath lines
- 7. Pneumatic lines
- 8. Waste lines

**Figure B.8** Vacuum and Sheath Fluid Connections

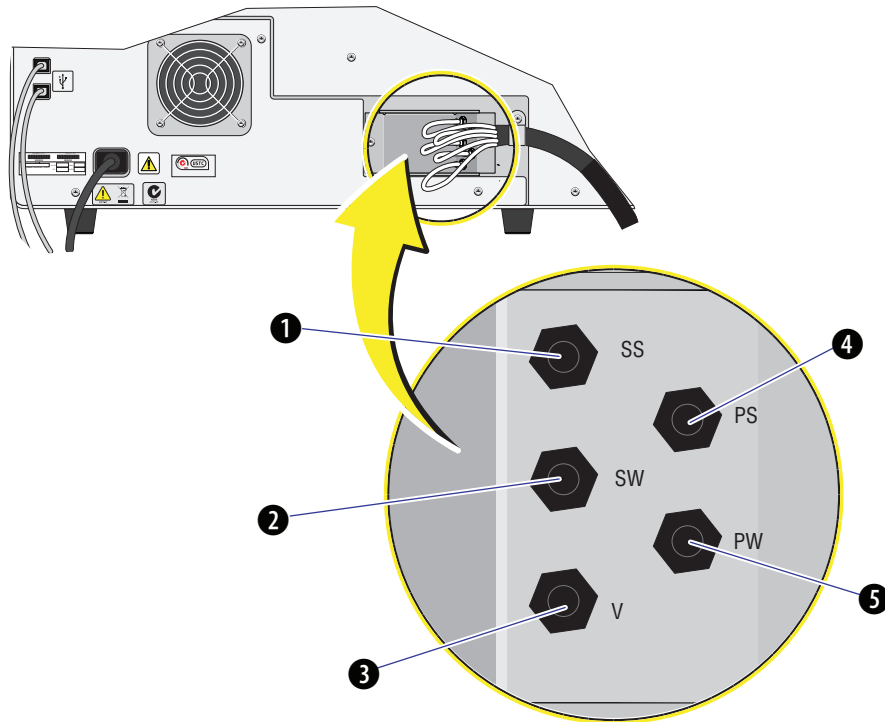


**Figure B.9** Waste Connections



## Cytometer

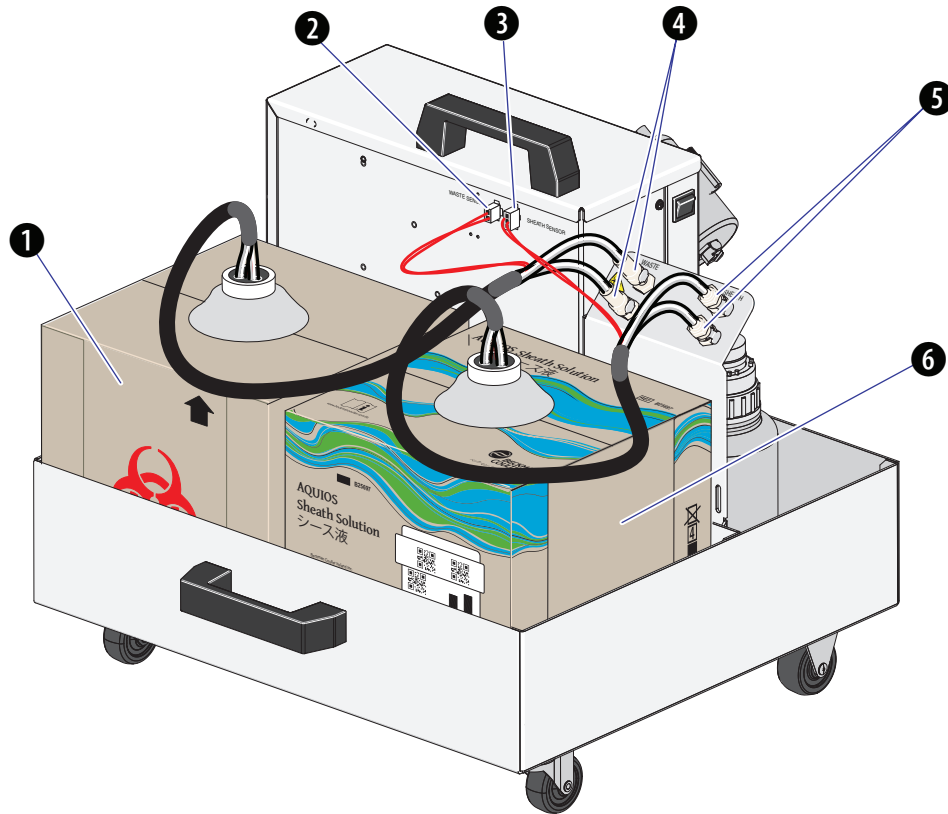
Figure B.10 Fluidics Connections (Five-Tubing Bundle) on the Rear of the Cytometer



1. Prep Wash Station in; connects to the supply cart.
2. Prep Wash Station out; connects to the supply cart.
3. Waste connection; connects to the supply cart.
4. Vacuum connection; connects to the supply cart.
5. Sheath connection; connects to the supply cart.

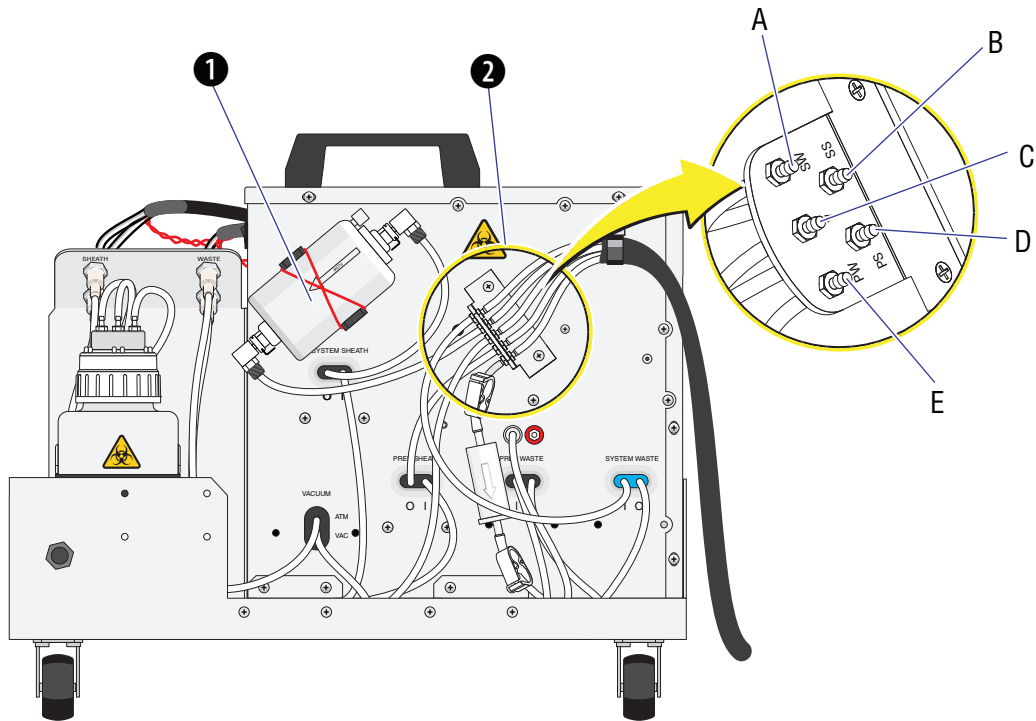
## Supply Cart

Figure B.11 Sheath and Waste Connections on the Supply Cart



- |  |   |
|--|---|
| 1. Waste container (10L), connects to the supply cart. | 5. Sheath connectors, connect to the Sheath container   |
| 2. Waste level sensor, connects to the supply cart.    | 6. Sheath container (10L), connects to the supply cart. |
| 3. Sheath Level Sensor, connects to the supply cart.   |   |
| 4. Waste connectors, connects to the waste container.  |   |

**Figure B.12** Fluidic Connections and Sheath Filter on the Supply Cart



1. Sheath filter (next to five-tubing bundle), connects to the supply cart with the bottom tubing and to the instrument with the top tubing.
2. Five-tubing bundle (right side near the bottom).
  - A. Prep Wash Station In connects to the instrument.
  - B. Prep Wash Station Out connects to the instrument.
  - C. Waste connection connects to the instrument.
  - D. Vacuum connection connects to the instrument.
  - E. Sheath connection connects to the instrument.







## Specimen Collection Tube Specifications

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Beckman Coulter does not recommend the use of one tube in preference to another nor guarantee the acceptability of the sample tube to produce quality results. If you need information on a tube not listed in [Table C.1](#), contact your Beckman Coulter Representative.

The AQUIOS CL features an autoloader capable of loading 40 samples at one time and is also equipped with a Single-tube Loader for one-at-a-time specimen sampling.

**Table C.1** Tube List for both the Autoloader and the Single-tube Loader

<b>Manufacturer</b>	<b>Part Number</b>	<b>Volume (mL)</b>	<b>Dimensions (mm)</b>	<b>AntiCoag</b>	<b>Min. Volume to Complete One Test On AQUIOS (µL)</b>
Becton Dickinson	367861	4	13x75	K <sub>2</sub> EDTA	750
Becton Dickinson	367856	3	13x75	K <sub>2</sub> EDTA	750
Becton Dickinson	367841	2	13x75	K <sub>2</sub> EDTA	750
Becton Dickinson	367842	2	13x75	K <sub>2</sub> EDTA	750
Becton Dickinson	367835	3	13x75	K <sub>2</sub> EDTA	750
Becton Dickinson	367844	4	13x75	K <sub>2</sub> EDTA	750
Covidien	8881311446	5	13x75	K <sub>3</sub> EDTA	750
Sarstedt	04.1917.100	2.7	13x75	K <sub>3</sub> EDTA	750
Sarstedt	04.1917	2.7	13x75	K <sub>3</sub> EDTA	750
Sarstedt	04.1931.001	4.9	13x90	K <sub>3</sub> EDTA	750
Sarstedt	04.1931.100	4.9	13x90	K <sub>3</sub> EDTA	750
Sarstedt	05.1167.001	2.7	11x66	K <sub>3</sub> EDTA	750
Sarstedt	05.1167.100	2.7	11x66	K <sub>3</sub> EDTA	750
Sarstedt	01.1605.001	7.5	15x92	K <sub>3</sub> EDTA	1500
Sarstedt	01.1605.100	7.5	15x92	K <sub>3</sub> EDTA	1500
Sarstedt	04.1901.001	2.6	13x65	K <sub>3</sub> EDTA	750
Sarstedt	04.1901.100	2.6	13x65	K <sub>3</sub> EDTA	750
Covidien	8881-311149	2	10.25x50	K <sub>3</sub> EDTA	650
Becton Dickinson	367863	6	13x100	K <sub>2</sub> EDTA	750
Becton Dickinson	366450	7	13x100	K <sub>3</sub> EDTA	750
Becton Dickinson	366643	10	16x100	K <sub>2</sub> EDTA	1000
Becton Dickinson	366457	10	16x100	K <sub>3</sub> EDTA	1000
Covidien	8881311743	10	16x100	K <sub>3</sub> EDTA	1000

**NOTE** Refer to the application specific System Guide for additional tubes.

## Autoloader

The autoloader can acquire a sample from a:

- Closed-vial (cap-pierce only) specimen tube (required)
- Specimen tube with a barcode label (required)
- Specimen tube using either K<sub>2</sub> and K<sub>3</sub> EDTA as an anticoagulant

- Specimen tube inserted into a compatible cassette type
  - Cassette Type 1 holds up to five specimen tubes with an outside diameter between 12 and 13 mm with a length of 75 mm.
  - Cassette Type 2 holds up to five specimen tubes with an outside diameter between 12 and 13 mm with a length of 100 mm.
  - Cassette Type 3 holds up to five specimen tubes with an outside diameter of 16 mm with a length of 100 mm.
  - Cassette Type 4 holds up to five specimen tubes with an outside diameter of 10.25 mm with a length of 50 mm.
  - Cassette Type 5 holds up to three AQUIOS IMMUNO-TROL or AQUIOS IMMUNO-TROL Low tubes.
  - Cassette Type 6 holds up to five Sarstedt tubes (tube must have an outside diameter of 13 mm with a length of 75 mm).
  - Cassette Type 7 holds up to five Sarstedt tubes (tube must have an outside diameter of 13 mm with a length of 90 mm).
  - Cassette Type 8 holds up to five Sarstedt tubes (tube must have an outside diameter of 11 mm with a length of 66 mm).
  - Cassette Type 9 holds up to five Sarstedt tubes (tube must have an outside diameter of 15 mm with a length of 92 mm).
  - Cassette Type 10 holds up to five Sarstedt tubes (tube must have an outside diameter of 13 mm with a length of 65 mm).

## Single-tube Loader



**Risk of biohazardous exposure if a Sarstedt brand tube or 10.25x50mm Covidien tube is run closed-vial in the Single-tube loader, only run Sarstedt tubes and 10.25x50mm Covidien tubes in open vial in the Single-tube loader.**

The Single-tube Loader can acquire samples from:

- Open-vial specimen tubes
- Closed-vial (cap-pierceable) specimen tubes
- Specimen tubes without a barcode
- Specimen tubes with a barcode
- Specimen tube using either K<sub>2</sub> and K<sub>3</sub> EDTA as an anticoagulant

**NOTE** For a list of tube part numbers compatible with the Single-tube Loader, see [Tube List for both the Autoloader and the Single-tube Loader](#).

**NOTE** Refer to the application specific System Guide for additional tubes.

**Tube List**

Specimen Collection Tube Specifications

# Barcode Specifications

## Barcode Labels

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Barcode symbols are a highly accurate and efficient procedure for identifying and processing laboratory samples. The Beckman Coulter AQUIOS instruments use four barcode symbologies (types) to identify specimens:

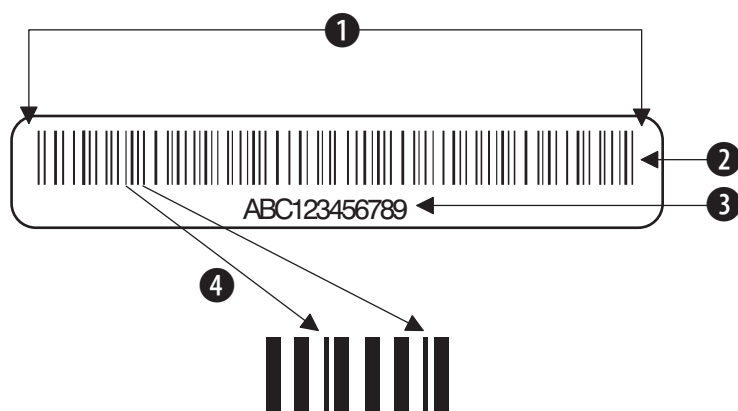
- Code 128
- Code 39®
- Interleaved 2-of-5
- Codabar

The barcode reader senses the difference between enabled barcode symbologies in a run.

A barcode consists of black lines (bars) and white lines (spaces), which are called elements. There are narrow elements (NE) and wide elements (WE). The barcode symbology determines their arrangement

**IMPORTANT** Sample misidentification can occur from the use of incorrect, poor quality, damaged, dirty or improperly placed barcode labels. Follow the specifications in this section to create your barcode labels to prevent incorrect sample identification.

**Figure D.1** Barcode Label



1. Quiet zone
2. Barcode symbol
3. Human readable format of the barcode symbol
4. Narrow Element (Bar)

## Barcode Symbolologies

Beckman Coulter AQUIOS instruments use three barcode symbolologies for specimen identification, see [Table D.1](#). Within the given specifications, the tube barcode reader automatically distinguish the following barcodes:

**Table D.1** Barcode Symbolologies

Barcode Type	Description
Code 128 (also known as USD-6)	<ul style="list-style-type: none"> <li>• Alphanumerics               <ul style="list-style-type: none"> <li>— Code 128A: ASCII characters 00 to 95 (0-9, A-Z), special characters</li> <li>— Code 128B: ASCII characters 32 to 127 (0-9, A-Z, a-z), special characters</li> <li>— Code 128C: 00-99, Requires an even number of digits to be encoded, a leading "0" must be added if the number count is odd.</li> </ul> </li> <li>• Self-checking</li> <li>• Continuous code; intercharacter space is part of code structure for higher density of code per square inch; compact barcode</li> <li>• Code 128 is recommended by the Clinical and Laboratory Standards Institute (CLSI) for its accuracy, compact form, and self-checking capabilities<sup>3</sup></li> </ul>
Code 39 (also known as 3-of-9 and USD-3)	<ul style="list-style-type: none"> <li>• Variable length</li> <li>• Includes 43 data characters; 26 letters (uppercase A-Z), 10 digits (0-9), six symbols (. / \$ + % -) and a space</li> <li>• Strong self-checking properties</li> <li>• Checksum on by default. Contact service to have the checksum for Code 39 disabled.</li> <li>• Discrete code; white spaces are not part of this code</li> </ul>
Interleaved 2-of-5 (also known as I2 of 5, USD-1, and USD-1.25)	<ul style="list-style-type: none"> <li>• Numerics only</li> <li>• Checksum on by default. Contact your local Beckman Coulter Representative to have the checksum for Interleaved 2-of-5 disabled.</li> <li>• Lower density of code per square inch; longer label</li> <li>• The length of the barcode must be 8, 10, 12, 14, or 16 characters.</li> </ul>
Codabar (also known as USD-4)	<ul style="list-style-type: none"> <li>• Variable length</li> <li>• Includes 16 data characters; 10 digits (0-9), and six symbols (. \$ / + : -)</li> <li>• Has specific start and stop characters which lead to improvement in readability</li> <li>• Checksum</li> <li>• Lower density of code per square inch; longer bar code</li> </ul>

For all symbolologies:

- 0.19mm (0.0075 in) minimum narrow bar width.
- 2.54 mm (0.10 in) minimum quiet zones.
- 5 to 25 characters
- Do not use the "\" character.

