WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: Determine HIV Early Detect
WHO reference number: PQDx 0243-013-00

Determine HIV Early Detect with product codes **7D2842, 7D2843, 7D2843SET and 7D2843SETS,** manufactured by **Abbott Diagnostic Medical Co. Ltd.**, **Rest-of-World regulatory version**, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 11 July 2016.

Summary of the WHO prequalification assessment for the Determine HIV Early Detect

	Date	Outcome
PQ listing	11 July 2016	listed
Dossier review	19 January 2016	MR
Site inspection(s) of the quality management system	29-31 March 2023	MR
Laboratory evaluation	13 November 2015	MR

MR: Meets requirements

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which the 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	Change of physical address of the Chiba Logistics Center to 483-2 Matsuhidai, Matsudo-shi, Chiba, 270-2214 Japan	18 October 2016
3.0	Introduction of safety blood lancets as a component of whole blood assay SET. Addition of new configurations of its IVDs, where lancets currently provided with the IVDs are replaced with contact-activated safety lancets. Addition of a product code that corresponds with the new safety lancet (7D2843SETS (Alere Determine HIV-Combo)).	1 March 2017

4.0	Shelf life extension of the Chase Buffer (7D2243) from 18 to 24 months. The Chase Buffer is included in the following SET products: PQDx 0243-013-00: Alere HIV Combo SET(7D2843SET) (100 tests/kit set for whole blood assay). Alere™ HIV Combo SETS(7D2843SETS) (100 tests/kit set for whole blood assay with safety lancet). Instruction for use (IFU) was updated. The updated points were related to limitations of the procedure and updated more points to clarify the current descriptions of the product.	26 November 2018
5.0	Change of the company name from Alere Medical Co., Ltd. to Abbott Diagnostics Medical Co., Ltd. Change the product name from Alere HIV Combo to Determine HIV ULTRA.	29 January 2020
6.0	Change of product name from Determine HIV Ultra to Determine HIV Early Detect. The product itself is completely the same.	15 July 2020
7.0	Determine HIV Early Detect SET", 7D2843SET, was added next to "7D2843" on the top of the IFU. Introduction of Lot. Number and EXP in each test strip. Downsizing of Determine HIV Early Detect SET for the benefits of shipments and storage. This SET Downsizing includes the change of Capillary Tubes from glass to plastic. Plastic is safer than glass.	14 April 2022
8.0	Updated the labelling of the Chase Buffer (7D2243) included in each SET product.	14 July 2023
9.0	1. IFU updated for the Determine HIV Early Detect based on the Gap Assessment against TSS-1. 2. Removed the CE mark from the included lancets from the external supplier; Health Canada registration of the lancets is retained.	18 September 2025

Intended use:

According to the claim of intended use by the manufacturer, "*Determine HIV Early Detect is an in vitro, visually read, qualitative immunoassay for the detection of antibodies (Ab) to HIV-1 and HIV-2 and the detection of non-immuno complexed (free) HIV-1 p24 antigen (Ag) in human capillary and venous whole blood, plasma or serum. Therefore, any reactivity on 1) the Ab bar alone 2) the Ag bar alone or 3) both the Ab and Ag bars simultaneously, is considered a reactive result suggestive of infection with HIV. The test is for professional use only and intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection in adults and children over the age of 18 months*".

Assay description:

According to the claim of intended use by the manufacturer, *"Determine HIV Early Detect is an immunochromatographic test for the qualitative detection of free HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2. Specimen is added to the sample pad. The specimen mixes with biotinylated anti-p24 antibodies and selenium colloid-conjugates coated with recombinant HIV-1, HIV-2 and HIV-1 group O antigens, synthetic HIV-2 peptide and anti p24 mouse monoclonal antibody. This mixture continues to migrate through the solid phase to the immobilized recombinant HIV-1/HIV-1 group O antigens and synthetic HIV-1/HIV-2 peptides at the Antibody (Ab) window, immobilized avidin at the Antigen (Ag) window. If antibodies to HIV-1 and/or HIV-2 are present in the specimen, the antibodies bind to the selenium colloid-conjugates coated with recombinant HIV-1, HIV-2 and HIV-1 group O antigens and synthetic HIV-2 peptide and to the immobilized recombinant HIV-1/HIV-1 group O antigens and synthetic HIV-1/HIV-2 peptides, forming one red bar at the Ab window site. If antibodies to HIV-1 and HIV-2 are absent, the selenium colloid conjugates flow past the Ab window and no red bar is formed at the Ab window site.*

If free HIV-1 p24 antigen is present in the specimen, the antigen binds to the biotinylated anti-p24 antibodies and the selenium colloid-conjugate coated with anti p24 mouse monoclonal antibody. This complex binds to the immobilized avidin forming a red bar at the Ag window site. If HIV-1 p24 antigen is not present, both the biotinylated anti-p24 antibodies and selenium colloid-conjugate flow past the Ag window and no red bar is formed at the Ag window site.

To ensure assay validity, a procedural control bar is incorporated in the assay device at the Control window."

Test kit contents:

Component	20 tests (product code 7D2842)	100 tests (product code 7D2843)	100 tests (product code 7D2843SET)	100 tests (product code 7D2843SETS)
Determine HIV Early Detect Test Card	2 cards of 10 tests	10 cards of 10 tests	20 cards of 5 tests	10 cards of 10 tests
Instructions for use (IFU)	1	1	1	1
Chase Buffer, prepared in phosphate buffer (7D2243)	Not provided	Not provided	1x 2.5ml bottle and IFU	1x 2.5ml bottle and IFU
Plastic capillary tubes	Not provided	Not provided	100	Not provided
EDTA Capillary tubes, glass (7D2222)	Not provided	Not provided	Not provided	100

Blood lancets, sterile	Not provided	Not provided	100	Not provided
Blood lancets, sterile (safety)	Not provided	Not provided	Not provided	100

Items required but not provided:

For all product codes

- Disposable gloves, timing device
- Micropipette capable of delivering 50 µL (other than fingerstick)
- Alcohol swab, gauze pad, lancet (for fingerstick).

For testing Whole Blood samples

- Chase Buffer (7D2243) 1 Bottle (2.5 mL) prepared in phosphate buffer. Preservatives: Antimicrobial Agents.

For testing Whole Blood samples (fingerstick assay)

- EDTA Capillary Tubes (7D2222). This is required for 7D2842 and 7D2843.

- For 7D2843SET, Plastic capillary tubes are provided within the SET.

Storage:
The test kit should be stored at 2 – 30°C.

Shelf life upon manufacture:
18 months for Determine HIV Early Detect test card.

Warnings/limitations:
Refer to the instructions for use.

Prioritization for prequalification:

Based on the established eligibility criteria, Determine HIV Early Detect (formerly Alere HIV Combo and Determine HIV ULTRA) was given priority for the WHO prequalification assessment.

Product dossier assessment

Abbott Diagnostic Medical Co. Ltd. (formerly called Alere Medical Co. Ltd) submitted a product dossier for Determine HIV Early Detect as per the "Instructions for compilation of a product dossier" (PQDx_018 v1). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The manufacturer's responses to the discrepancies found during dossier screening and assessment findings were accepted on 19 January 2016.

Based on the product dossier screening and assessment findings, the product dossier for Determine HIV Early Detect meets WHO prequalification requirements.

Manufacturing site inspection

At the time of considering the product application for Prequalification, the Manufacturer of the product had a well-established quality management system and manufacturing practices in place that would support the manufacture of a product of consistent quality. Routine inspections of the Manufacturing site will be conducted with copies of the WHO Public Inspection Report (WHOPIR) published on the WHO Prequalification web page as per Resolution WHA57.14 of the World Health Assembly. Note that a WHOPIR reflects the information on the most current assessment performed at a manufacturing site for in vitro diagnostic products and summarises the assessment findings.

https://extranet.who.int/pqweb/vitro-diagnostics/who-public-inspection-reports

All published WHOPIRs are with the agreement of the manufacturer.

Based on the site inspection and corrective action plan review, the quality management system for Determine HIV Early Detect meets WHO prequalification requirements.