- Barcode symbol height 6.35mm (0.25 in.) minimum.

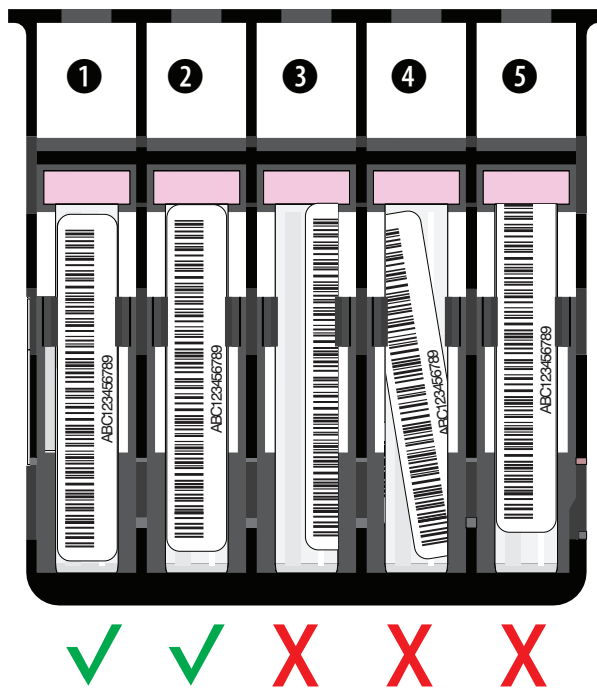
**IMPORTANT** If Code 39, Interleaved 2 of 5, or Codabar checksums are turned off by service, you should either:

- Turn off "Default Test" (when "Default Test" is turned off, the system will alert you if the scanned barcode does not match the Test Request), or
- Verify each barcode read.

## Correct Placement Of The Barcode Label

Put labels on the tubes so that the bars follow one another in a vertical sequence. Refer to [Figure D.2](#).

**Figure D.2** Bar-Code Label Placement



Put the tubes in the cassette so that the barcode symbols are visible through the front of the cassette. When viewed at eye level, the full symbol, including the quiet zones, must be visible.

## Barcode Label Specifications

**IMPORTANT** A misread label can cause one sample ID to be read as another sample ID. The laboratory's process for printing, placing, and meeting all barcode specifications is important to achieve highly accurate reading. Follow the bar-code label specifications to keep the rate of misread labels to a minimum.

The quality of the barcode symbol and the label is important for accurate reading. For high accuracy, use labels that meet all of the specifications.

Figure D.3 Barcode Label Specifications



1. Quiet zones 2.54 mm (0.10 in.) minimum
2. Barcode symbol height 6.35 mm (0.25 in.) minimum
3. Label length, refer to [Figure D.4](#).

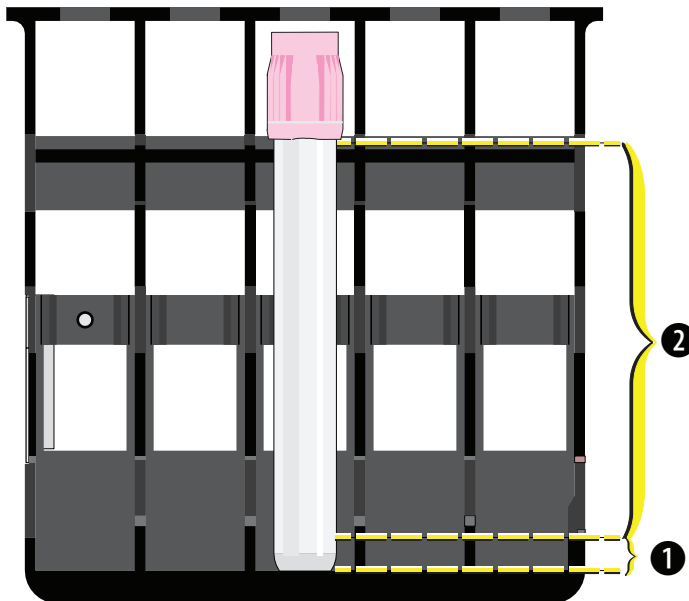
Label thickness, including adhesive, must be 0.14mm (0.0055 in.) maximum.

Two labels, in addition to the tube manufacturer's label, may be put onto the tubes prior to use.

The barcode label, when wrapped around the tube, must not overlap itself. If this occurs, then only one label, in addition to the manufacturer's label, may be placed on the tube.

Labels can contain from 5 to 25 characters. As printer tolerances differ from printer to printer, please check and ensure that the labels printed fit correctly on the specimen tubes.

Figure D.4 Barcode Label Length



1. Starting at 0.25 inches from the bottom lip of the cassette opening
2. Maximum length
  - 50mm or 75mm tube: Starting at 0.25 inches from the bottom lip of the cassette opening, the label can go up to, but not onto, the cap
  - 100mm tube: Starting at 0.25 inches from the bottom lip of the cassette opening, the label can go up to 3.25 inches



## Label and Print Quality

All barcode symbols must agree with the American Identification Manufacturer's (AIM) Uniform Symbology Specification.<sup>4</sup>

All barcode symbols must be printed at print quality class "B" or better as defined by the American National Standards Institute (ANSI).<sup>5</sup> Several factors affect print quality:

- Labels must be clean, not yellowed, and used before the expiration date.
- Print the barcode symbol on material that is non-reflective and has a matte finish. Use a background diffuse reflectance of 80% or more for maximum contrast.
- The labels must not have defects such as spots, lines, missing sections, cuts, folds, or density problems.
- The bars in the barcode symbol must be well-defined. Edges must be constant (not irregular), so the bars and spaces have the correct widths for the barcode symbology used.

## Barcode Error Rate

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**IMPORTANT** A misread label can cause one sample ID to be read as another sample ID. Whenever possible use a barcode symbology and configuration choices that provide the most accurate barcode reading.

The quality of the barcode symbol and the label is important for accurate reading. To get the highest possible accuracy only use labels that meet all the specifications described for labels and symbols. Deviations from these specifications make the barcode more difficult to read and allow for a possible increase in the error rate.

Certain features of the symbologies and the selections made by the laboratory have an important effect on the accuracy of the barcode reading system. In general:

- Code 128 and Code 39 are more accurate and have lower error rates than Interleaved 2-of-5.
- CLSI recommends Code 128 because of its accuracy, compact form, and self-checking capabilities.<sup>6</sup>
- To keep label and printing flaws to a minimum, use a narrow element of more than 0.19 mm (0.0075 in.).

**Beckman Coulter recommends the use of:**

- Code 128
- Checksum for all other symbologies
- Narrow bar sizes of 0.19 mm (0.0075 in.) minimum.
- Minimum Quiet Zones of 2.54 mm (0.10 inch).

## Barcode Label Optical Characteristics at 625 nm $\pm$ 10%

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- Print Contrast Signal (PCS): 80% minimum.
- Reflectivity of Media (RW): 80% minimum.

- Reflectivity of Ink (RB): 16% maximum.
- No spots or voids; no ink smearing.
- Edge roughness is included in the bar and space tolerances.

$$PCS = \frac{RW + RB}{RW} \times 100\%$$

**IMPORTANT** To prevent incorrect identification of sample tubes, do not use FNC1, FNC4, and FS (hexadecimal 1C) characters in your barcode information.

**Table D.2** Code-Related Specifications

Code	Interleaved 2-of-5*	Code 39*	Code 128*
Narrow element (NE) width	0.0075 in. ±0.001	0.0075 in. ±0.001	0.0075 in. ±0.001
Wide element/narrow element ratio (WE/NE)	3:1	3:1	N/A
Intercharacter gap	No	_NE	No

\* See AIM Uniform Symbology Specification, Rev. 1995 for detailed specification.

## Checksum Algorithm

Beckman Coulter strongly recommends the use of barcode checksums to provide automatic checks for read accuracy.

**IMPORTANT** Use of barcodes is an extremely accurate and effective method of positive patient identification. Certain features, such as checksum digits, maximize accuracy in reading Code 39, Interleaved 2-of-5, and Codabar labels. In one study, the use of checksum digits detected 97% of misread errors.

Use checksums to provide protection against occasional misread errors caused by problems such as damaged or misapplied labels. If you must use barcodes without checksums, Beckman Coulter recommends that you verify each barcode reading to assure correct patient identification.

# Customer Replaceable Parts

## Ordering Consumables and Accessories

To order reagents and accessories, please contact your Beckman Coulter Representative.

### Orderable Consumables



**Risk of erroneous results. Use only reagents and deep well plates provided by Beckman Coulter for use with the AQUIOS CL Flow Cytometer.**

Orderable consumables and accessories are shown in [Table E.1](#).

**Table E.1** Orderable Consumables and Accessories

Reagents	Volume
AQUIOS Sheath Solution, IVD	10 L cubitainer
AQUIOS Cleaning Agent, IVD	500 mL bottle
AQUIOS Sodium Hypochlorite Solution, IVD	4x50 mL bottle
AQUIOS Deep Well Plate, IVD <sup>a</sup>	carton of 50 - (96 well plate)
Type 1 cassette	For standard tube, 13x75 mm
Type 2 cassette	For standard tube, 13x100 mm
Type 3 cassette	For standard tube, 16x100 mm
Type 4 cassette	For standard tube, 10.25x50 mm
Type 5 cassette	For control tube
Type 6 cassette	For Sarstedt tube, 13x75 mm
Type 7 cassette	For Sarstedt tube, 90x13 mm
Type 8 cassette	For Sarstedt tube, 66x11 mm
Type 9 cassette	For Sarstedt tube, 92x15 mm
Type 10 cassette	For Sarstedt tube, 65x13 mm

a. A small quantity of plates is supplied with each new AQUIOS CL Flow Cytometer.

## Accessories

The accessories listed below are shipped with the AQUIOS CL. There may be additional application specific accessories, please refer to the application specific System Guide.

**Table E.2** AQUIOS CL Accessories

Item	Description	Quantity
Waste tubing	Deposits the waste from the instrument into the waste container.	1
Sheath pickup tube	For Sheath Solution	1
12x55 mm tubes <sup>a</sup>	12x55mm tubes used in Gravimetrics procedure	25
Waste container	10L empty container	1
Gravimetrics Bottle	Empty bottle used in Gravimetrics procedure	2
40-tube Specimen Rack	40-tube rack used in Gravimetrics procedure	1
Type 1 cassette	For standard tube, 13x75 mm	2
Type 2 cassette	For standard tube, 13x100 mm	1
Type 3 cassette	For standard tube, 16x100 mm	1
Type 4 cassette	For standard tube, 10.25x50 mm	2
Type 5 cassette	For control tube	2
Type 6 cassette	For Sarstedt tube, 13x75 mm	2

- a. 12X55 mm tubes are needed to perform syringe gravimetrics. A small initial quantity of tubes is supplied with the AQUIOS CL Flow Cytometer. When needed, additional tubes should be procured from commercial lab-ware distributors.

# Security Features



## Good Practices for Cyber Security

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The following procedures are the only validated and approved recommendations for cyber privacy and security. Contact your IT professional for assistance.

### CAUTION

System integrity could be compromised and operational failures could occur if:

- You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.
- You apply domain policies which alter the default configuration.
- You alter the system in a manner other than the approved changes outlined below.

### CAUTION

Risk of software failure. To avoid software failure, only install operating system updates approved by Beckman Coulter.

### CAUTION

Risk of unauthorized access and modification. To avoid unauthorized access and modification, enable all product security features and install all approved operating system patches.

### CAUTION

Risk of AQUIOS workstation transmits unencrypted data to the LIS, LIS Middleware and any network printer. Ensure adequate network protection mechanism are in place to avoid unauthorized access to transmitted data.

**IMPORTANT** BitLocker is the only approved encryption method.

- Your Windows 10 system is equipped with BitLocker. Use BitLocker disk encryption software to prevent unauthorized access to your hard drive, refer to [BitLocker Keys](#). For instructions on BitLocker Encryption or BitLocker Decryption, see [BitLocker Encryption](#) or [BitLocker Decryption](#).

- Direct TCP/IP LIS network connections with the workstation are only supported on systems with all security features available and active.
- Before connecting to an external device such as a hard drive, USB, or DVD/CD, verify that it does not have a virus or malware.
- Auto-run is disabled on your system to prevent the automatic launching of an application on external media. Leave auto-run disabled on the system.
- Close all unnecessary applications while operating the AQUIOS software.
- Ensure all Beckman Coulter approved operating system security patches are installed once validated and approved.
- Beckman Coulter supports continuous network connectivity on Windows 10 systems.
- Changes below require Administrator Level Windows access.
- BitLocker is not supported on Windows 7 Operating System.

## Drive Encryption

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The BitLocker drive encryption is XTS-AES 256-bit.

### BitLocker Keys

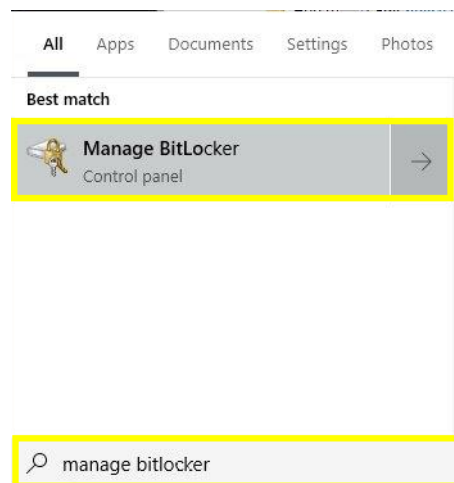


**Risk of data loss. Store your BitLocker key in a safe place. For instructions on saving your BitLocker key, refer to the [Backing Up Your Recovery Key](#) section. If you lose your BitLocker Key, you will lose access to your entire hard drive including all of your data. Beckman Coulter is not responsible for security keys and will not be able to recover your data off of your hard drive. Work with your IT department in creating and storing the keys in a safe place.**

## BitLocker Encryption

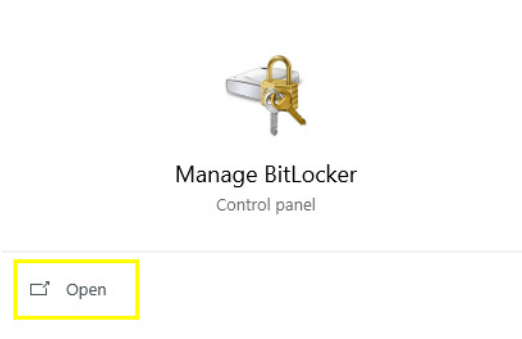
### Enabling BitLocker

- 1 Type **Manage BitLocker** from the Windows search bar to locate the **Manage BitLocker Control Panel**.



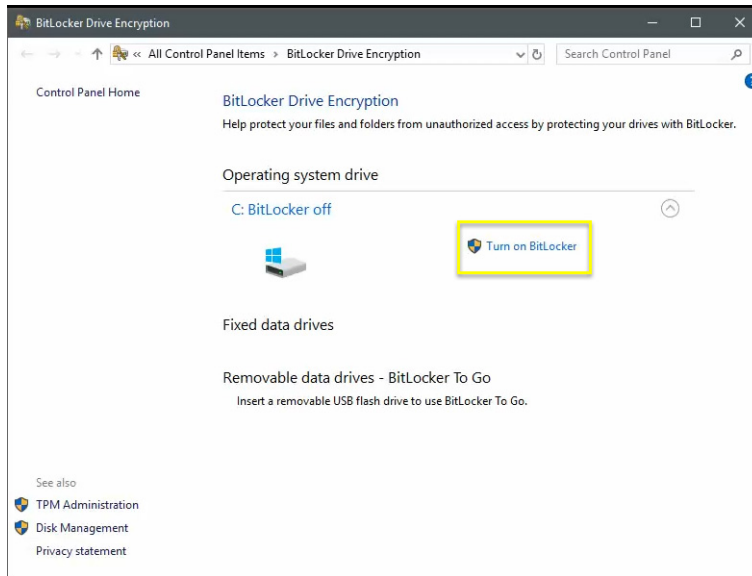
- 2 Select **Open** on the **Manage BitLocker Control Panel**. See [Figure F.1](#).

**Figure F.1** Manage BitLocker Control Panel



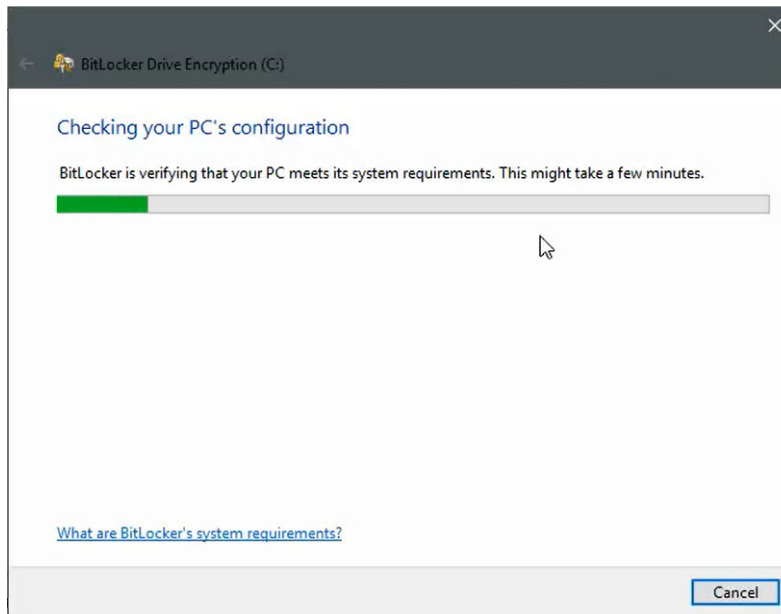
- 3 Select **Turn on BitLocker** from the Control Panel screen, see [Figure F.2](#).

**Figure F.2** Turning on BitLocker



- 4 BitLocker will verify your PC meets the requirements, see [Figure F.3](#).

**Figure F.3** Checking PC Configurations

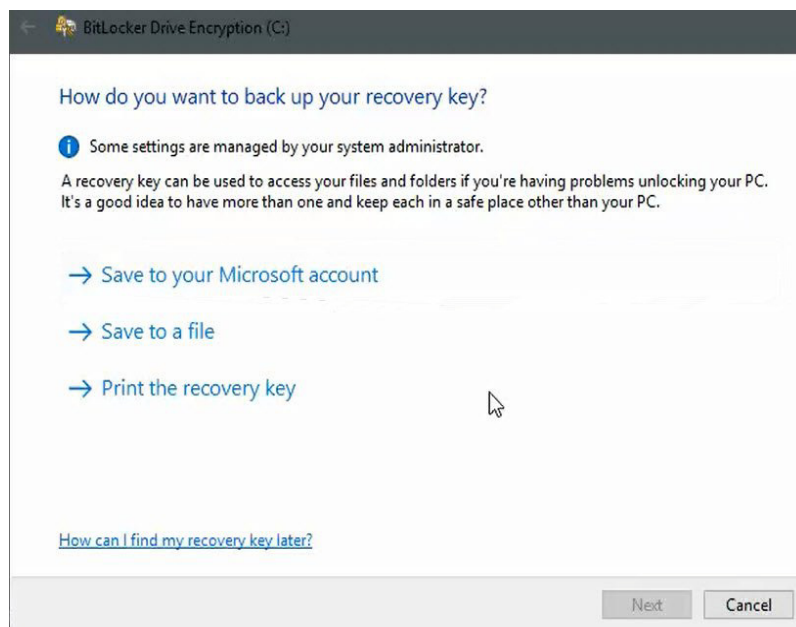




**IMPORTANT** The Back Up Your Recovery Key to your Microsoft Account is not supported at this time.

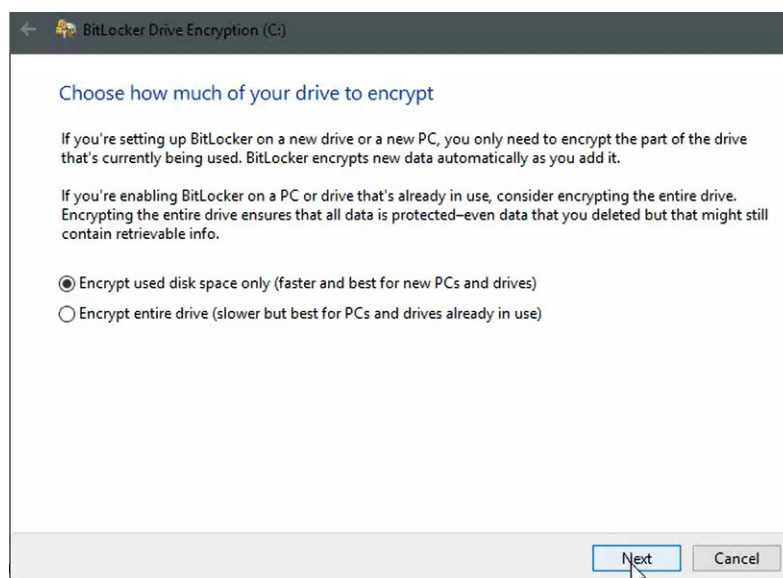
- 5 Select either **Save to a File**, or **Print the Recovery Key** to back up your recovery key then select **Next**. See [Figure F.4](#). For instructions on backing up your recovery key, refer to [Backing Up Your Recovery Key](#).

**Figure F.4** Backing Up Your Recovery Key



- 6 Select "Encrypt used disk space only (faster and best for new PCs and drives)", then select **Next**. See [Figure F.5](#).

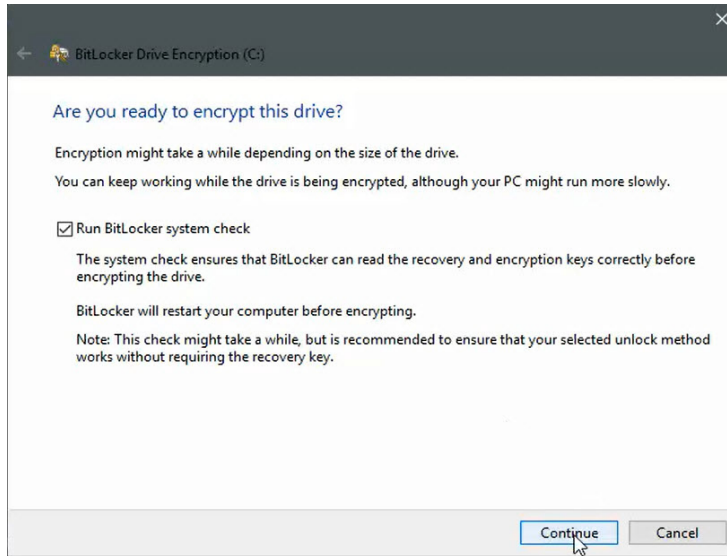
**Figure F.5** Choosing How Much of Your Drive to Encrypt



**IMPORTANT** The system check will ensure that BitLocker can read the recovery and encryption keys correctly before encrypting the drive. This check may take some time, but it is recommended to ensure that your selected unlock method works without requiring the recovery key.

7 Select “Run BitLocker system check” checkbox, then select **Continue**. See [Figure F.6](#).

**Figure F.6** Encrypting the Drive



**NOTE** BitLocker will restart your computer before encrypting.

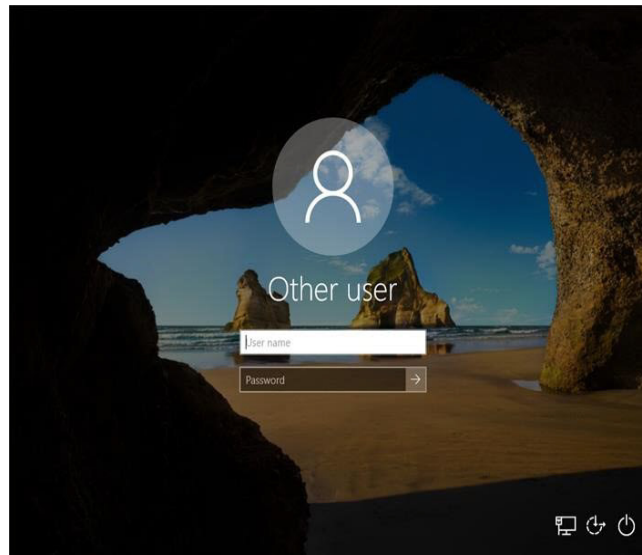
8 Select **Restart now** to begin the BitLocker System Check. See [Figure F.7](#).

**Figure F.7** Restarting Your Computer



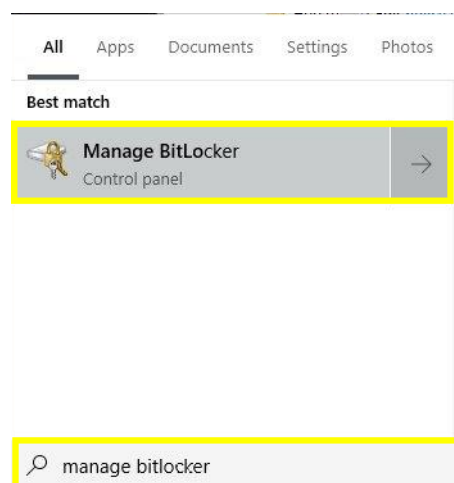
- 9 Enter your User Name and Password and follow the onscreen prompts, see [Figure F.8](#).

**Figure F.8** Password Screen

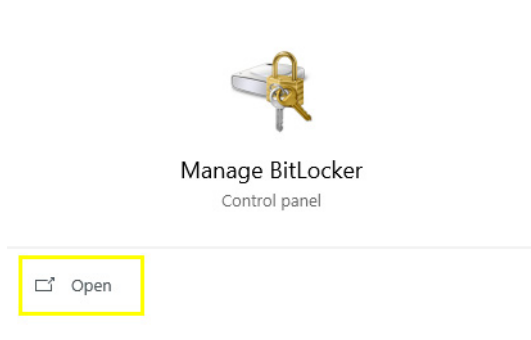


**NOTE** After logging in you may see a Window that says **Encrypting in Progress**.

- 10 Type **Manage BitLocker** from the Windows search bar to locate the **Manage BitLocker Control Panel**.

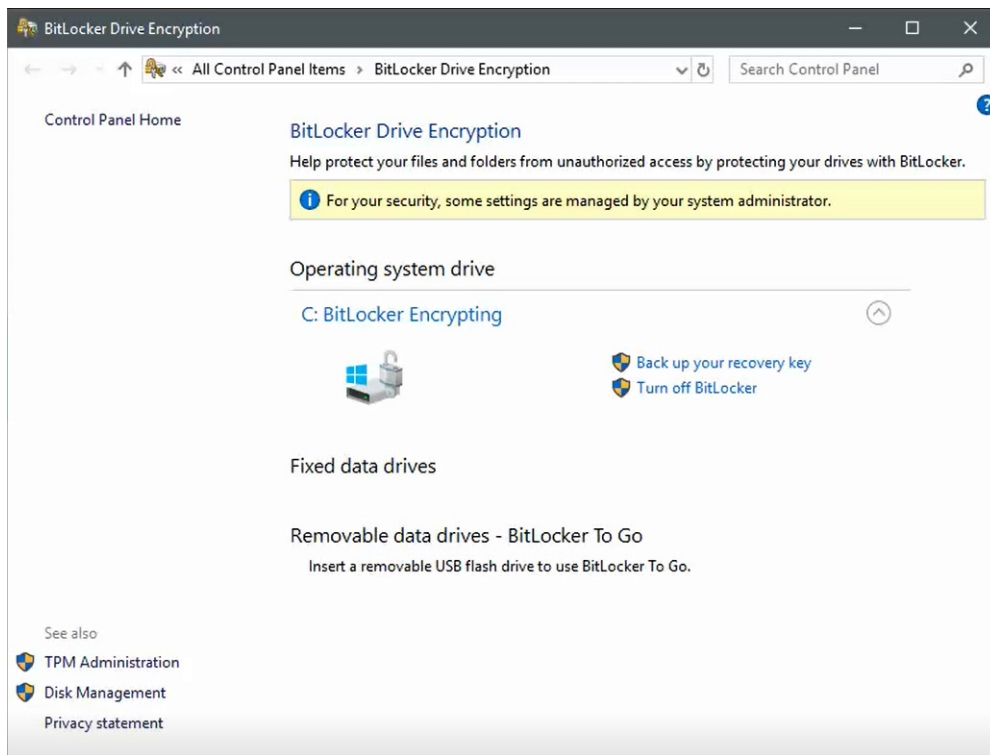


11 Select **Open** on the **Manage BitLocker Control Panel**.



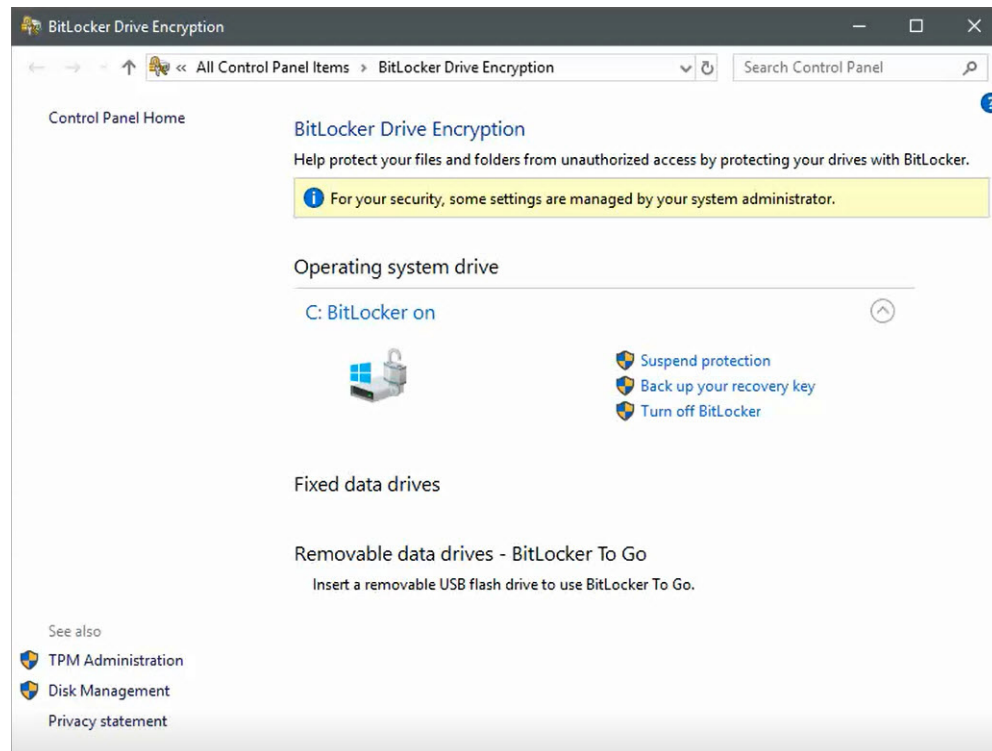
12 Under Operating System Drive, you will see the BitLocker is Encrypting the drive. See [Figure F.9](#).

**Figure F.9** BitLocker Encrypting the Drive



13 Once the BitLocker has encrypted the drive, the BitLocker will be on. See [Figure F.10](#).

**Figure F.10** BitLocker Successfully On



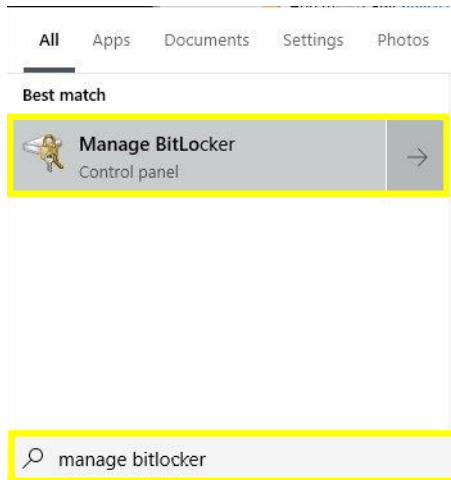
## Backing Up Your Recovery Key

**IMPORTANT** The Back Up Your Recovery Key to your Microsoft Account is not supported at this time.

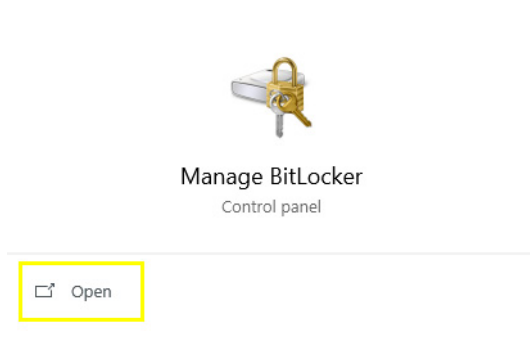
### Backing up your recovery key to a file

---

- 1 Type **Manage BitLocker** from the Windows search bar to locate the **Manage BitLocker Control Panel**, see below.