Product performance evaluation

Determine HIV Early Detect was evaluated by WHO in the 3rd quarter of 2015 using serum/plasma specimens. From this evaluation, we drew the following conclusions:

Determine HIV Early Detect is a lateral flow immunochromatographic rapid diagnostic test for the detection of HIV-1/2 antibodies and HIV-1 p24 antigen in human serum/plasma and venous/capillary whole blood specimens. A volume of 50 µL of specimen is needed to perform the assay. This type of assay requires no sophisticated equipment and can therefore

be performed in laboratories with limited facilities and non-laboratory settings. Reading of the results can be done visually, i.e. subjectively read.

In this limited evaluation on a panel of 1119 specimens, we found an initial sensitivity (95% CI) of 100% (99.2% - 100%) and an initial specificity (95% CI) of 98.9% (97.8% - 99.6%) compared to the reference assays. The final sensitivity (95% CI) was 100% (99.2% - 100%), and the final specificity (95% CI) was 99.4% (98.4% - 99.8%) compared to the reference assays. Lot to lot variation observed was within the acceptance range.

For eight seroconversion panels, Determine HIV Early Detect detected HIV-1 antigen and/or HIV-1/2 antibodies on average 0.875 specimens earlier than the benchmark assay (Enzygnost Anti-HIV 1/2 Plus [Siemens Healthcare Diagnostics]. It also detected HIV-1 p24 antigen on average 0.5 specimens later than INNOTEST HIV p24 Antigen mAb (Fujirebio Europe).

25/25 specimens were characterized for the presence of HIV infection correctly through the detection of either presence of antigen or antibody. Of the 25 specimens, 23 contained HIV-1/2 antibodies, Determine HIV Early Detect identified all 23 specimens. Of the 25 specimens, 12 contained detectable HIV p24 antigen, Determine HIV Early Detect identified 5 specimens.

25/25 specimens were characterized for the presence of HIV infection correctly through the detection of either presence of antigen or antibody. Of the 25 specimens, 11 contained HIV-1/2 antibodies, Determine HIV Early Detect identified all 11 specimens. Of the 25 specimens, 22 specimens contained detectable HIV p24 antigen, Determine HIV Early Detect identified 13 specimens.

For the HIV culture supernatant panel, Determine HIV Early Detect detected all HIV-1 subtypes and the HIV-2 culture isolate was also detected.

For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], Determine HIV Early Detect detected all subtypes tested (HIV-1 A, HIV-1 B, HIV-C, HIV-1 CRF01_AE, HIV-1 O and HIV-2).

For the HIV-1 p24 antigen standard [NIBSC code 90/636], Determine HIV Early Detect detected to 3.125 international units. In contrast, Vironostika HIV Ag/Ab (bioMérieux) detected to 12.5 international units.

In this study, 0% of the results were recorded as indeterminate. Results were interpreted independently by three technicians; the overall inter-reader variability was 0.18%. The invalid rate was 0%.

Performance characteristics in comparison with an agreed reference standard		
	Initial (95% CI)	**Final (95% CI)**
Sensitivity %	100.0%	100.0%
Specificity %	98.9%	99.4%
Invalid rate %	0%	
Inter-reader variability %	0.18%	
Additional performance characteristics		
Sensitivity during seroconversion on 8 seroconversion panels in comparison with a benchmark assay (3rd generation EIA); Enzygnost Anti-HIV 1/2 Plus	Seroconversion sensitivity index of -0.875. Therefore, detection is 0.875 specimens earlier than the benchmark assay (Enzygnost Anti-HIV 1/2 Plus).	
Sensitivity during seroconversion on 8 seroconversion panels in comparison with a p24 antigen EIA; INNOTEST HIV p24 Antigen mAb	Seroconversion sensitivity index of +0.5. Therefore detection is 0.5 specimens later than INNOTEST HIV p24 Antigen mAb.	
Analytical sensitivity on a mixed titer panel in comparison with an agreed reference standard	25/25 specimens were characterized for the presence of HIV infection correctly through the detection of either presence of antigen or antibody.	
Analytical sensitivity on an HIV p24 antigen panel in comparison with an agreed reference standard	25/25 specimens were characterized for the presence of HIV infection correctly through the detection of either presence of antigen or antibody.	
Lot to lot variation on a dilution panel in comparison with an agreed reference standard	Acceptable	

Key operational characteristics	
Validated specimen types	Serum, plasma (EDTA), venous whole blood (EDTA), and capillary whole blood.
Number of steps	2 steps are required, if finger stick/venous whole blood 1 step with the precision required if serum/plasma.
Time to result	20 minutes after the specimen was added.
Endpoint stability	40 minutes after the specimen was added.
Internal QC	Yes. The procedural control indicates the successful flow of reagents along the test strip. It does not indicate if a specimen or sufficient specimen has been added.
In-use stability of reagents	Same as the expiry date on the test kit outer packaging.

Labelling

1. 7D2842, 7D2843

1.1 Labels

1.1.1 7D2842 Outer Label

1.1.2 7D2843 Outer Label

1.2 Instruction For Use

2. 7D2843SET

2.1 Labels

2.1.1 Outer Box Label (7D2843SET)

2.1.2 100 Test Pouch Label (7D2843SET)

2.1.3 Chase Buffer Bottle Label (7D2843SET)

2.1.4 Capillary Tubes Label (7D2843SET)

2.1.5 Sterile Blood Lancet Label (7D2843SET)

2.2 Instruction For Use

1. 7D2842, 7D2843

1.1 Labels

1.1.1 7D2842 Outer Label

DETERMINE™

HIV EARLY DETECT

4 571226 473818

EN

Determine™ HIV Early Detect is an *in vitro*, visually read, qualitative immunoassay for the detection of antibodies (Ab) to HIV-1 and HIV-2 and the detection of non-immunocomplexed (free) HIV-1 p24 antigen (Ag) in human capillary and venous whole blood, plasma or serum.
For professional use only.
7D2243 Chase buffer is required for whole blood testing.
Kit contains:
2 test cards coated with HIV-1/2 recombinant antigen and synthetic peptides, antibodies to p24 antigen and avidin.

2°C – 30°C | Σ 20 | IVD | REF 7D2842

ES

Determine™ HIV Early Detect es un inmunoanálisis cualitativo *in vitro* con lectura visual para la detección de anticuerpos (Ab) a VIH-1 y VIH-2 y la detección del antígeno (Ag) no inmunocomplejo p24 del VIH-1 (en forma libre) en sangre total humana capilar y venosa, plasma o suero.
Solo para uso profesional.
7D2243 Se requiere buffer de detección para todas las pruebas por sangre.
Contenido del kit:
2 tarjetas de prueba recubiertas con antígeno HIV-1/2 recombinante y péptidos sintéticos, anticuerpos al antígeno p24 y avidina.

FR

Determine™ HIV Early Detect est un test immunologique qualitatif *in vitro* à lecture visuelle pour la détection des anticorps (Ab) anti-VIH-1 et anti-VIH-2 et la détection de l'antigène (Ag) p24 du VIH-1 libre non immunocomplexé dans le sang total par prélèvement capillaire ou veineux, plasma ou sérum humain.
À usage professionnel uniquement.
La solution tampon de migration 7D2243 est nécessaire pour tester les échantillons de sang total.
Ce kit contient:
2 planches de tests recouverts d'un antigène recombinant et de peptides de synthèse correspondant aux VIH-1/2, d'anticorps dirigés contre l'antigène p24 du VIH-1 et d'avidine.

PT

Determine™ HIV Early Detect é um ensaio imunológico qualitativo de leitura visual *in vitro* para a deteção de anticorpos (Ab) ao VIH-1 e VIH-2 e do antigénio (Ag) p24 do VIH-1 não imunocomplexo (livre) em sangue total capilar e venoso, plasma ou soro humano.
Exclusivamente para uso profissional.
7D2243 É necessário o tampão de detecção para realizar análises em sangue total.
O Conteúdo do kit:
2 cartões de testes revestidos com antigénio recombinante de VIH-1/2 e peptídeos sintéticos, anticorpos anti-p24 e avidina.