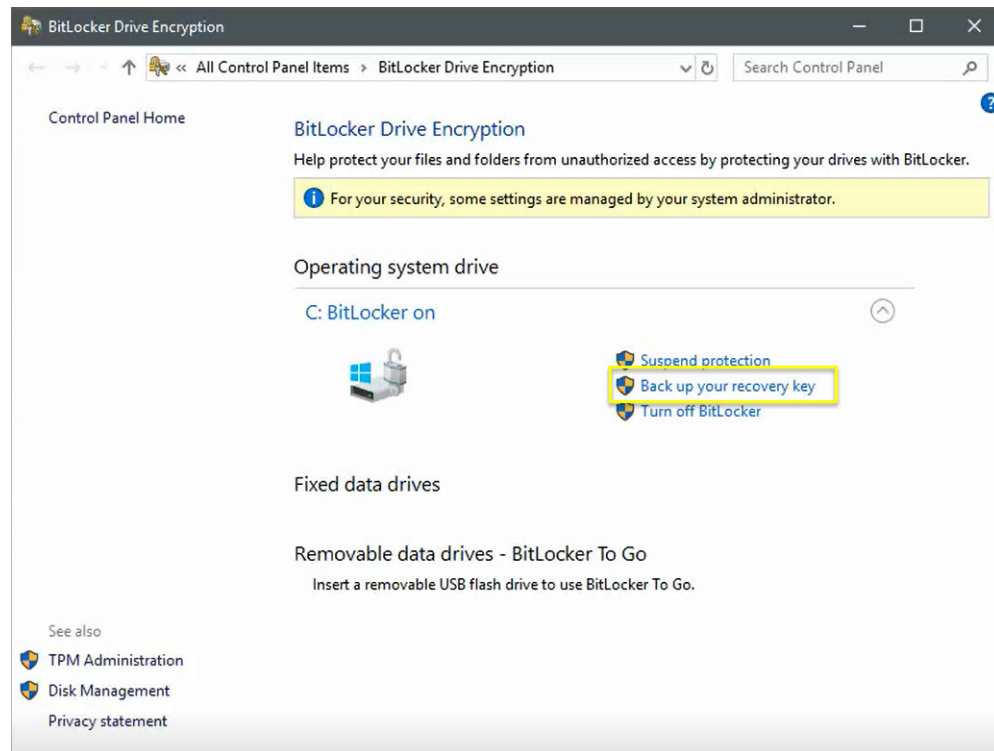


- 2 Select **Open** on the **Manage BitLocker Control Panel**.



- 3 Select “Backup your recovery key”. See Figure F.11.

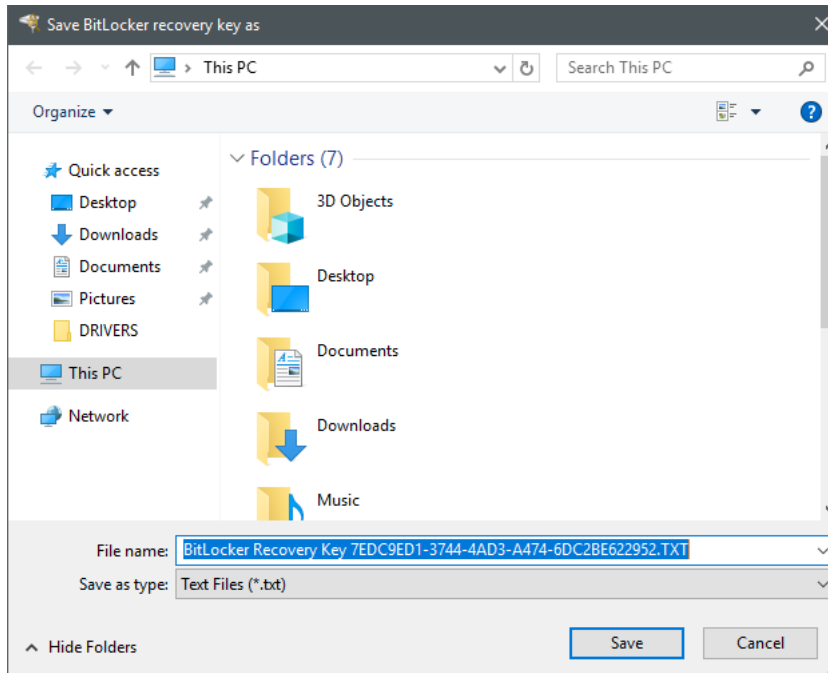
**Figure F.11** Back Up Your Recovery Key to a File



**IMPORTANT** The Recovery Key can only be saved to a USB or external drive. You cannot save to a location on your PC.

- 4 Select “**Save to a file**” as shown in [Figure F.4](#) and the **Save BitLocker recovery key as** screen appears. See [Figure F.12](#).

**Figure F.12** Save BitLocker Recovery Key Screen



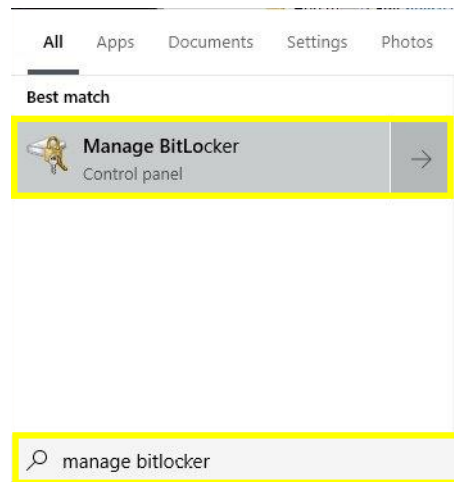
- 5 Select **Save** then select **Finish**.



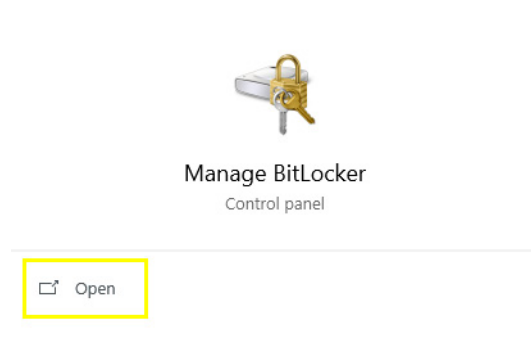
## Backing up your recovery key in PDF form

---

- 1 Type **Manage BitLocker** from the Windows search bar to locate the **Manage BitLocker Control Panel**.

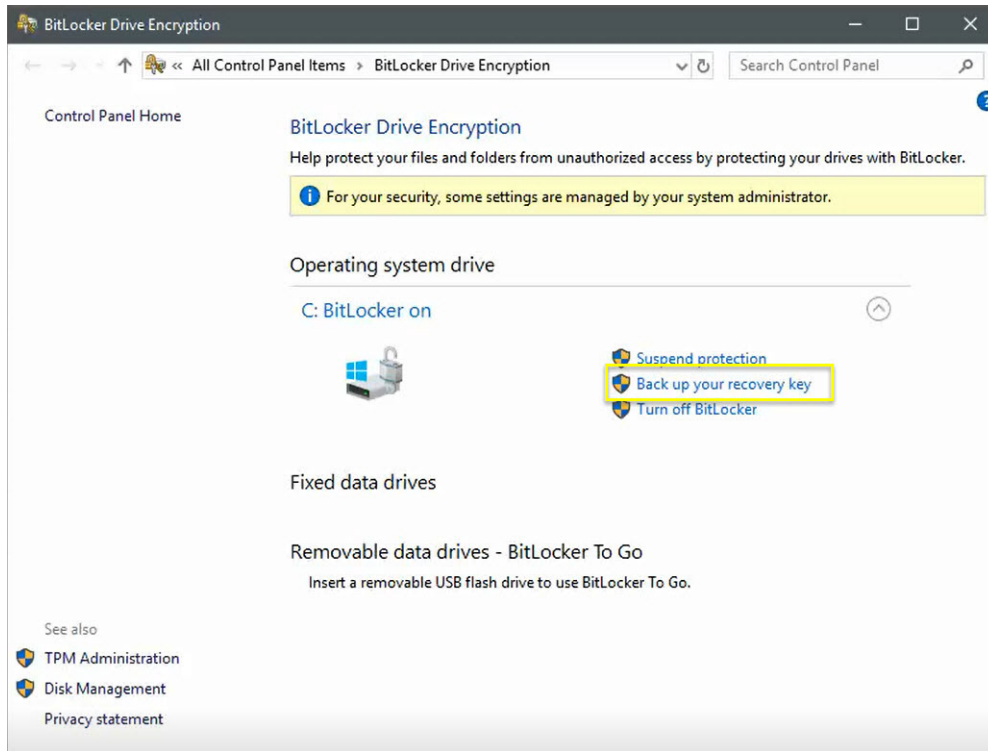


- 2 Select **Open** on the **Manage BitLocker Control Panel**.



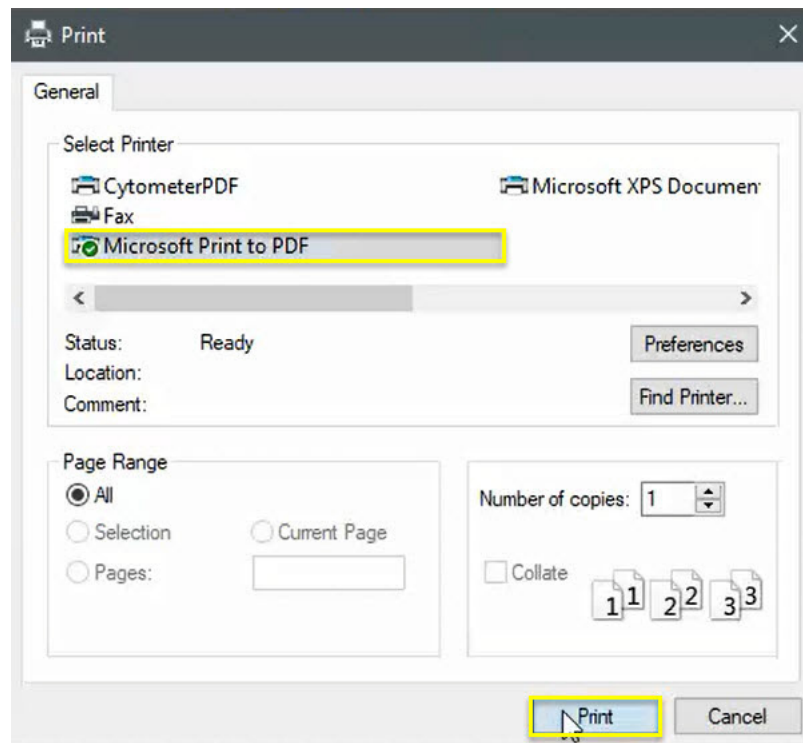
- 3 Select “Backup your recovery key”. See Figure F.13.

Figure F.13 Back Up Your Recovery Key to a PDF



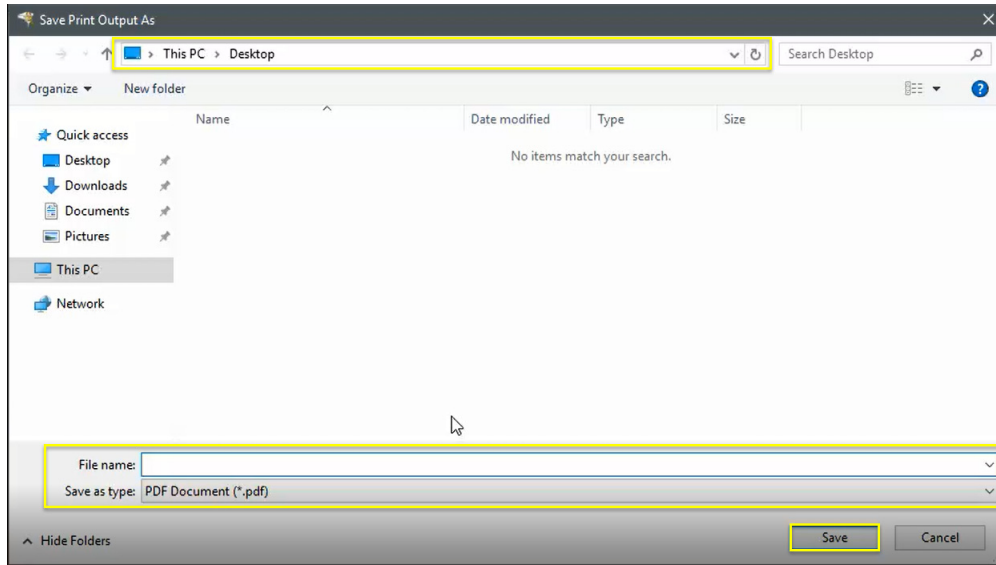
- 4 Select “*Print the recovery key*”, then select Next.
- 5 Select “*Microsoft Print to PDF*”, then select **Print**. See [Figure F.14](#).

**Figure F.14** Print to PDF Menu



- 6 Select the location that you want the file saved. In the File name, type **BitLocker Key** and in the Save as type, ensure that it is listed as .pdf. Then select **Save** and **Finish**. See [Figure F.15](#).

**Figure F.15** Print Recovery Key Location



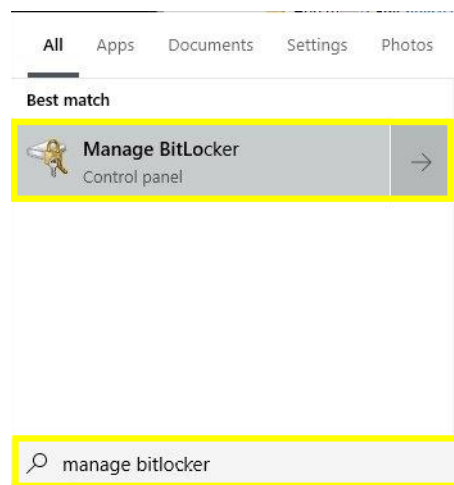
## BitLocker Decryption

**IMPORTANT** Turning off the BitLocker feature will decrypt all the data on the drive. Decrypting your operating system means that you have removed BitLocker from your system. The BitLocker key will change each time BitLocker is re-enabled. Only the latest BitLocker key will work. Previous BitLocker keys will be invalid and will not unlock the system. Please note this is a time-consuming process. However, you can also suspend BitLocker instead of decrypting the drive, see [Suspending BitLocker Drive Encryption](#).

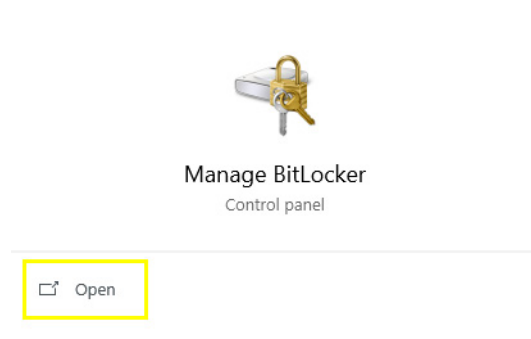
### Turning off BitLocker

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- 1 Type **Manage BitLocker** from the Windows search bar to locate the **Manage BitLocker Control Panel**.

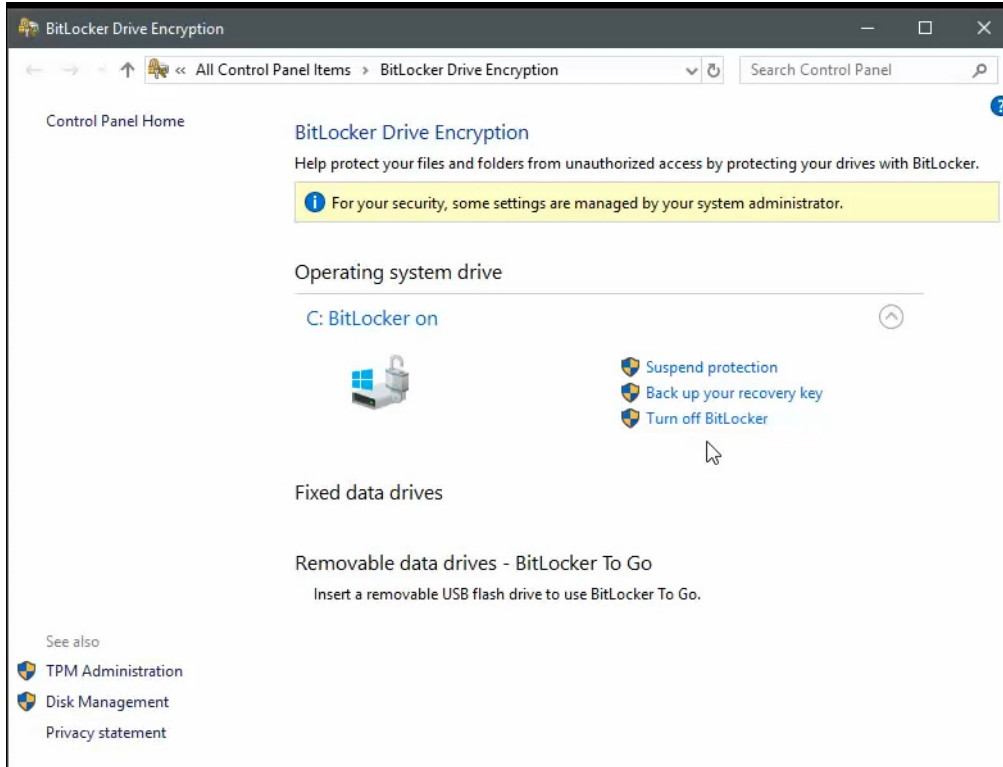


- 2 Select **Open** on the **Manage BitLocker Control Panel**.



- 3 Select **Turn off BitLocker**. See [Figure F.16](#).

**Figure F.16** Disabling BitLocker Functionality



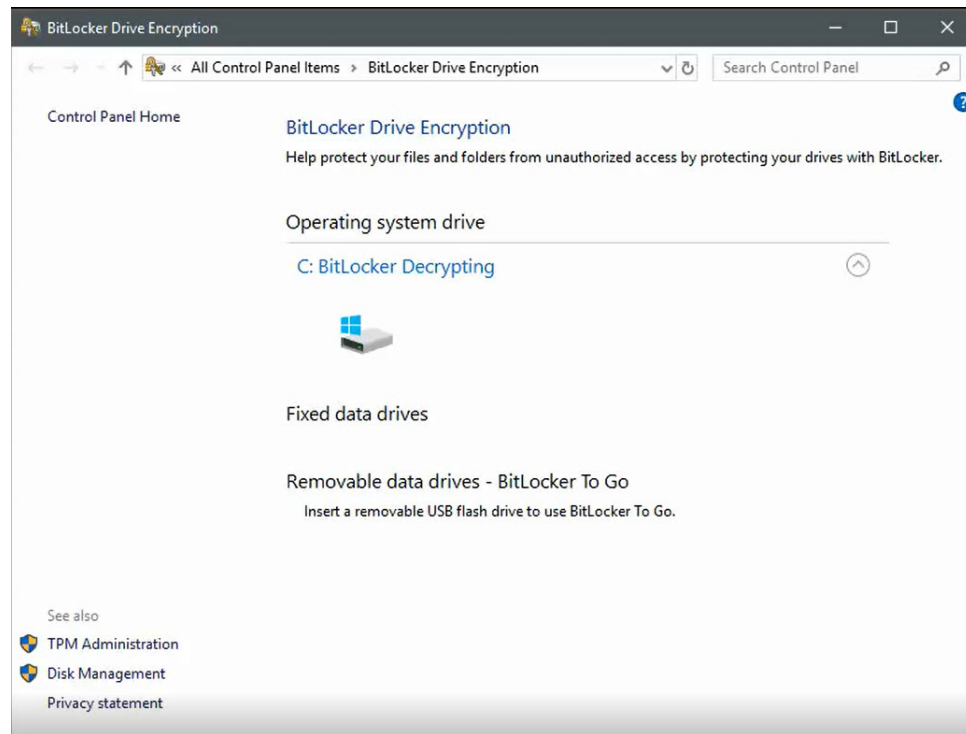
- 4 A message will appear "Your drive will be decrypted. This might take a long time, but you can keep using your PC during the decryption process.". Select **Turn Off BitLocker**. See [Figure F.17](#).

**Figure F.17** Turning Off BitLocker Message



- The BitLocker Drive Encryption screen will be displayed, see [Figure F.18](#).

**Figure F.18** BitLocker Decrypting



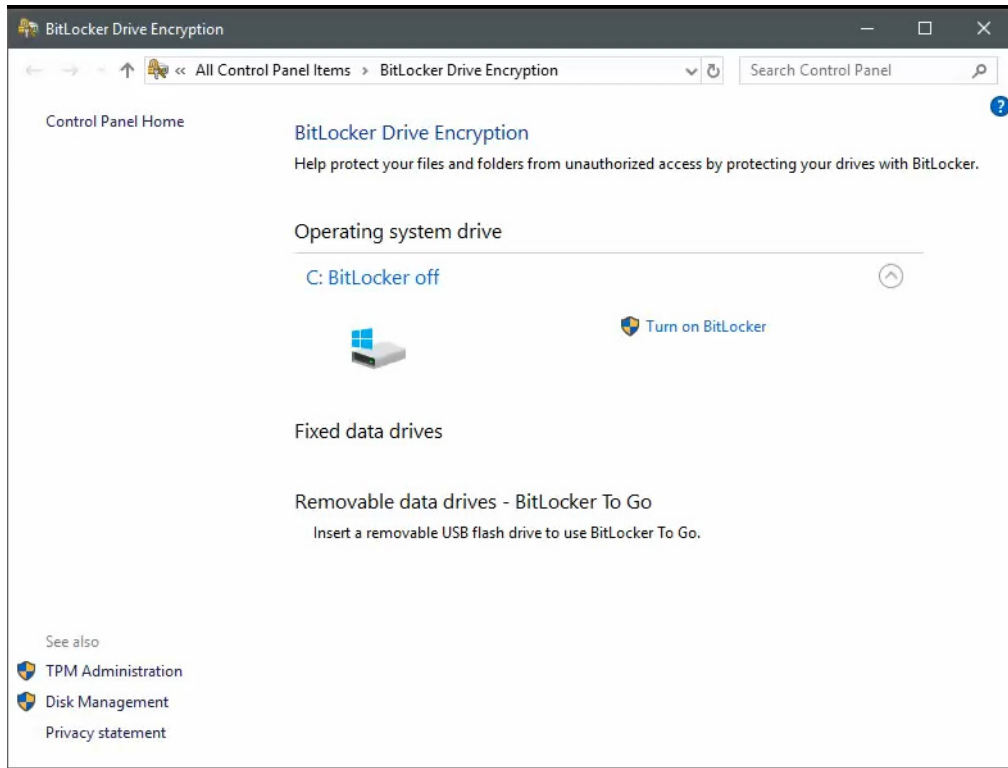
- A message will appear “Decryption has started. Click for more information.”. See [Figure F.19](#).

**Figure F.19** Decryption in Progress Message



7 After the decryption has completed, the following screen will be displayed. See [Figure F.20](#).

**Figure F.20** BitLocker Off Notification





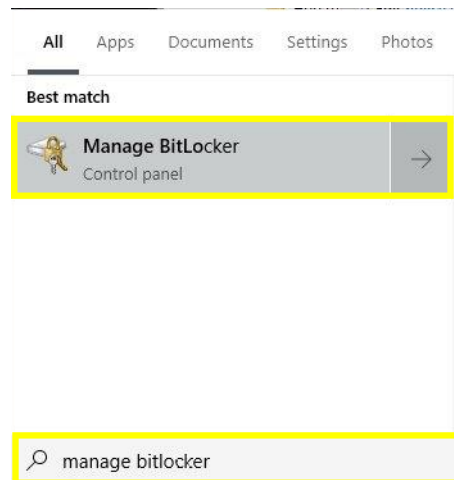
## Suspending BitLocker Drive Encryption

**IMPORTANT** Suspending BitLocker Drive Encryption is a temporary method for removing BitLocker protection without decrypting the Windows drive. Use Suspend BitLocker if you need to update the BIOS firmware or Windows bootloader/startup files that requires access to the drive in a pre-boot environment. This will help prevent BitLocker from locking the drive and may avoid a lengthy decryption process.

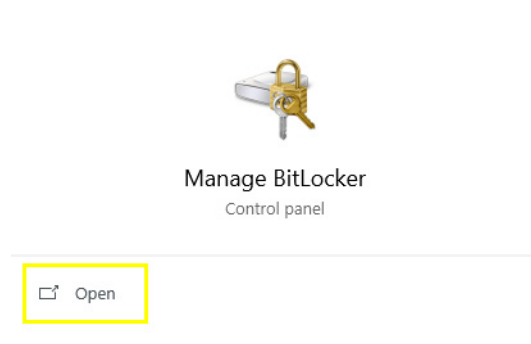
### Suspending BitLocker

---

- 1 Type **Manage BitLocker** from the Windows search bar to locate the **Manage BitLocker Control Panel**.

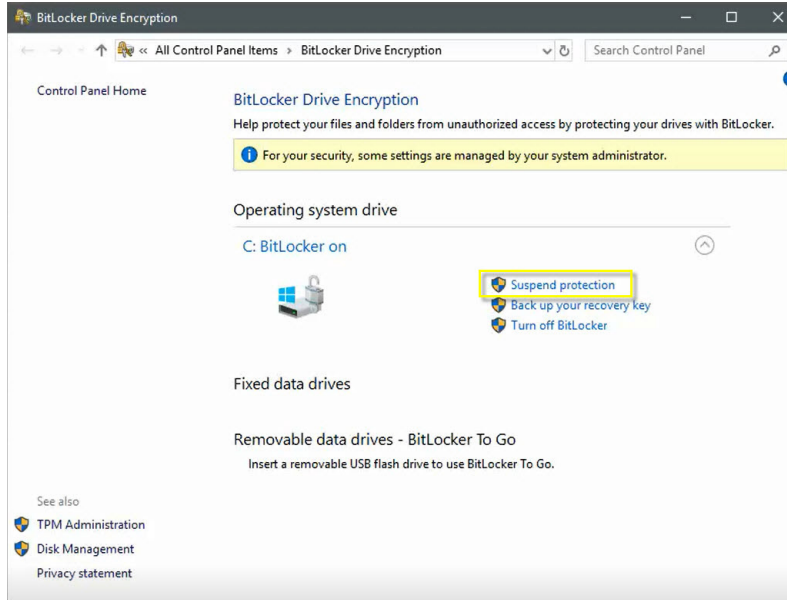


- 2 Select **Open** on the **Manage BitLocker Control Panel**.



- 3 Select **Suspend Protection**, see [Figure F.21](#).

**Figure F.21** Suspending BitLocker



**IMPORTANT** If you choose to suspend BitLocker, your data will not be protected.

- 4 A confirmation screen will be displayed, “Do you want to suspend BitLocker protection?”.



If you want to proceed, select **Yes** and the following popup information screen will be display.



If you do not want to proceed, select **No**.

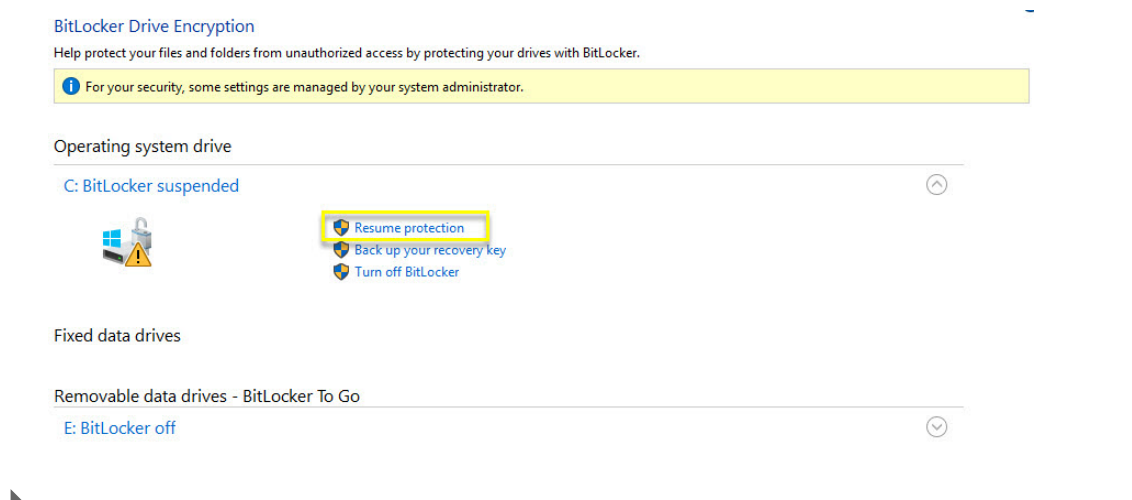
**NOTE** There are certain situations where you may want to suspend BitLocker such as updating your PC's firmware, hardware, or operating system. If you forget to resume BitLocker after these updates are completed, BitLocker will resume automatically the next time you restart your PC.

## Restarting BitLocker Protection

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- 1 Select **Resume Protection**. See [Figure F.22](#).

**Figure F.22** Resume Protection



## BitLocker Recovery Mode

There may be situations where the BitLocker Key is requested from your computer, such as:

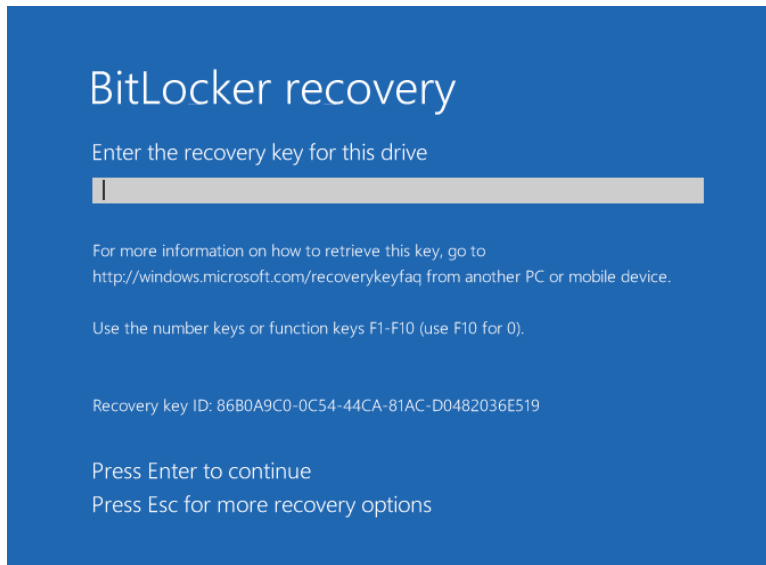
- Your drive is placed onto another computer
- Computer requests your recovery key, it may be due to one of the following but is not limited to:
  - Hardware changes
  - Firmware changes
  - Other Windows updates

## BitLocker Recovery

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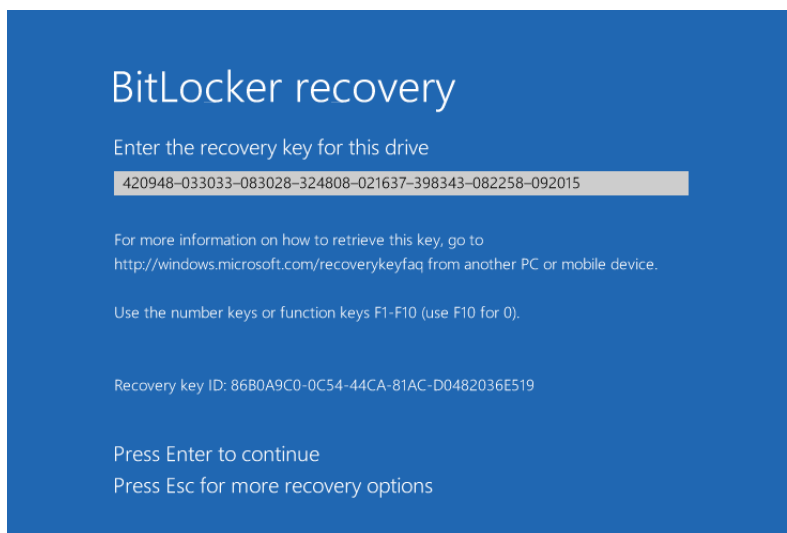
- 1 BitLocker Recovery window will be displayed upon powering on your system. See [Figure F.23](#).

**Figure F.23** BitLocker Recovery Screen



- 2 Enter your key from your saved text file or printed copy, then select **Enter**. See [Figure F.24](#).

**Figure F.24** BitLocker Recovery Key



- 3 Windows will reboot your computer.
-

## Encryption of the Database

---

** CAUTION**

**Risk of data loss. Databases in Windows 10 are encrypted and cannot be restored to a system with an earlier operating system. Save a copy of the unencrypted database in a secure location. Refer to [CHAPTER 8, Backup Database](#).**

The database is AES-CBC 256-bit encrypted at the bit level.

## Password Security

---

Enter your User Password. Passwords are a minimum of 6 characters and a maximum of 24 characters. Blanks are not allowed. Software is configured to disallow reuse of a user's previous 12 passwords.

It is recommended that you establish user passwords that meet the complexity requirements outlined below.

- Password Timeout must be set to 90 days or greater
- Password must be at least 10 characters in length.
- Password must contain the following 4 requirements to meet complexity requirements.
  - One upper case alpha character;
  - One lower case alpha character;
  - One numeric value; Base 10 digits (0 through 9)
  - A special character (i.et., !, @, #, \$, %, ^, &)

## Application Control

---

Application control is a computer administration practice used to prevent unauthorized programs from running. This ensures that the system is configured to only run authorized software defined in the application control and anything else is prevented from running. Application control is preferable to traditional Anti-virus solutions as it is less hardware resource intense, and it does not need any updates to protect the product against future vulnerabilities.

**IMPORTANT** Beckman Coulter will not alter the application control to permit installation of any software not listed below.

The following executables and installers can be installed:

- AQUIOS software
- AQUIOS PLG software
- AQUIOS Designer Software 2.0 (ADS2)

- Microsoft Operating Systems downloaded from Beckman Coulter RSU Portal
- Printer Drivers provided by Beckman Coulter

The control will prevent the following:

- Installing any software other than the ones stated above.
- Running batch or executables files from USB or any other network drive into the AQUIOS computer.
- Running batch, executable files or programs downloaded to the AQUIOS computer.

## Error Messages

Table F.2 lists the messages, with their cause and what to do about them. These are the messages produced by the system.

Table F.1 Operating System Patching Messages

Message	Probable Cause	Recommended Action
Windows cannot access the specified device, path, or file. You may not have the appropriate permissions to access the item.	Insufficient rights to access the device, path, or file.	<ol style="list-style-type: none"><li>1. Ensure you have sufficient rights.</li><li>2. If problem persists, <a href="#">Contact us</a> for additional assistance.</li></ol>
System does not run or install a program not on allowed software list.	Refrain from trying to install unvalidated/unauthorized programs.	User is attempting to run or install an unvalidated/unauthorized program.

## Operating System Updates

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**IMPORTANT** Before installing the operating system update, ensure you have a recent backup of the instrument database, refer to [CHAPTER 8, Backup Database](#) and [Restore Database](#), and the current BitLocker key, refer [Backing Up Your Recovery Key](#).