Abbott Diagnostics Medical Co., Ltd.
357 Matsuhidai, Matsudo-shi, Chiba, 270-2214, Japan
Tel +81 47 311 5750

241848/R6

Determine HIV Early Detect **ROW** 2 Test Pouch Label **PN:** 241848/R6	**Pouch Size:** 544mm(w) x 160mm(h) **Label Artwork Size:** 204mm(w) x 132mm(h)	PMS 303 Pantone 2577 White

1.1.2 7D2843 Outer Label

DETERMINE™

HIV EARLY DETECT

Abbott

4 571226 473825

2°C 30°C | Σ 100 | IVD

REF 7D2843

EN

Determine™ HIV Early Detect is an *in vitro*, visually read, qualitative immunoassay for the detection of antibodies (Ab) to HIV-1 and HIV-2 and the detection of non-immunocomplexed (free) HIV-1 p24 antigen (Ag) in human capillary and venous whole blood, plasma or serum.

For professional use only.

7D2243 Chase buffer is required for whole blood testing.

Kit contains:
10 test cards coated with HIV-1/2 recombinant antigen and synthetic peptides, antibodies to p24 antigen and avidin.

ES

Determine™ HIV Early Detect es un inmunoanálisis cualitativo *in vitro* con lectura visual para la detección de anticuerpos (Ab) a VIH-1 y VIH-2 y la detección del antígeno (Ag) no inmunocomplejo p24 del VIH-1 (en forma libre) en sangre total humana capilar y venosa, plasma o suero.

Solo para uso profesional.

7D2243 Se requiere buffer de detección para todas las pruebas por sangre.

Contenido del kit:
10 tarjetas de prueba recubiertas con antígeno HIV-1/2 recombinante y péptidos sintéticos, anticuerpos al antígeno p24 y avidina.

FR

Determine™ HIV Early Detect est un test immunologique qualitatif *in vitro* à lecture visuelle pour la détection des anticorps (Ab) anti-VIH-1 et anti-VIH-2 et la détection de l'antigène (Ag) p24 du VIH-1 libre non immunocomplexé dans le sang total par prélèvement capillaire ou veineux, plasma ou sérum humain.

À usage professionnel uniquement.

La solution tampon de migration 7D2243 est nécessaire pour tester les échantillons de sang total.

Ce kit contient:
10 planches de tests recouverts d'un antigène recombinant et de peptides de synthèse correspondant aux VIH-1/2, d'anticorps dirigés contre l'antigène p24 du VIH-1 et d'avidine.

PT

Determine™ HIV Early Detect é um ensaio imunológico qualitativo de leitura visual *in vitro* para a deteção de anticorpos (Ab) ao VIH-1 e VIH-2 e do antigénio (Ag) p24 do VIH-1 não imunocomplexo (livre) em sangue total capilar e venoso, plasma ou soro humano.

Exclusivamente para uso profissional.

7D2243 É necessário o tampão de detecção para realizar análises em sangue total.

O Conteúdo do kit:
10 cartões de testes revestidos com antigénio recombinante de VIH-1/2 e peptídeos sintéticos, anticorpos anti-p24 e avidina.

Abbott Diagnostics Medical Co., Ltd.
357 Matsuhidai, Matsudo-shi, Chiba, 270-2214, Japan
Tel +81 47 311 5750

241849/R7

Determine HIV Early Detect **ROW** 100 Test Pouch Label **PN:** 241849/R7	**Pouch Size:** 544mm(w) x 160mm(h) **Label Artwork Size:** 204mm(w) x 132mm(h)	PMS 303 Pantone 2577 White

1.2 Instruction For Use (IFU)[1]

[1] 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.

DETERMINE™ HIV EARLY DETECT

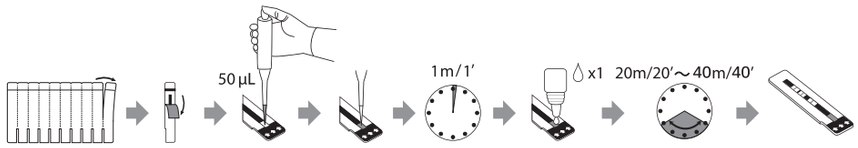
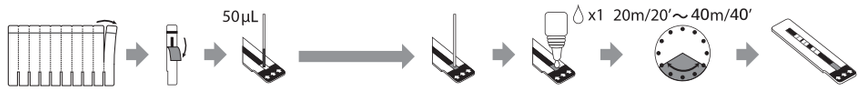
Abbott

Read Highlighted Changes

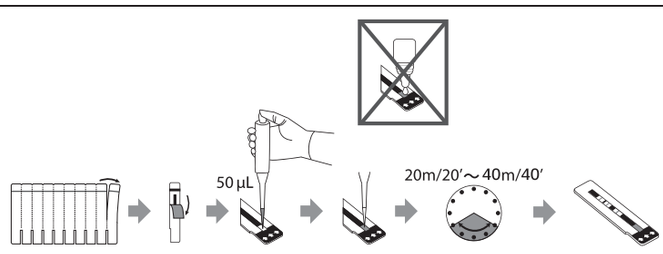
REF 7D2842, 7D2843

January 2025
D10193271_AA

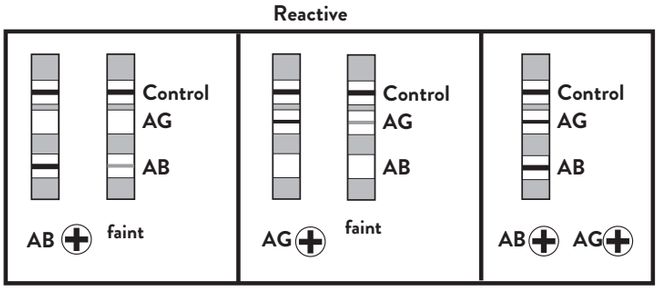
Whole Blood / Sangre Total / Sang Total / Sangue Total

Pipette Pipeta Pipette Pipeta	
EDTA Capillary Tubes Tubos capilares EDTA Tubes capillaires avec EDTA Tubos Capilares EDTA	

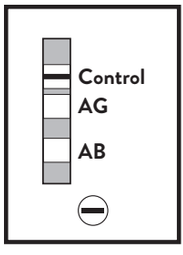
Serum, Plasma / Suero, Plasma / Sérum, Plasma / Soro, Plasma

Pipette Pipeta Pipette Pipeta	

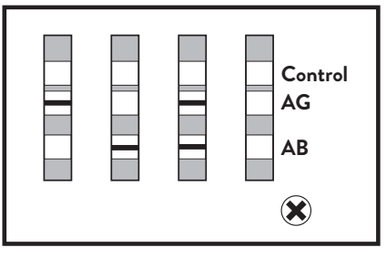
Reactive



Non-Reactive



Invalid



Abbott Diagnostics Medical Co., Ltd.
357 Matsuhidai, Matsudo-shi,
Chiba, 270-2214 Japan

EN

January 2025
D10193271_AA

This package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are deviations from the instructions in this package insert.

NAME AND INTENDED USE

Determine™ HIV Early Detect is an *in vitro*, visually read, qualitative immunoassay for the detection of antibodies (Ab) to HIV-1 and HIV-2 and the detection of non-immunocomplexed (free) HIV-1 p24 antigen (Ag) in human capillary and venous whole blood, plasma or serum. Therefore, any reactivity on 1) the Ab bar alone 2) the Ag bar alone or 3) both the Ab and Ag bars simultaneously, is considered a reactive result suggestive of infection with HIV. The test is for professional use only and intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection in adults and children over the age of 18 months.