### WARNING

**Risk of software incompatibility. Only operating system updates posted to the Beckman Coulter website should be installed on the instrument controller PC. Installation of operating system updates from other sources has been disabled.**

**Install the update on one instrument and verify functionality before installing on other instruments.**

## Creating a Restore Point

A restore point is used to remove all software installations and operating system changes that occurred after it was created. If installing an update on your PC causes any loss of functionality, the restore point may be used to place the system back into the operable state present before the update installation. In all cases, a system restore with any restore point would not cause loss of any data (For Example: LMD files) on the system. Refer to Step 9 - 17 in [Recovering from Failed Operating System Updates](#).



### CAUTION

**Risk of unexpected software modification. To ensure a system recovery point is available that is indicative of the most recent software configuration, the user should create a system restore point immediately prior to running the operating system update installer. Otherwise, a user would need to utilize the most recent automatically created restore point which may be up to 72 hours old and not include all recent software modifications.**

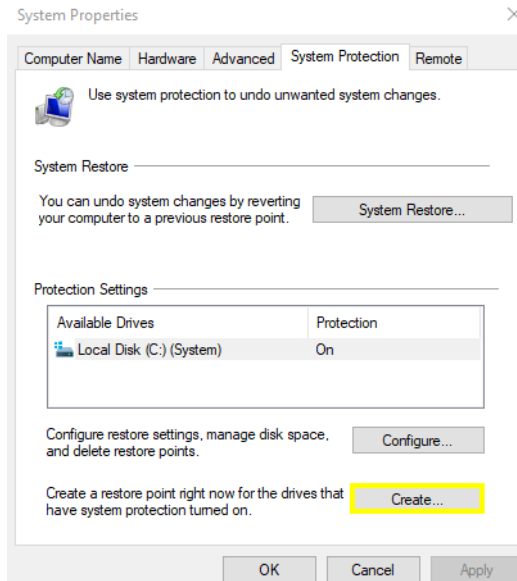
## Creating a Restore Point

---

- 1 In the Start Menu , type **Restore** and select **Create a Restore Point**.

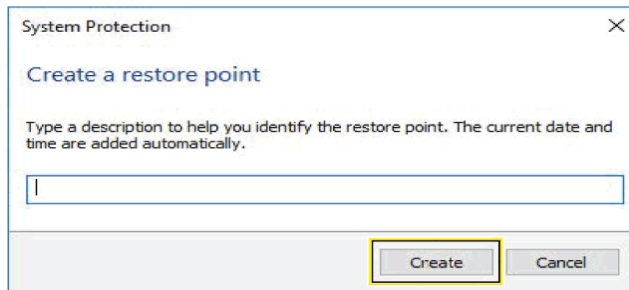
2 Select **Create**.

Figure F.25 Creating a Restore Point



3 Type a name for the restore point and select **Create**.

Figure F.26 Name of Restore Point



4 Wait for the restore point creation to complete and then select **Close**.

5 Close the System Properties window by selecting **OK**.



## Downloading Operating System Updates

In order to download and install operating system updates, you will need to access the Beckman Coulter website at [www.beckmancoulter.com](http://www.beckmancoulter.com).

### Downloading Operating System Updates

---

- 1 Go to [www.beckmancoulter.com](http://www.beckmancoulter.com).

---

- 2 Using the menu bar in the upper right hand corner of the screen, hover over **Login**, then scroll down to select **Software Downloads**.


---

- 3 To search by product:
  - a. Select **Research & Discovery** from the Market Segment drop-down menu.
  - b. Select **Clinical Flow Cytometry** from the Product Line drop-down menu.
  - c. Select **Instruments** from the Product Series drop-down menu.
  - d. Select **AQUIOS CL** from the Product drop-down menu.

---

- 4 Select **Search**.

**IMPORTANT** Print out the Release Notes for each update as they will not be available when the next update is released. The Component Name section of the release notes identifies the Microsoft updates that are included in the download. This information may be requested by your IT team and will be needed to recover from a failed update.

- 5 Each operating system update is cumulative and only the most recent validated set of updates will be available for download. Select the first file in the results to view the release notes and then select .
  - a. If downloading the installer from Internet Explorer on the AQUIOS controller PC, select **Save** when prompted.
  - b. You may see a file security warning. Do not make any selection.

**NOTE** If the installer is downloaded with another browser, the required actions to save the file may vary.

If more than one update is listed in the search results, select, and repeat this step for each update.

If the operating system updates cannot be downloaded directly to the instrument controller PC, transfer the downloaded files via an encrypted external media or secured network drive to the instrument controller system.

## Downloading Your AQUIOS Manuals

In order to download your AQUIOS manuals, you will need to access the Beckman website at [www.beckman.com/techdocs](http://www.beckman.com/techdocs).

### Downloading AQUIOS Manuals

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- 1 Go to [www.beckman.com/techdocs](http://www.beckman.com/techdocs).

---

  - 2 Enter **AQUIOS** or the part number of the instrument in the search dialog box and select **(Enter)** to locate the available documents.

---

  - 3 Select the **Technical Documents** tab.

---

  - 4 To narrow your results use the panel to the left of your results search:
    - a. Select **Document Type** and select **Instrument IFU**.
    - b. Select **TechDoc Language** and select your IFU language.
- 

## Notification Options

To receive notification when a new operating system update is validated and available for download, you must sign up for an account on [www.beckmancoulter.com](http://www.beckmancoulter.com) and follow the procedure for setting up subscriptions.

### Signing Up for Product Notifications

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- 1 Go to [www.beckmancoulter.com](http://www.beckmancoulter.com).

---

- 2 Using the menu bar in the upper right hand corner of the screen, hover over **Login**, then scroll down to select **My Technical Document**.

---

- 3 To search for your product:
  - a. Select the **Document Language** consistent with your IFU language.
  - b. Select **Research & Discovery** from the Market Segment drop-down menu.
  - c. Select **Clinical Flow Cytometry** from the Product Line drop-down menu.
  - d. Select **Instruments** from the Product Series drop-down menu.
  - e. Select **AQUIOS CL** from the Product drop-down menu.

---

**4** Select **Search**.

If you do not sign up for product notifications, you will have to check periodically for newly released operating system updates, see [Downloading Operating System Updates](#).

## Installing the Operating System Updates on the Instrument Controller PC

**⚠ CAUTION**

**Risk of software incompatibility. Beckman Coulter only supports operating system updates on unmodified systems. Application of domain policies or other system configuration changes may impact compatibility.**

**IMPORTANT** If more than one update is available for your product, install the updates in the order indicated by the sequence number as outlined in the file naming convention below. Downloads with different sequence numbers contain different Microsoft updates. A sequence revision number higher than 0 indicates an update for previously released installer.



RSU - <operating system>-<product name>-<Year><Month>\_<Sequence #>\_<Sequence Revision #>

**Example:** RSU-W10-AquiosCL-2020May\_1\_0

### Installing Operating System Updates

---

- 1** Ensure you have a recent backup of the instrument database, refer to [CHAPTER 8, Backup Database](#) and [Restore Database](#), and the current BitLocker key, refer to [Backing Up Your Recovery Key](#). Ensure the backups are saved to an encrypted external media or secured network drive.
- 2** Login to Windows as a user with Administrator access.
- 3** Close all programs and save open files.
- 4** Power down the instrument. See [CHAPTER 6, Power the Computer and Cytometer OFF](#).

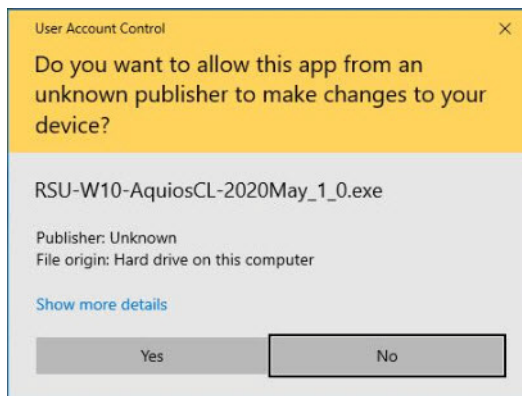
**IMPORTANT** If you downloaded the installer from Internet Explorer on the AQUIOS controller PC, the files may be accessed from the downloads folder in **This PC** section of File Explorer program (  key + **E** ). If you saved to encrypted external media or used a different browser, access the file from its saved location in File Explorer program (  key + **E** ).

- 5 Open the first operating system update file (For example: RSU-W10-AquiosCL-2020May\_1\_0) on the Instrument Controller PC by right-clicking on the file and select **Run As Administrator**. If the Microsoft Windows Defender SmartScreen prompt appears, select **More Info** and then select **Run Anyway** to launch the installer, see [Figure F.27](#). Select **Yes** on the User Account Control prompt, see [Figure F.28](#). The installation process may take several minutes, see [Figure F.29](#).

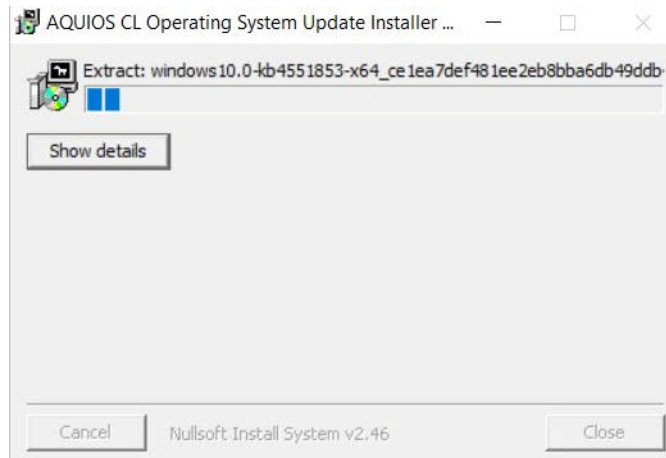
**Figure F.27** Microsoft Windows Defender SmartScreen



**Figure F.28** User Account Control



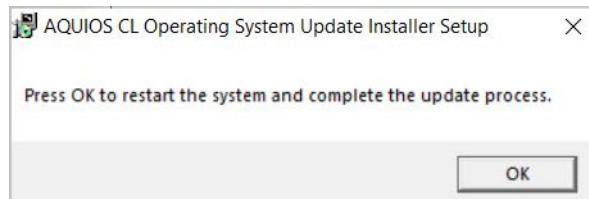
**Figure F.29** Operating System Update Setup Installation



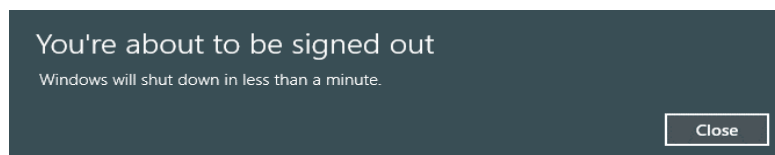
**NOTE** The operating system update installer will automatically detect and install only the necessary updates.

- 6 Once the operating system update setup has completed, select **OK** to restart the system and complete the update process. See [Figure F.30](#) and [Figure F.31](#).

**Figure F.30** Operating System Update Setup Successfully Installed

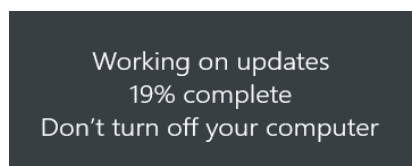


**Figure F.31** Windows Shutdown



- 7 Wait while the system completes the installation of the operating system updates. This process may take several minutes and will return you to the Windows login screen. See [Figure F.32](#).

**Figure F.32** Working on Completing Operating System Updates



- 8 Install any additional downloaded operating system updates (sequence numbers above 1) by repeating steps 5 to 7.
- 9 Verify functionality of instrument software. If functionality is impaired, see [Recovering from Failed Operating System Updates](#).
- 10 Repeat Steps 1 through 9 for installing operating system updates on other AQUIOS systems.

## Error Messages

Table F.2 lists the messages, with their cause and what to do about them. These are the messages produced by the system.

**Table F.2** Operating System Patching Messages

Message	Probable Cause	Recommended Action
Extract: error writing to file.	Hard disk does not have sufficient space to extract the installation files.	<ol style="list-style-type: none"> <li>1. Empty the recycle bin.</li> <li>2. Free up disk space on the C drive by removing files.</li> <li>3. Retry operating system update installation.</li> </ol>
Application software not found. This update may only be installed on a valid system.	Update installer is being run on a PC that does not have AQUIOS software installed.	<ol style="list-style-type: none"> <li>1. Ensure the update utility is only run on a AQUIOS PC with the AQUIOS software installed.</li> <li>2. <a href="#">Contact us</a> for additional assistance.</li> </ol>
All updates included in this download package have been previously installed.	All updates included have been previously installed.	<ol style="list-style-type: none"> <li>1. Ensure you have the latest updates, refer to the instructions provided in <a href="#">Downloading Operating System Updates</a>.</li> <li>2. No further action is necessary.</li> </ol>
One or more updates failed to install, please contact BEC support.	Update installer was not able to install one or more updates.	<ol style="list-style-type: none"> <li>1. If C drive has less than 20 GB of space available, free up disk space by moving files to external media.</li> <li>2. Run the update installer again.</li> <li>3. <a href="#">Contact us</a> for additional assistance.</li> </ol>
This update is not compatible with the installed operating system.	Update installer is being run on a AQUIOS PC Controller PC with an operating system incompatible with the update.	<ol style="list-style-type: none"> <li>1. Ensure you have the correct update, refer to the instructions provided in <a href="#">Downloading Operating System Updates</a>.</li> <li>2. <a href="#">Contact us</a> for additional assistance.</li> </ol>

**Table F.2** Operating System Patching Messages (Continued)

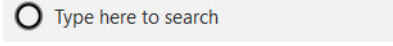
Message	Probable Cause	Recommended Action
Administrator rights required!	Windows user running the update installer does not have administrator privileges in Windows.	<ol style="list-style-type: none"> <li>1. Login as windows administrator.</li> <li>2. Run the installer as administrator again.</li> </ol>
System software is running. Please close the software and try again.	AQUIOS software is open.	<ol style="list-style-type: none"> <li>1. Close the AQUIOS software.</li> <li>2. Run the update installer again.</li> <li>3. <a href="#">Contact us</a> for additional assistance.</li> </ol>

## Recovering from Failed Operating System Updates

These steps below should only be followed if the instrument software or operating system functionality is impaired after an operating system update was applied.

### Recovering Failed Operating System Updates:

- 1 Power down the instrument and close all programs. See [CHAPTER 6, Power the Computer and Cytometer OFF](#), see Step 4 only. Do not turn your workstation off.

- 2 In the start menu , type **View Update** and select **View your Update History**.

- 3 Select **Uninstall Updates**.

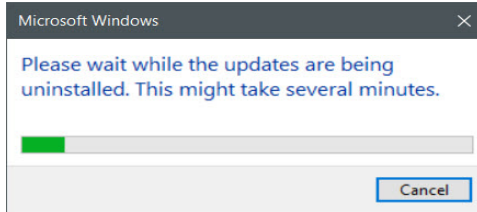
- 4 Highlight the update listed under Microsoft Windows that matches the cumulative security update KB number in the release notes. Refer to Component Name section of the Release Notes, see Step 5, [Downloading Operating System Updates](#).

**Figure F.33** Microsoft Windows Operating System Update List

Microsoft Windows (14)				
<input type="checkbox"/>	Security Update for Microsoft Windows (KB4549949)	Microsoft Windows	Microsoft Corporation	5/19/2020
<input type="checkbox"/>	Security Update for Microsoft Windows (KB4549947)	Microsoft Windows	Microsoft Corporation	5/13/2020
<input type="checkbox"/>	Security Update for Microsoft Windows (KB4539571)	Microsoft Windows	Microsoft Corporation	3/24/2020
<input type="checkbox"/>	Security Update for Adobe Flash Player	Microsoft Windows	Microsoft Corporation	11/4/2019

- 5 Select **Uninstall** and select **Yes** when prompted to verify the uninstall. This process may take several minutes to complete.

Figure F.34 Uninstalling Updates



- 6 When prompted to restart, select **Restart Now**.

Figure F.35 Computer Restart

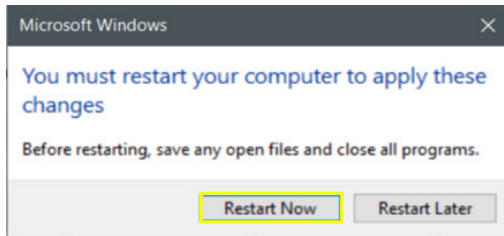
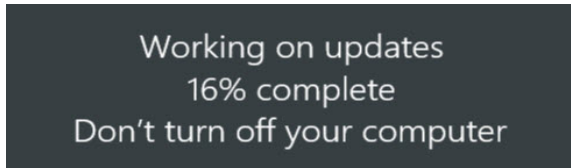



Figure F.36 System Completing Updates



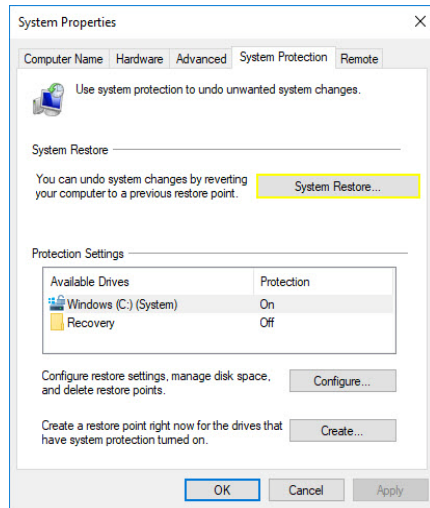
- 7 Once the PC has been rebooted, login and verify Microsoft update has been removed by repeating steps 1 and 2. Verify the KB selected in Step 3 is no longer listed.
- 8 Power on the instrument and verify restored software functionality.
  - a. If software functionality has been restored, continue using your instrument without the update installed. [Contact us](#) for troubleshooting the update incompatibility. **Do Not proceed to Step 9.**
  - b. If software functionality has not been restored, continue to Step 9.