SUMMARY AND EXPLANATION OF THE TEST

AIDS (Acquired Immunodeficiency Syndrome) is characterized by changes in the population of T-cell lymphocytes. In an infected individual, the virus causes depletion of CD4 helper T-cells, which leaves the person susceptible to opportunistic infections and some malignancies. The virus that causes AIDS exists as two related types known as HIV-1 and HIV-2. The multiplication of the HIV in the infected cells leads to cell rupture and thus the release of HIV virus particles, which are first detected in the form of HIV RNA and next in the form of HIV antigen.[1,2] This is followed by production of specific antibodies to either HIV-1 or HIV-2.[3,4,5] HIV antigen may become undetectable at this time because of the formation of antibody-antigen complexes.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

Determine HIV Early Detect is an immunochromatographic test for the qualitative detection of free HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2.
Specimen is added to the sample pad. The specimen mixes with biotinylated anti-p24 antibodies and selenium colloid-conjugates coated with recombinant HIV-1, HIV-2 and HIV-1 group O antigens, synthetic HIV-2 peptide and anti p24 mouse monoclonal antibody. This mixture continues to migrate through the solid phase to the immobilized recombinant HIV-1/HIV-1 group O antigens and synthetic HIV-1/HIV-2 peptides at the Antibody (Ab) window, immobilized avidin at the Antigen (Ag) window.
If antibodies to HIV-1 and/or HIV-2 are present in the specimen, the antibodies bind to the selenium colloid-conjugates coated with recombinant HIV-1, HIV-2 and HIV-1 group O antigens and synthetic HIV-2 peptide and to the immobilized recombinant HIV-1/HIV-1 group O antigens and synthetic HIV-1/HIV-2 peptides, forming one red bar at the Ab window site. If antibodies to HIV-1 and HIV-2 are absent, the selenium colloid-conjugates flow past the Ab window and no red bar is formed at the Ab window site.
If free HIV-1 p24 antigen is present in the specimen, the antigen binds to the biotinylated anti-p24 antibodies and the selenium colloid-conjugate coated with anti p24 mouse monoclonal antibody. This complex binds to the immobilized avidin forming a red bar at the Ag window site. If HIV-1 p24 antigen is not present, both the biotinylated anti-p24 antibodies and selenium colloid-conjugate flow past the Ag window and no red bar is formed at the Ag window site.
To ensure assay validity, a procedural control bar is incorporated in the assay device at the Control window.

CONTENTS

Determine HIV Early Detect 20 Test (7D2842) or 100 Test (7D2843)

- **Determine** HIV Early Detect Test Card, 2 or 10 cards (containing 10 tests/card) coated with HIV-1/2 recombinant antigen, synthetic peptides, anti-p24 antibodies and avidin.

Accessories (required but not provided)

For testing Whole Blood samples

- Chase Buffer (7D2243) 1 Bottle (2.5 mL) prepared in phosphate buffer. Preservatives: Antimicrobial Agents.

For testing Whole Blood samples (fingerstick assay)

- EDTA Capillary Tubes (7D2222)

Determine HIV Early Detect SET (7D2843SET) (100 Test for testing whole blood samples)

- Determine HIV Early Detect (7D2843)
- Chase Buffer (7D2243)
- EDTA Capillary Tubes (7D2222)
- Blood Lancet (7D2233)

Materials Required But Not Provided

- Disposable gloves, timing device
- Micropipette capable of delivering 50 µL (other than fingerstick)
- Alcohol swab, clean or sterile gauze pad, lancet (for fingerstick)

WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use.
For professional use only.
Safety data sheet available for professional user on request.

CAUTION: When handling specimens and reagents, use appropriate biosafety practices[7,8]. These precautions include, but are not limited to the following:

- Wear gloves.
- Do not pipette by mouth.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
- Clean and disinfect all spills of specimens or reagents using suitable disinfectant, such as 0.5% sodium hypochlorite, or other suitable disinfectant.[7,8]
- Decontaminate and dispose of all specimens, used test strips, and other potentially contaminated materials in accordance with local regulations.[7,8]

STORAGE

Store **Determine** HIV Early Detect Test Cards and Chase Buffer at 2 °C to 30 °C until expiration date.

- When handled and stored as directed, kit components are stable until the expiration date. Do not use kit components beyond expiration date.
- Immediately reseal all unused tests in the foil pouch containing the desiccant by pressing seal from end to end to close.
- Do not use devices that have become wet or if the packaging has become damaged.

SPECIMEN COLLECTION

Serum, Plasma, and Whole Blood Collection by Venipuncture.

Use EDTA collection tubes for whole blood and plasma specimens.

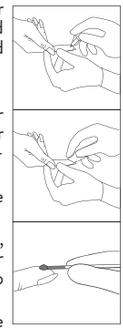
- Collect human serum, plasma and whole blood by venipuncture aseptically.
- To obtain serum, separate from the clot. To obtain plasma, separate from the packed cells. Separate specimens as soon as possible to avoid any hemolysis.

Whole Blood Collection by Fingerstick[6] (See Fig.1)

Use EDTA Capillary Tubes (7D2222).

CAUTION: Glass capillaries may be damaged during transportation or when in use. Handle with care in order to avoid injury when removing from the package as well as during use and during disposal.
Before collecting a fingerstick specimen, place a capillary tube on a clean dry surface.

Fig. 1



1. Choose the fingertip of the middle, ring, or index finger (whichever is the least callused). Warm the hand as needed with a warm, moist towel or warm water to increase blood flow.
2. Clean fingertip with alcohol swab; allow to air dry.
3. Position the hand palm-side up. Place the lancet off-center on the fingertip. Firmly press the lancet against the finger and puncture the skin. Dispose of the lancet in an appropriate biohazard sharps container.
4. Wipe away the first drop of blood with a clean or sterile gauze pad.
5. Hold the finger lower than the elbow and apply gentle, intermittent pressure to the base of the punctured finger several times, avoiding the puncture wound. Touch the tip of the capillary tube to the drop of blood. Avoid air bubbles.
   Fill the tube with blood between the 2 lines marked on the capillary tube.

SPECIMEN STORAGE

- Store serum and plasma specimens at 2 °C to 8 °C and run the test within 7 days of collection. If testing is delayed more than 7 days, freeze the specimen at -20 °C or colder.
- Avoid repeated freeze/thaw cycles.
- If serum or plasma specimens show particulate matter or turbidity, centrifuge at 10,000g for 5 minutes at room temperature before sampling. Carefully remove the 50 µL test sample from the supernatant. If a lipid layer is formed on the surface of the liquid, ensure to take the sample from the clear liquid below that layer.
- For whole blood collected by venipuncture, store at 2 °C to 8 °C. Do not freeze whole blood specimens. Run the test within 7 days of collection.
- For whole blood collected by fingerstick, test immediately.

TEST PROCEDURE

Remove the desired number of test strips from the 10-test card by bending and tearing at the perforation.
The test is to be performed at 15 °C to 30 °C.

NOTE:

- To preserve the lot number which appears on the left side of the test card, remove individual test strips starting from the right side of the test card.
- After removing the protective foil cover from each test strip, start the assay immediately. At under 80 % or less relative humidity, the test can be used within 30 minutes after removing the protective foil cover.
- For serum or plasma, ensure thorough mixing of sample prior to use. For whole blood sample, mix well by gentle inversion of the tube immediately before testing.
- Running the test in high temperature/low humidity may affect the appearance of the Ag or Ab bar. If the test strip is partially dried and difficult to read at 20 to 40 minutes, the test should be repeated using a new test strip and result read at 20 minutes. When the test strip is partially dried, it appears as mixed white spot and grayish area. At 30 °C/ 20 % RH or low humidity conditions, the test strip dries at 40 minutes.
- If serum or plasma sample does not flow or shows abnormal flow, such as stopping in the middle of the window, centrifuge the specimen and repeat the test with a new test strip.

CAUTION: Abnormal flow may occur with a whole blood (fingerstick) sample, if the capillary tube is not placed in the middle of the sample pad at an upright (vertical) position. If this occurs, collect a new sample and repeat the test using a new strip.

1. Remove the protective foil cover from each test.
2. For serum or plasma samples:
   a. Apply 50 µL of sample (precision pipette) to the sample pad (marked by the arrow symbol).
   b. Wait a minimum of 20 minutes from addition of the sample (up to 40 minutes maximum) and read result.
3. For whole blood (venipuncture) samples:
   a. Apply 50 µL of sample (precision pipette) to the sample pad (marked by the arrow symbol).
   b. Wait until the blood is absorbed and there is no droplet on the sample pad (approximately 1 minute), then apply one drop of Chase Buffer to the sample pad, holding the bottle vertically.
   c. Wait a minimum of 20 minutes from addition of the sample (up to 40 minutes maximum) and read result.
4. For whole blood (fingerstick) samples using an EDTA Capillary Tube:
   a. Place the capillary tube containing the blood sample onto the middle of the sample pad (marked by the arrow symbol) at an upright (vertical) position.
   b. Wait until all the blood is transferred from the capillary tube to the sample pad. Then immediately apply one drop of Chase Buffer to the sample pad, holding the bottle vertically.
   Caution: do not lift the capillary tube from the sample pad before all the blood has been transferred – a bubble may form which will prevent the complete transfer of sample and invalidate the test. It may take more than one minute for full transfer of the sample.
   c. Wait a minimum of 20 minutes from addition of the sample (up to 40 minutes maximum) and read result.

QUALITY CONTROL

To ensure assay validity, a procedural control is incorporated in the device and is labeled "C". If the control bar does not appear by assay completion, the test result is invalid. Repeat the test using a new test strip. A visible control bar confirms a lateral flow through the membrane.

INTERPRETATION OF RESULTS (See pictures)

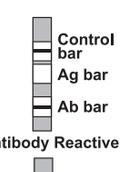
NOTES:

- Any reactivity on 1) the Ab bar alone 2) the Ag bar alone or 3) both, the Ab and Ag bar simultaneously, is considered a reactive result suggestive of infection with HIV.
- Interpret any visible red bar (even very faint) in the control window as a valid result.
- The test result is reactive even if the Ag or Ab bars appear lighter or darker than the control bar. Any visible red bar, no matter how faint, together with a control bar is interpreted as reactive.
- A test that has a very red background color making the Ag, Ab, and Control bars difficult to read, as can occur with hemolytic specimens, should be considered invalid.
- If an invalid result occurs repeatedly, or for technical assistance, contact your local distributor or call Technical Support.

ANTIBODY REACTIVE

(Two Bars - Control and Ab Bars)

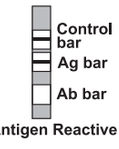
Red bars appear in both the control window (labeled "C") and in the Ab window (labeled "AB") of the strip. Interpret any visible red bar, no matter how faint, in the Ab window as reactive.



Antibody Reactive

ANTIGEN (p24) REACTIVE (Two Bars - Control and Ag Bars)

Red bars appear in both the control window (labeled "C") and in the Ag window (labeled "AG") of the strip. Interpret any visible red bar, no matter how faint, in the Ag window as reactive. The presence of only an antigen

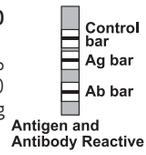


Antigen Reactive

response suggests that the infection is at an early stage. Follow up testing may be suggested in order to track the expected future detection of antibodies.

ANTIBODY REACTIVE AND ANTIGEN (p24) REACTIVE (Three Bars - Control, Ab and Ag Bars)

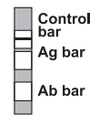
Red bars appear in the control window (labeled "C"), the Ab window (labeled "AB") and the Ag window (labeled "AG") of the strip. Interpret any visible red bar in the Ab and Ag windows as reactive.



Antigen and Antibody Reactive

NON-REACTIVE (One Bar - Control Bar)

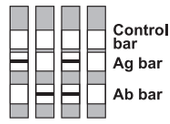
One red bar appears in the control window of the strip (labeled "C"), and no red bar appears in the Ab and Ag windows of the strip (labeled "AG" and "AB").



Non-Reactive

INVALID (No Control Bar)

If there is no red bar in the control window of the strip, and even if a red bar appears in the Ab or Ag window of the strip, the result is invalid. Repeat the test using a new test strip.



Invalid

LIMITATIONS OF THE PROCEDURE

- **Determine** HIV Early Detect is designed to detect antibodies (Ab) to HIV-1 and/or HIV-2 and non-immunocomplexed (free) HIV-1 p24 antigen (Ag), in human serum, plasma and capillary and venous whole blood specimens. Other body fluids or pooled specimens may not give accurate results and should not be used.
- The intensity of the Ab and Ag bars does not necessarily correlate to the titer of antibody and antigen in the specimen, respectively.
- A reactive result for antibodies to HIV-1/2 combined with a non-reactive result for HIV-1 p24 antigen does not preclude the possibility of acute HIV infection.
- Reactivity for both antibody and antigen bar or for antigen reactivity only may be confirmed by 4th generation EIA or NAT where the IVD is indicated as an aid for diagnosis. Antibody reactivity only can also be confirmed by using another HIV Ab RDT. If non-reactive in subsequent testing, retest at least 14 days after the original test is recommended. Follow the local guideline for confirmatory methods if applicable.
- No test provides absolute assurance that a specimen does not contain low levels of HIV-1 p24 antigen and/or antibodies to HIV-1 and HIV-2 such as those present at a very early stage or late stage of HIV infection.
- A non-reactive result for both antibodies to HIV-1/2 and HIV-1 p24 antigen does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2 viruses.
- The absence of Ag bar may occur when all p24 antigen is bound by antibodies. When high levels of antibodies against the p24 antigen are present in the blood after seroconversion, the antibodies tend to bind to the antigens, forming immunocomplexes. **Determine** HIV Early Detect detects only non-immunocomplexed (free) antigens; it does not detect immunocomplexed (bound) antigens.
- Some known HIV-infected persons taking antiretroviral medication have been shown to produce false negative results when tested by rapid diagnostic tests.[10,11,12]
- Where clinical presentation is inconsistent with the non-reactive **Determine** HIV Early Detect test result, the individual should be re-tested for antibodies to HIV with **Determine** HIV Early Detect at least 14 days after the original test, or with a NAT assay that is indicated for diagnosis.
- Whole blood or plasma specimens containing anticoagulants other than EDTA have not been validated for use with the **Determine** HIV Early Detect and may give incorrect results.
- Infants born to HIV-infected mothers may carry maternal antibodies and will test antibody positive until eighteen months of age, which may not necessarily indicate the true infection status of the new born. The use of HIV- 1 p24 antigen testing to exclude infection in neonates (up to around eighteen months) is not recommended by CDC, because of poor sensitivity, especially in the presence of HIV antibody. Definitive diagnosis of HIV infection in early infancy requires other assays, including HIV nucleic acid test or viral culture.[9]
- Biotin treatment higher than 20mg per day may lead to decreased Ag bar intensity. Biotin concentrations up to 200 ng/mL in serum or whole blood did not impact the sensitivity. There is no impact to Ab bar by biotin.

PERFORMANCE CHARACTERISTICS

SENSITIVITY

Sensitivity was evaluated by testing confirmed HIV antibody positive specimens, commercial seroconversion panels and HIV-1 subtype virus panels.

1. HIV Antibody Positive Specimens:

Table I
HIV Antibody Positive Specimens

Types	Number of Specimens Tested	Reactive by **Determine** HIV Early Detect	Sensitivity
HIV-1	422	422	100.0%
HIV-1 non B subtypes *	56	56	100.0%
HIV-1 group O	4	4	100.0%
HIV-2	100	100	100.0%
HIV**	100	100	100.0%
Total	**682**	**682**	**100.0%**

* Subtypes: A, C, D, F, G, H, J, K, and CRF01-AE, CRF02-AG, CRF03-AB, CRF05-DF, CRF09-A/U, CRF11-cpx

** Specimens collected in Europe

A total of 682 confirmed HIV positive specimens were tested (Table I). The antibody diagnostic sensitivity of **Determine** HIV Early Detect on this population of specimens was calculated to be 100%.

2. HIV Seroconversion Panels: (See Table II on the last page.)

The sensitivity of the **Determine** HIV Early Detect was evaluated using 31 sets of seroconversion panels; each including early seroconversion panel members (98 early samples in total). The results were compared with the results of commercially available CE marked HIV 4th generation rapid immunochromatographic test kit, CE marked HIV 3rd generation rapid immunochromatographic test kit, HIV antibody EIA kit, HIV antigen EIA kit. Additionally, the results of 20 seroconversion panels were compared with the data of CE marked HIV 4th generation kit (Chemiluminescent microparticle immunoassay (CMIA)).