- 9 In Start Menu  Type here to search, type **Restore** and select **Create a Restore Point**.



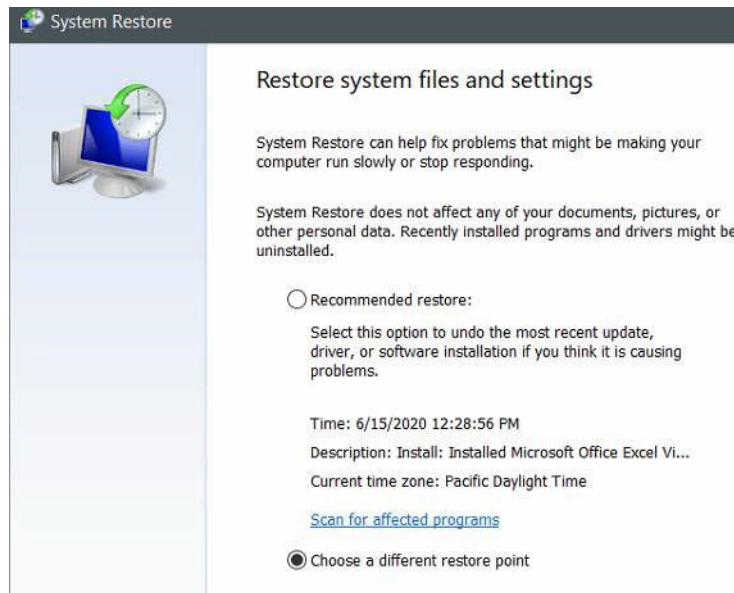
10 Select **System Restore**. See [Figure F.37](#).

**Figure F.37** System Properties



11 If the option is presented **Recommended Restore** or **Choose a different restore point**, select **Choose a different restore point** and select **Next**. See [Figure F.38](#). If the option is not presented, select **Next**.

**Figure F.38** Restoring System Files and Settings

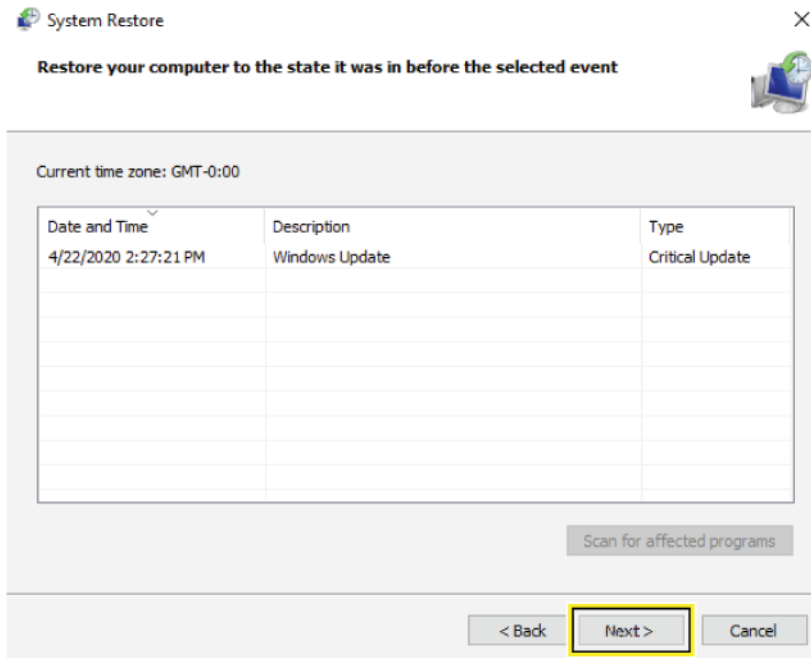


**WARNING**

**Risk of software changes.** All software installations and operating configuration system changes that occurred after the selected restore point timestamp will be removed during the restore process.

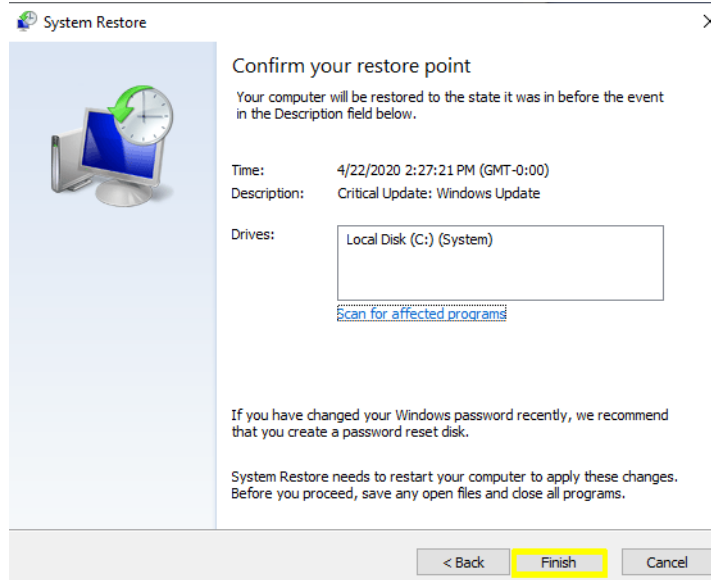
- 12 Select the Restore Point with the most recent date and time and select **Next**. See [Figure F.39](#).

Figure F.39 Selecting Your Restore Point



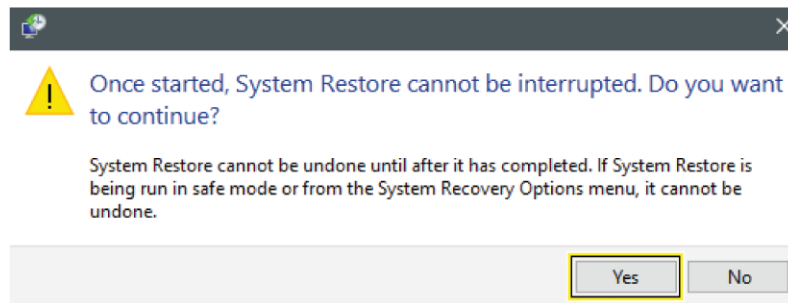
- 13 Select **Finish** to restart your computer and restore it to the state before operating system updates were installed. Your data files will not be deleted. See [Figure F.40](#).

**Figure F.40** Confirming Your Restore Point



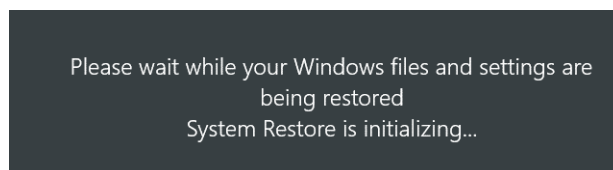
- 14 Select **Yes** when prompted. See [Figure F.41](#).

**Figure F.41** Start System Restore



- 15 Wait while the system restores. This process may take several minutes to return to the Windows login screen. See [Figure F.42](#).

**Figure F.42** Initializing System Restore



---

**IMPORTANT** Operating system updates removed during a restore operation will remain listed on the windows update history screen. Refer to Steps [2](#) - [3](#), and [7](#) to verify the update has been removed.

**16** Login to the system and test functionality of the software.

---

**17** [Contact us](#) for assistance in troubleshooting the update incompatibility or for assistance restoring functionality.

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# Software Observations

## Software Observations

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### AQUIOS TETRA Software

None noted

### AQUIOS PLG

None noted

### AQUIOS Designer Software 2.0 (ADS2)

The following table provides information and recovery instructions regarding observed behaviors.

**Table G.1** ADS2 Software Anomalies

Summary Description	Recovery
When creating a protocol, if a region is removed, the region IDs may get out of sequence. The Stop Criteria functionality may not work as expected if a region with an incorrect region ID is selected.	1. Re-create the protocol without removing a region.
When the configuration of a Test is updated, the Test can be published again and its version number will increase by 1. When the number of versions reaches 10, the version number is not increased anymore.	1. Publish the Test with a new name so that the version restarts from 1.



# References

1. Koepke JA and Landay AL. Precision and accuracy of absolute lymphocyte counts. *Clin Immunol Immunopathol*, 1989, 52:19-27.
2. Coulter, Wallace H., Means for counting particles suspended in a fluid, Patent number 2656508, October, 1953
3. Clinical and Laboratory Standards Institute (CLSI), *Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard. AUTO2-A*. <http://www.clsi.org>
4. American Identification Manufacturer's group (AIM), *Uniform Symbology Specifications Code 39, Interleaved 2 of 5, Codabar, and International Symbology Specifications Code 128*. ANSI/AIM BC1, BC2, BC3, BC4, 1995. <http://www.aimusa.org>
5. American National Standards Institute (ANSI) *Bar Code Print Quality Guidelines. X3. 182-1990 (R2000)*. <http://www.ansi.org>
6. Clinical and Laboratory Standards Institute (CLSI), *Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard. AUTO2-A*. <http://www.clsi.org>





# Abbreviations

<b>µm</b> — micrometer	<b>L</b> — liter
<b>µL</b> — microliter	<b>LIS</b> — Laboratory Information System
<b>A</b> — ampere	<b>LMD</b> — Listmode file in FCS format
<b>ADC</b> — Analog to Digital Converter	<b>Log</b> — logarithmic
<b>Admin</b> — System Administrator	<b>mL</b> — milliliter
<b>CD</b> — Cluster designation of lymphocyte subsets	<b>MSDS</b> — Material Safety Data Sheet
<b>CDRH</b> — Center for Devices and Radiological Health	<b>NR</b> — no result
<b>CRD</b> — extension of an encrypted XML file created by the AQUIOS System that stores all of the results of a sample run	<b>PDF</b> — Portable Data Format file from Adobe Systems, Inc.
<b>COM</b> — Serial communications port on the computer	<b>PE</b> — phycoerythrin
<b>CSV</b> — comma separated value file format readable by Microsoft Excel	<b>PIC</b> — programmable interface controller
<b>CV</b> — coefficient of Variation	<b>PMT</b> — photomultiplier tube
<b>dba</b> — A-weighted decibel	<b>QC</b> — Quality Control
<b>ECD</b> — Energy Coupled Dye	<b>RT</b> — room temperature
<b>EV</b> — Electronic Volume	<b>SD</b> — standard deviation
<b>FCS</b> — Flow Cytometry Standard	<b>SDS</b> — Safety Data Sheet
<b>FITC</b> — Fluorescein Isothiocyanate Dye	<b>SQ</b> — Separation Quotient
<b>FL</b> — fluorescence	<b>SS</b> — side scatter
<b>FS</b> — forward scatter	<b>UPM</b> — Uninterruptible Power Manager
<b>FPGA</b> — Field-programmable Gate Array	<b>USB</b> — Universal Serial Bus
<b>Hrs</b> — hours	<b>USPTO</b> — US Patent and Trademark Office
<b>Hz</b> — hertz	<b>V</b> — volts
<b>ID</b> — Identification	<b>Vac</b> — volts alternating current
<b>IFU</b> — Instructions for Use (manual)	
<b>IQAP</b> — Interlaboratory Quality Assurance Program	



# Glossary

**Accuracy** — The ability of the instrument to agree with a predetermined reference (true) value.

**AQUIOS CL System** — System that consists of a fully integrated Load & Go Cytometer equipped with a Single-tube Loader and an autoloader and on-board sample preparation, a Supply Cart, and a Workstation.

**Assay values** — Values for a control established by extensive repeat testing of that control.

**Autoloader** — Stacker module for 5-tube cassettes for loading up to 40 samples at once.

**Carousel** — A circular holder for reagents.

**Cassette** — A type of holder for specimen tubes.

**Cleaning agent** — A detergent used to flush sample from tubing and minimize protein buildup.

**Coefficient of variation (CV%)** — Standard deviation expressed as a percentage of the Mean.

**Color Compensation** — The subtraction of a percentage of the signal from one fluorescence light sensor, from the signal from another fluorescence light sensor, to correct for the overlap of one dye's emission into another dye's emission measurement.

**Control** — A substance used to routinely monitor the performance of an analytical process that has the characteristic being measured [For example: Whole blood controls].

**Cytometer** — The system component that analyzes the sample.

**Defaults** — Original settings for the instrument. You can change them to customize the settings for your laboratory.

**Discriminator** — A channel setting for a parameter that ignore events below the setting. The Discriminatory is used to eliminate signals caused by debris.

**Dotplot** — A graphical representation of two-parameter data. Each axis of the plot displays values of one parameter. A dot represents a cell or particle.

**Electronic Volume** — A electrical measure of impedance of the cell.

**Flag** — AQUIOS system error indicating that results are highly questionable.

**Flow Cytometry** — A process for measuring the characteristics of cells or other biological particles as they pass through a measuring apparatus in a fluid stream.

**Flow Cytometry Standard (FCS)** — A flow cytometry data file standard that provides the specifications needed to describe flow cytometry data sets within the confines of the file containing the data.

**Fluorescent light** — The emission of electromagnetic radiation that occurs when the emitting body absorbs radiation from some other source. For example, when a fluorescent dye is excited (absorbs radiation), it emits fluorescent light at a wavelength that is different from the wavelength of the light that excited it.

**Forward Scatter (FS)** — The amount of laser light scattered at a 0 to 10° angle to the axis of the laser beam.

**Gating** — The use of criteria that must be met before an event is included in a histogram.

**Histogram** — A graph showing the relative number and distribution of events.

**Indicators** — See Controls and Indicators.

**Instrument Controls and indicators** — Instrument controls are the mechanisms you use to communicate with the instrument. Indicators are the mechanisms the instrument uses to communicate with you.

**IQAP** — Abbreviation for Beckman Coulter's Interlaboratory Quality Assurance Program. A service for all worldwide users of Beckman Coulter controls, the IQAP statistically compares your control data with that of other laboratories.

**Laboratory Information System (LIS)** — Software that can generate a test request or receive and store patient results for a laboratory.

**Load** — Placing a blood specimen in the Single-tube Loader or on the autoloader.

**Monoclonal Antibody** — Antibodies produced by a single cell or its identical progeny, specific for a given antigen.

**Mean** — Arithmetic average of a group of data. See also standard deviation and coefficient of variation.

**Mouse** — A pointing device. The cursor on the Workstation screen moves as you slide the mouse on your desk or other flat surface.

**Notification** — AQUIOS system warning indicating that results from running a sample are questionable.

**Optical filters** — Mediums, such as glass, that separate fluorescent light by wavelength, which is measured in nanometers (nm).

**Panel** — In general, a group of protocols for analyzing a series of samples corresponding to one specimen.

**Parameter** — A property of the sample that is measured by the system. Parameters are displayed on the data plots as axis labels.

**Precision** — A measure of the ability of the instrument to reproduce similar results when a sample is run repeatedly. May also be referred to as repeatability.

**Protocol** — A set of instructions that tells the Cytometer what and how to acquire data.

**Quality control (QC)** — A comprehensive set of procedures a laboratory sets up to ensure that an instrument is working accurately and precisely.

**Reagent** — Substance used to process samples and generate results.

**Reagent door** — Larger of the two doors on the cytometer front cover. Opening this door allows you to replace reagents.

**Sample ID** — Identification assigned to a specimen tube.

**Sample Prep** — The preparation of the whole blood sample with the monoclonal antibodies and lytic reagents, to allow for analysis of the populations of interest by the flow cytometer.

**Scroll bar** — The area on the right of a pop-up window. The bar's arrows let you move (scroll) the window's content up or down so that you can see other parts of it.

**Select** — To position the mouse cursor on an item, and then press and release a mouse button to choose that item.

**Sensitivity** — The ability of the instrument to distinguish very low levels of light scatter and fluorescence from background light or electronic noise.

**Separation Quotient** — An indicator of relative sensitivity and resolution and can be used as an index that indicates how well separated two different regions are, such as sample versus debris, or lymphocytes versus monocytes. The larger the separation quotient, the better the separation.

**Sheath fluid** — A balanced electrolyte solution.

**Side Scatter (SS)** — The amount of laser light scattered at about a 90° angle to the axis of the laser beam. The amount of side scatter is proportional to the granularity of the cell that scattered the laser light.

**Single-tube Loader** — Area used to load a single specimen tube.

**Single-tube Loader door** — Smaller of the two doors on the cytometer front cover. Opening this door allows you to load a specimen tube one-at-a-time.

**SQL** — Standard query language.

**Standard Deviation (StDev)** — A measure of difference from the mean. A measure of precision.

**Supply Cart** — The system component that provides direct current power, pressure, and vacuum to the Cytometer, and collects waste from the Cytometer.