On 28 of 31 panels, **Determine** HIV Early Detect detected HIV infection earlier than a 3rd generation rapid immunochromatographic test kit. On 11 of 31 panels, **Determine** HIV Early Detect detected HIV infection earlier than a rapid 4th generation immunochromatographic test kit.

Detection of six of 20 panels by **Determine** HIV Early Detect was delayed by 1 bleed date when compared to a 4th generation kit (CMIA).

Detection of eight of 31 panels by **Determine** HIV Early Detect was delayed by 1 bleed date when compared to HIV Antigen Kit (EIA).

3. HIV-1 p24 Subtype Antigens:

50 HIV virus panels were prepared by diluting 50 different cultured HIV isolates including HIV-1 group M subtypes: A(4), B(8), C(7), D(5), F(5), G(2), H(1), and CRF01-AE(10), CRF02-AG(2), HIV-1 group O(4) and HIV-2(2) with HIV negative human serum. The **Determine** HIV Early Detect detected all HIV-1 panels and did not detect HIV-2 panels.

4. Analytical Sensitivity of HIV-1 p24 antigen

The analytical sensitivity of the **Determine** HIV Early Detect was evaluated by testing WHO International Standard HIV-1 p24 Antigen (NIBSC code 90/636). The results demonstrated that the test could detect a concentration of 2 IU/mL HIV-1 p24 antigen.

SPECIFICITY

A total of 2509 confirmed negative serum or plasma specimens were tested with the **Determine** HIV Early Detect and the specificity was **Determine**d for the antibody (Ab) bar and for the antigen (Ag) bar (Table III). The specificity was 99.92% for the antibody (Ab) bar and 99.72% for the antigen (Ag) bar.

Table III
Specificity of Determine HIV Early Detect

Population	Number of Tested Specimens	**Determine** HIV Early Detect					
		Ab bar		Ag bar		Combined Ab and Ag bar	
		Reactive	Non-reactive	Reactive	Non-reactive	Reactive	Non-reactive
Seronegative specimens*	1749	0	1749	2	1747	2	1747
Hospitalized specimens	218	1	217	2	216	3	215
Pregnant women	206	0	206	0	206	0	206
potentially cross-reacting specimens**	336	1	335	3	333	4	332
Total	2509	2	2507	7	2502	9	2500
Specificity (%)		99.92		99.72		99.64	

* Including specimens collected in Europe (300), USA (1299) and Africa (150)

** Disease states other than HIV, and potentially interfering substances: Rheumatoid factor (1), antinuclear antibody, systemic lupus erythematosus, high cholesterol, high total protein, high IgM (1), human anti mouse IgG, other infections (HBV, HCV, acute HAV (1), HTLV I or II, CMV, Toxo IgG, Syphilis, HSV 1/2, varicella zoster virus, influenza A and B, malaria, visceral leishmaniasis, and acute or chronic EBV), Flu vaccinated patients, measles (1), and dialysis patient specimens. Numbers in ( ) indicates number of specimen that showed false positive results.

INTERFERENCE

- 20mg/dL bilirubin, 500mg/dL hemoglobin, 3300mg/dL triglyceride, and 12g/dL protein did not interfere with test results.
- At 15g/dL protein, the test result presented false positive on Ab bar with Ab negative samples. No interference was observed on Ag bar.
- When specimens diagnosed as positive to rheumatoid factor were spiked with p24 antigen, the test result of 2 out of 5 samples presented false negative on Ag bar.

SAMPLE TYPE

Table IV
Antibody sensitivity in matched whole blood (venipuncture and fingerstick), serum and plasma specimens

No. of matched specimens tested	Type of Specimens and No. of Reactive by **Determine** HIV Early Detect (Ab detection)				Correlation between matrices
	Serum	Plasma	Whole Blood venipuncture	Whole Blood fingerstick*	
25	25	25	25	NT	100.0%
25	25	25	25	25	100.0%

NT: not tested *EDTA capillary tubes

Multiple (matched) specimens: Seropositive specimens from a total of 50 individuals from Africa were tested with the **Determine** HIV Early Detect (Table IV). Multiple (matched) specimens, 50 serum specimens, 50 plasma specimens, 50 whole blood (venipuncture) specimens and 25 whole blood (fingerstick) specimens were obtained from the donors in Africa. The results obtained from all specimen matrices showed 100% correlation, demonstrating that **Determine** HIV Early Detect gives identical results for these types of specimen matrices.

Table V
Specificity in matched whole blood (venipuncture and fingerstick), serum and plasma specimens

No. of matched specimens tested	Type of Specimens and No. of Non-reactive by **Determine** HIV Early Detect				Correlation between matrices
	Serum	Plasma	Whole Blood venipuncture	Whole Blood fingerstick*	
25	25	25	25	NT	100.0%
25	25	25	25	25	100.0%

NT: not tested *EDTA capillary tubes

Multiple (matched) specimens: Seronegative specimens from a total of 50 individuals from Africa were tested with the **Determine** HIV Early Detect (Table V). Multiple (matched) specimens, 50 serum specimens, 50 plasma specimens, 50 whole blood (venipuncture) specimens and 25 whole blood (fingerstick) specimens were obtained from the donors in Africa. The results obtained from all specimen matrices showed 100% correlation, demonstrating that **Determine** HIV Early Detect gives identical results for these types of specimen matrices.

Table II
HIV Seroconversion Panels

No	Panel	Days to First Reactive Results				
		Determine™ HIV Early Detect	4th gen rapid test	3rd gen rapid test	4th gen kit (CMIA)*	HIV antigen EIA*
		Ag/Ab	Ag/Ab	Ab	Ag/Ab	Ag
1	PRB943	12	12	19	7	7
2	PRB956	47	50	>50	47	47
3	PRB958	9	15	15	7	7
4	PRB961	27	29	>29	27	27
5	PRB962	14	14	>17	14	14
6	PRB963	17	17	>21	17	17
7	PRB966	48	51	51	44	44
8	PRB967	17	17	17	17	17
9	PRB968	26	26	28	26	26
10	PRB969	70	70	70	63	63
11	PRB970	7	7	14	0	0
12	PRB972	18	18	18	18	18
13	PRB973	11	11	>11	7	7
14	PRB974	9	16	>16	9	9
15	PRB975	14	>14	>14	14	14
16	PRB976	7	7	>9	7	7
17	PRB977	13	13	15	13	13
18	PRB924	26	26	33	NT	26
19	PRB926	7	7	27	NT	7
20	PRB934	0	7	7	NT	0
21	PRB935	28	28	43	NT	28
22	PRB940	7	7	15	NT	7
23	PRB945	13	13	15	NT	13
24	PRB947	9	9	11	NT	9
25	PRB948	23	23	>23	NT	23
26	PRB949**	18	18	>18	NT	18
27	PRB951	11	11	19	NT	8
28	PRB955	7	12	12	NT	3
29	9018	28	35	35	28	28
30	9022	25	32	32	25	25
31	9079	40	42	55	40	40
Total		31	31	31	20	31
Detected earlier than **Determine** HIV Early Detect			0	0	6	8
Detected same day as **Determine** HIV Early Detect			20	3	14	23
Detected later than **Determine** HIV Early Detect			11	28	0	0

* Vendor certificate data, **PRB949 No.5 was not tested. NT: not tested

Advice Line

For further information, please contact your distributor, or call one of the following Abbott Product Support Care Centers:

Region	Phone	E-Mail Address
Europe	+ (44) 161 483 9032	EME.TechSupport@abbott.com
Middle East	+ (965) 2202 2828	EME.TechSupport@abbott.com
Asia Pacific	+ (61) 7 3363 7711	AP.TechSupport@abbott.com
Africa	+ (27) 10 500 9700	arcis.techsupport@abbott.com
Russia & CIS	+ (7) 499 403 9512	arcis.techsupport@abbott.com
Latin America	+ (57) 601 482 4033	LA.TechSupport@Abbott.com

Glossary of Symbols	
	Temperature limit (2°C to 30°C)
	Catalogue number
	Do not reuse
	*In vitro* diagnostic medical device
	Do not use if package is damaged and consult instructions for use
	Keep away from sunlight
	Contains Sufficient for n tests
	Consult instructions for use
	Batch Code
	Use-by date
	Unique device identification
	Manufacturer

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12. O'Connell RJ, Agan BK, Anderson SA, et al. Sensitivity of the Multispot HIV-1/HIV-2 Rapid Test Using Samples from Human Immunodeficiency Virus Type 1-Positive Individuals with Various Levels of Exposure to Highly Active Antiretroviral Therapy. *Journal of Clinical Microbiology*. 2006; 44(5): 1831-1833.

2. 7D2843SET

2.1 Labels

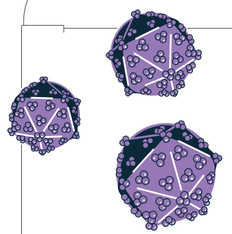
2.1.1 Outer Box Label (7D2843SET)

Determine HIV Early Detect SET
100 Test Set Box
PN: 241976/R1

Size: 151×60×115mm

PMS 303

PMS 2577



100 Tests

DETERMINE™
HIV EARLY DETECT SET

Abbott

Abbott

DETERMINE™
HIV EARLY DETECT SET

EN
Determine™ HIV Early Detect is an *in vitro*, visually read, qualitative immunoassay for the detection of antibodies (Ab) to HIV-1 and HIV-2 and the detection of non-immunocomplexed (free) HIV-1 p24 antigen (Ag) in human capillary and venous whole blood, plasma or serum.
For professional use only.

ES
Determine™ HIV Early Detect es un inmunoanálisis cualitativo *in vitro* con lectura visual para la detección de anticuerpos (Ab) a VIH-1 y VIH-2 y la detección del antígeno (Ag) no inmunocomplejo p24 del VIH-1 (en forma libre) en sangre total humana capilar y venosa, plasma o suero.
Solo para uso profesional.

FR
Determine™ HIV Early Detect est un test immunologique qualitatif *in vitro* à lecture visuelle pour la détection des anticorps (Ab) anti-VIH-1 et anti-VIH-2 et la détection de l'antigène (Ag) p24 du VIH-1 libre non immunocomplexé dans le sang total par prélèvement capillaire ou veineux, plasma ou sérum humain.
À usage professionnel uniquement.

PT
Determine™ HIV Early Detect é um ensaio imunológico qualitativo de leitura visual *in vitro* para a deteção de anticorpos (Ab) ao VIH-1 e VIH-2 e do antigénio (Ag) p24 do VIH-1 não imunocomplexo (livre) em sangue total capilar e venoso, plasma ou soro humano.
Exclusivamente para uso profissional.

EN
Contents:
- **Determine**™ HIV Early Detect (100 tests)
- Chase Buffer (1 bottle)
- Capillary Tubes (100 tubes)
- Blood Lancets (100 lancets)

ES
Contenido:
- **Determine**™ HIV Early Detect (100 pruebas)
- Buffer de detección (1 frasco)
- Tubos capilares (100 tubos)
- Lancetas para extracción de sangre (100 lancetas)

Abbott

DETERMINE™
HIV EARLY DETECT SET

2°C – 30°C | 100 | IVD | REF 7D2843SET

4 571226 473993

FR
Contenu:
- **Determine**™ HIV Early Detect (100 tests)
- Tampon de migration (1 flacon)
- Tubes capillaires (100 tubes)
- Lancettes de sang (100 lancettes)

PT
Conteúdo:
- **Determine**™ HIV Early Detect (100 testes)
- Tampão de detecção (1 frasco)
- Tubos Capilares (100 tubos)
- Lancetas de sangue (100 lancetas)