**Symbology** — A set of rules for encoding and decoding information contained in a bar-code symbol. Examples of symbologies include Interleave 2 of 5 (with checksum), Code 39 Regular (with and without checksum; default is with checksum), and Code 128 (Code A, Code B, and Code C).

**Uninterruptible Power Manager** — A power conditioner and battery backup for the AQUIOS system.

**Workstation** — The system component that runs the software that controls the instrument. It displays sample results and other information.

**XLS** — spreadsheet file format used by Microsoft Excel



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## Related Documents

**AQUIOS CL Flow Cytometer Instructions for Use**

PN B21896

**AQUIOS Tetra System Guide**

PN B26364

**AQUIOS Tetra Host Transmission**

PN B26365

**AQUIOS PLG System Guide**

PN B43671

**AQUIOS PLG Host Transmission**

PN B45252

**AQUIOS Designer Software Addendum**

PN B68285

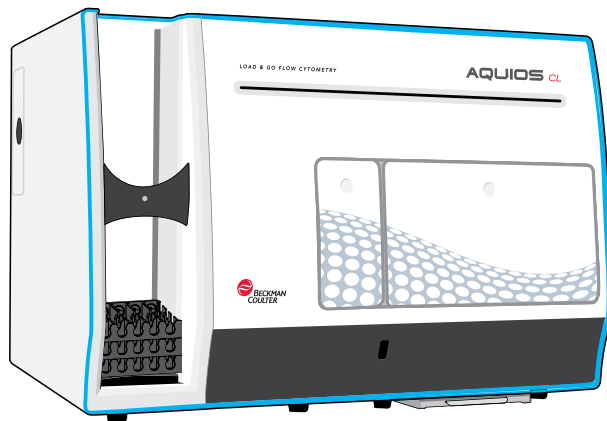
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# AQUIOS Addendum

## AQUIOS CL Flow Cytometer Signal Tower Rx Only in the U.S.A.



PN C64389AA  
October 2020



Beckman Coulter Ireland Inc.  
Lismeehan  
O'Callaghan's Mills  
Co. Clare, Ireland 353-65-683-1100



**AQUIOS Flow Cytometer**  
**AQUIOS Signal Tower Addendum**  
PN C64389AA (October 2020)

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If you have any questions, contact our Customer Support Center.

- Worldwide, find us via our website at [www.beckman.com/support/technical](http://www.beckman.com/support/technical).
- Outside of the USA and Canada, contact your local Beckman Coulter Representative.

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

*May be covered by one or more pat. - see [www.beckman.com/patents](http://www.beckman.com/patents)*

Glossary of Symbols is available at [beckman.com/techdocs](http://beckman.com/techdocs) (PN C24689).

Original Instructions

# Revision History

**Version AA, Initial Issue October 2020**

Software version 2.2

*This document applies to the latest software listed and higher versions. When a subsequent software version affects the information in this document, a new issue will be released to the Beckman Coulter Web site. For labeling updates, go to [www.beckman.com/techdocs](http://www.beckman.com/techdocs) and download the latest version of the manual for your instrument.*



# Safety Notice

Read all product manuals and consult with Beckman Coulter-trained personnel before attempting to operate instrument. Do not attempt to perform any procedure before carefully reading all instructions. Always follow product labeling and manufacturer's recommendations. If in doubt as to how to proceed in any situation, [contact us](#). Beckman Coulter recommends that only persons who have completed the AQUIOS CL Basic Operator Online Training and AQUIOS CL Advanced Operator Online Training operate the system to create tests.

Beckman Coulter, Inc. urges its customers and employees to comply with all national health and safety standards such as the use of barrier protection. This may include, but is not limited to, protective eyewear, gloves, and suitable laboratory attire when operating or maintaining this or any other automated laboratory analyzer.

## Alerts for Warning, Caution, Important, and Note

---



**WARNING** indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis.



**CAUTION** indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis.

**IMPORTANT** IMPORTANT is used for comments that add value to the step or procedure being performed. Following the advice in the IMPORTANT adds benefit to the performance of a piece of equipment or to a process.

**NOTE** NOTE is used to call attention to notable information that should be followed during installation, use or maintenance of this equipment.

 **WARNING**

Risk of operator injury if:

- All doors, covers, and panels are not closed and secured in place prior to and during instrument operation.
- The integrity of safety interlocks and sensors is compromised.
- Instrument alarms and error messages are not acknowledged and acted upon.
- You contact moving parts.
- You mishandle broken parts.
- Doors, covers, and panels are not opened, closed, removed, and/or replaced with care.
- Improper tools are used for troubleshooting.

To avoid injury:

- Keep doors, covers, and panels closed and secured in place while the instrument is in use.
- Take full advantage of the safety features of the instrument. Do not defeat safety interlocks and sensors.
- Acknowledge and act upon instrument alarms and error messages.
- Keep away from moving parts.
- Report any broken parts to your Beckman Coulter Representative.
- Open/remove and close/replace doors, covers, and panels with care.
- Use the proper tools when troubleshooting.

 **CAUTION**

System integrity could be compromised and operational failures could occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
- You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.
- You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.
- You connect external devices such as thumb drives, external hard drives, and CD/DVDs. Ensure that all external devices are free from viruses before connecting.



 **CAUTION**

If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, [contact us](#).

 **WARNING**

Risk of personal injury if the instrument cover is removed or a door is left open due to possible exposure to high voltages, laser radiation, and/or moving parts. Never operate the instrument without a cover or with a door opened.

 **WARNING**

Risk of personal injury. The laser beam can cause eye damage if viewed either directly or indirectly from reflective surfaces (such as a mirror or shiny metallic surfaces). To prevent eye damage, avoid direct exposure to the laser beam. Do not view it directly or with optical instruments.

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## Related Documents

# Illustrations

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- 1.2 [Reconnect USB Cable, 1-3](#)
- 1.3 [Overview of Power and Signal Cables Connections \(Windows 10\), 1-4](#)



## Overview

---

The Signal Tower allows you to see when there is an interaction that is necessary, the light will display either Red or Amber, or Green.

## Specifications

---

For the specification for the Signal Tower, refer to the manufacturer's instructions.

## Related Documents

---

Keep this Addendum with your current product documentation. Use the AQUIOS CL Instructions For Use manual, PN B21896, along with this Addendum.

The AQUIOS System Software manages the sample preparation process. Refer to the Sample Processing chapter in the AQUIOS CL Instructions For Use manual for additional information.

## About this Addendum

---

This AQUIOS Addendum contains the following information:

- [Introduction](#)
- [System Overview](#)
- [Startup and Shutdown](#)

## Conventions

---

This addendum uses the following conventions:

- [Blue](#) text indicates that you can click on the text to access related information.
- **Bold font** indicates a screen icon, menu item, or software option on the Workstation screen.
- *Italics font* indicates screen text displayed on the Workstation.

- The term ‘select’ is used to indicate either one or both of the following actions:
  - to tap or touch your finger to the touch screen of the computer
  - to click with a mouse
- Tabs in the software are blue when not selected and inactive. Tabs in the software turn green when selected and active.

## Graphics

---

All graphics, including screens and printouts, are for illustration purposes only and must not be used for any other purpose.

## Overview

---

This chapter contains information about the AQUIOS Signal Tower and how they are used in conjunction with your AQUIOS CL Flow Cytometer. This section includes information on [System Components](#) which includes information on the Signal Tower, and [System Connections](#).

## System Components

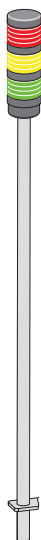
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### Cytometer with Stand and Signal Tower

#### Signal Tower (Optional)

The Signal Tower may be purchased separately from Beckman Coulter and is only applicable to Windows 10. See [Figure 1.1](#). The Signal Tower will be installed onto the customer's bench if purchased separately. The Signal Tower is installed by Service Personnel only.

**Figure 1.1** Signal Tower



- **Red** - The system is not running samples or requires attention.
- **Amber** - System is experiencing a reagent volume, plate, or waste issue that will result in not being able to run samples (a red light) if not addressed.
- **Green** - Samples are running properly.

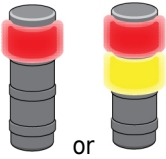
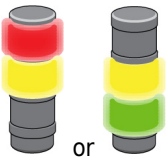
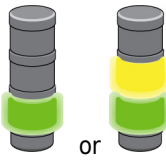
## Signal Tower Operations

**IMPORTANT** In order for the Signal Tower to work successfully, you must enable **Pause for QC**.

Once the Signal Tower is installed on your system, it is enabled once you are logged onto the AQUIOS system.

Table 1.1 lists the possible lights, behaviors, and the conditions of each light.

**Table 1.1** Signal Tower Lights

Light	Behavior	Condition
	Red light is on. The amber light may be on as well.	<p>The System has stopped. This could be because:</p> <ul style="list-style-type: none"> <li>The system successfully finished running samples.</li> <li>There was a system error.</li> <li>Pause for QC is enabled and QC fails.</li> </ul> <p>The amber light may or may not be on.</p>
	Amber light is on, and either the red or green light is on.	<p>The amber light indicates the condition of reagents, plate and waste needing attention.</p> <p>The amber light always occurs in combination with either the green or red light.</p> <p>For the amber light to turn on; the system components must have the following:</p> <ul style="list-style-type: none"> <li>Plate - No plate, no wells available, low wells (based on setting).</li> <li>Antibodies/Lyse/Flow Count - Level low (based on setting) or empty.</li> <li>Sheath - Level low or empty.</li> <li>Waste - Full.</li> </ul>
	Green light is on. The amber light may be on as well.	<p>Indicates that the instrument is running samples. The light will change from red to green when the sample changes from the <b>Add Request</b> tab to the <b>Running</b> tab and there is at least one sample in the <b>Running</b> tab.</p>



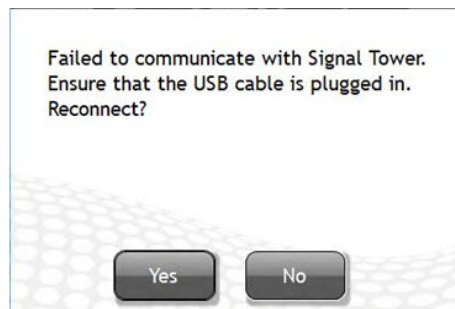
If you accidentally disconnect the Signal Tower, see [Reconnecting the USB Hub for the Signal Tower](#) for instructions on reconnecting it.

### Reconnecting the USB Hub for the Signal Tower

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- 1 Reconnect the USB Cable to the USB Hub.
- 2 Select **Yes** to turn on the Signal Tower. See [Figure 1.2](#).

**Figure 1.2** Reconnect USB Cable



## System Connections

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### Power and Signal Cable Connections

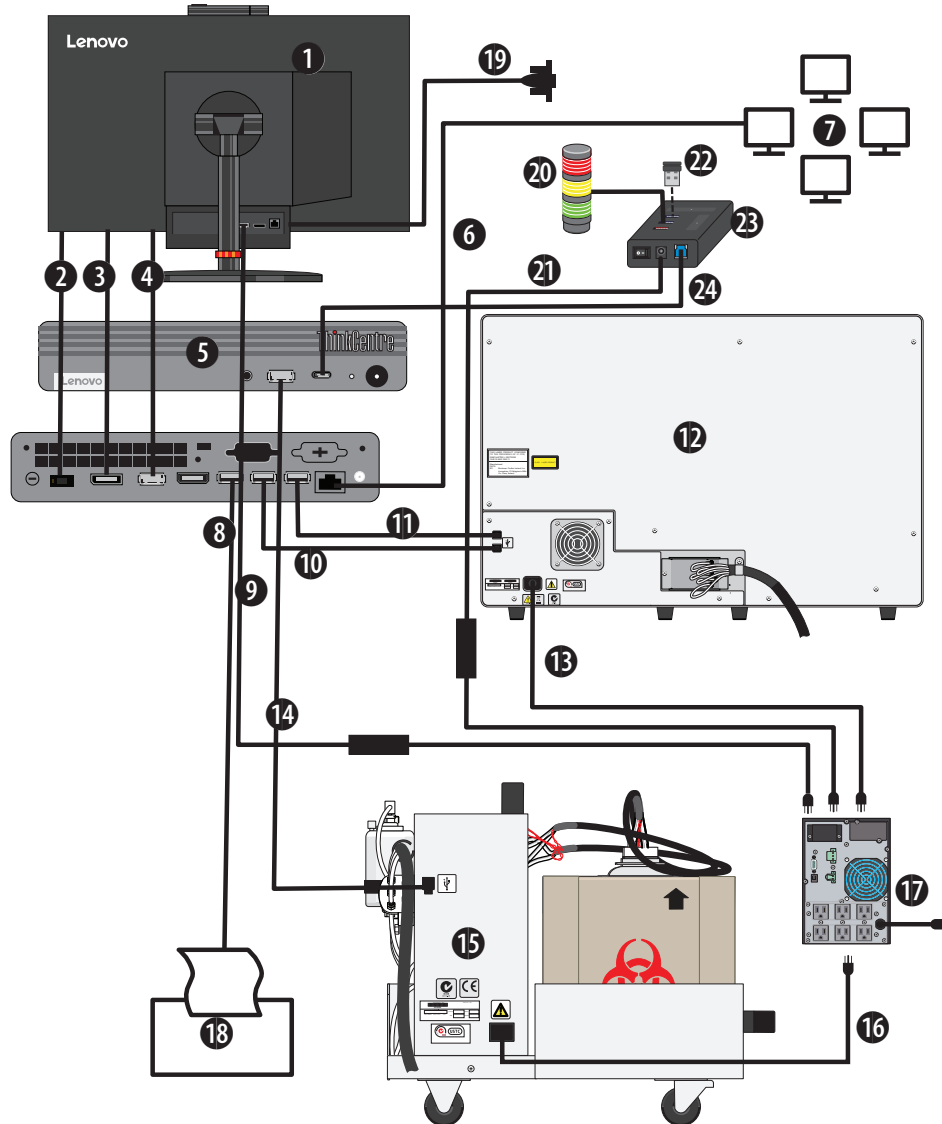


#### **WARNING**

**Risk of interference with instrument communications which may affect instrument performance. The USB Cables to the Instrument (10 and 11) and the USB Cable to the Reagent /Pneumatic Cart (14) cannot be plugged into the USB Hub (23) under any circumstances.**

[Figure 1.3](#) shows the inter-unit connections of the power and signal cables.

Figure 1.3 Overview of Power and Signal Cables Connections (Windows 10)



- |  |  |
|--|--|
| <ol style="list-style-type: none"> <li>1. Tiny-In-One Monitor</li> <li>2. Power Connection - workstation to monitor when docked</li> <li>3. Video connection - workstation to monitor when docked</li> <li>4. USB - workstation to monitor when docked</li> <li>5. Tiny-In-One Workstation</li> <li>6. RJ45 Ethernet Cable to Lab network</li> <li>7. Laboratory Network</li> <li>8. USB A 2.0 Cable to printer</li> <li>9. Power Adapter from Tiny-in-One monitor to UPS</li> <li>10. USB A 2.0 Cable to instrument</li> <li>11. USB A 2.0 Cable to instrument</li> </ol> | <ol style="list-style-type: none"> <li>12. AQUIOS Cytometer</li> <li>13. Power Cable from instrument to UPS</li> <li>14. USB A 2.0 Cable to Reagent/Pneumatic Cart</li> <li>15. Instrument Reagent/Pneumatic Cart</li> <li>16. Power Cable from Reagent/Pneumatic Cart to UPS</li> <li>17. UPS</li> <li>18. Printer</li> <li>19. USB A to Serial Adapter for LIS Connection (optional)</li> <li>20. Signal Tower (connected via USB A 2.0 to USB)</li> <li>21. Power Adapter from USB Hub to UPS</li> <li>22. USB A Receiver for wireless and keyboard (connected with USB C to A adapter)</li> <li>23. USB Hub</li> <li>24. USB A 2.0 Cable to USB Hub</li> </ol> |
|--|--|

**NOTE** Computer configurations may vary.

## Signal Tower Software Initialization

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**IMPORTANT** In order for the Signal Tower to work successfully, you must enable **Pause for QC**.

**NOTE** If you intend to run samples, refer to Daily Startup in the AQUIOS CL Instructions For Use.

**NOTE** The AQUIOS Signal Tower Software can only be used once you are logged onto the system.

### Startup

#### Software Initialization

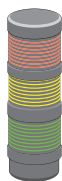
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- 1 Login to the system. Refer to Chapter 3, Daily Startup in the AQUIOS CL Instructions for Use.

**NOTE** The Signal Tower automatically activates once you log on the system.

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- 2 At the beginning of the software initialization, all lights are off at startup.



Each light turns on and off, one at a time. This sequence will be repeated three times. This verifies that all lights are operational.

After the light test is completed, the system assesses its status and the Signal Tower will display a solid Red light and the status of the reagents on the system.



## Shutdown

- 
- 1 Exit the system software.
- 
- 2 The software turns off all lights when exiting the software.
-



## Related Documents

**AQUIOS Addendum for Signal Tower**

PN C64389

**AQUIOS CL Flow Cytometer Instructions for Use**

PN B21896

**AQUIOS Host Transmission**

PN B26365

[www.beckman.com](http://www.beckman.com)