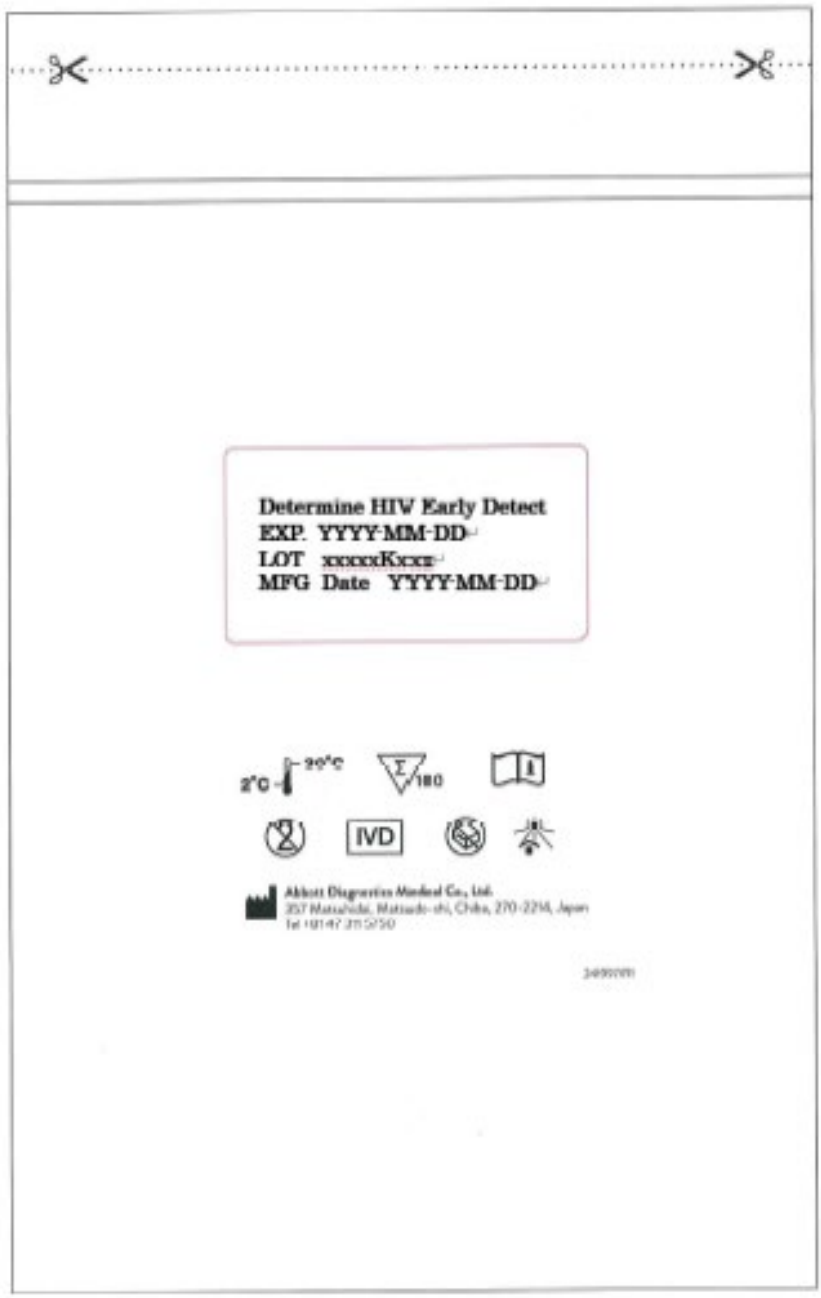
Abbott

DETERMINE™
HIV EARLY DETECT SET

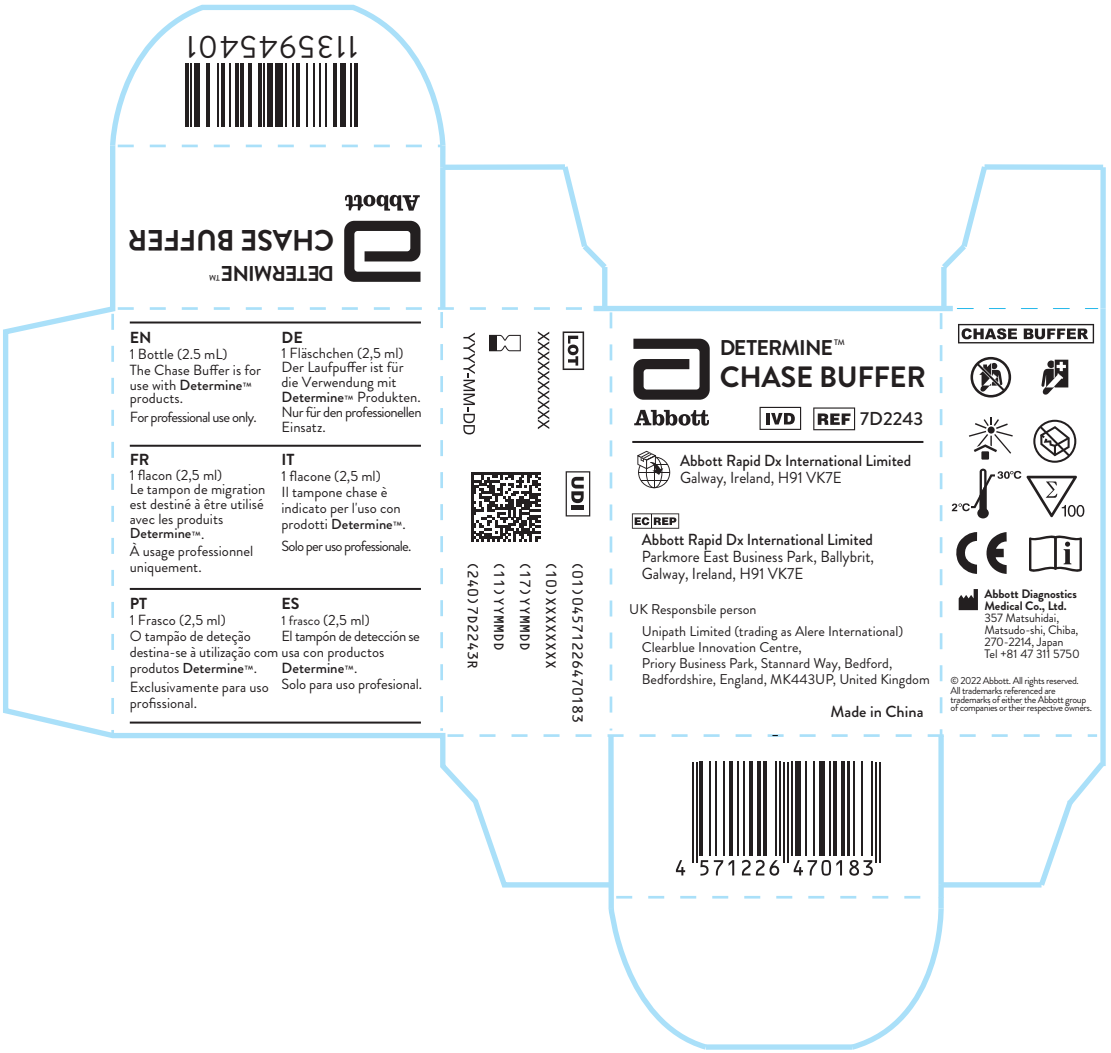
Abbott Diagnostics Medical Co., Ltd.
357 Matsuhidai, Matsudo-shi,
Chiba, 270-2214, Japan
+81 47 311 5750

241976/R1 May, 2021

2.1.2 100 Test Pouch Label (7D2843SET)



2.1.3 Chase Buffer Bottle Label (7D2843SET)



Chase Buffer Box Size: (W)22mm x (L)44mm x (H)56mm	Black	PN: 1135945401

1156253101

REF 7D2243

1156253101
April 2022

DETERMINE™ CHASE BUFFER

Abbott

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270-2214, Japan
Tel +81 47 311 5750

EC REP Abbott Rapid Dx International Limited
Parkmore East Business Park, Ballybrit,
Galway, Ireland, H91 VK7E

UK Responsible person Unipath Limited (trading as Alere International)
Clearblue Innovation Centre,
Priory Business Park, Stannard Way, Bedford,
Bedfordshire, England, MK443UP, United Kingdom

EN

Intended Purpose
Chase Buffer is intended for use with Determine™ in vitro diagnostic rapid test devices. Chase Buffer enables the migration of the specimen and conjugate through the test device when testing whole blood specimens. It is specially formulated and optimised to ensure the Determine™ test performs correctly and controls assay flow. It is for professional use and near-patient testing, and not for self-testing.

For full procedure refer to the diagnostic assay IFUs:
- Determine™ HIV-1/2 (7D23)
- Determine™ HIV Early Detect (7D28)
- Determine™ HBsAg 2 (7D29)
- Determine™ Syphilis TP (7D24)
- Determine™ HBsAg (7D25)

When adding Chase Buffer to the sample pad, hold the bottle vertically. One drop to be used per test (one bottle of Chase Buffer can be used for 100 tests). Avoid drop with bubble, do not add buffer to specimen.

USER TRAINING, QUALIFICATION AND EXPERIENCE REQUIREMENTS
This Chase Buffer is designed for use by professionals in both laboratory and near-patient settings including laboratory technologists. Suitable personnel shall have a consummate level of training and experience in specimen preparation, the running and interpretation of specimens, management of all supplies and waste disposal as per local regulations and generation of reports.

Caution: Do not eat, drink, smoke or apply make-up while using this product.
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.

Contents
CHASE BUFFER 1 Bottle (2.5 mL) Chase Buffer contains: phosphate buffer solution (20mM pH7.4) containing preservatives Nipasept™ and A56620 (sarafloxacin).

Storage Instruction
Recap the Chase Buffer to avoid evaporation or spillage and store at 2-30 °C until expiration date.

ES

Finalidad prevista
Chase Buffer está destinado a utilizarse con los dispositivos de pruebas rápidas de diagnóstico in vitro Determine™. Chase Buffer permite la migración de la muestra y el conjugado a través del dispositivo de prueba cuando se analizan muestras de sangre completa. Está especialmente formulado y optimizado para garantizar que la prueba Determine™ funcione correctamente y controle el flujo del ensayo. Es para uso profesional y para pruebas cercanas a los pacientes, no es apto para autopruebas.

Para conocer el procedimiento completo, consulte las instrucciones de uso del ensayo de diagnóstico:
- Determine™ HIV-1/2 (7D23)
- Determine™ HIV Early Detect (7D28)
- Determine™ HBsAg 2 (7D29)
- Determine™ Syphilis TP (7D24)
- Determine™ HBsAg (7D25)

Cuando añada Chase Buffer a la almohadilla de muestras, mantenga el frasco en posición vertical. Se debe utilizar una gota por prueba (un frasco de Chase Buffer puede utilizarse para 100 pruebas). Evite que la gota tenga una burbuja, no añada tampón a la muestra.

REQUISITOS DE FORMACIÓN, CUALIFICACIÓN Y EXPERIENCIA DEL USUARIO
Chase Buffer está diseñado para ser utilizado por profesionales tanto en el laboratorio como en entornos cercanos al paciente, incluidos técnicos de laboratorio. El personal adecuado deberá tener un nivel consumado de formación y experiencia en la preparación de muestras, la ejecución e interpretación de las mismas, la gestión de todos los suministros y la eliminación de residuos de acuerdo con la normativa local y la generación de informes.

Precaución: No coma, ni beba, ni fume, ni se maquille mientras usa este producto.
Para los pacientes/usuarios/terceros en la Unión Europea y en países con idéntico régimen normativo (Reglamento 2017/746/UE sobre productos sanitarios de diagnóstico in vitro); si ocurriera un incidente grave durante el uso de este dispositivo o como resultado de su uso, informe al fabricante o a su representante autorizado, así como a su autoridad nacional.

Contenido
CHASE BUFFER 1 frasco (2.5 mL) de Chase Buffer contiene: solución tampón de fosfato (20mM pH 7.4) que contiene los conservantes Nipasept™ y A56620 (sarafloxacina).

Instrucción de almacenamiento
Vuelva a tapar el frasco de Chase Buffer para evitar que se evapore o derrame y conserve a 2-30 °C hasta la fecha de caducidad.

DE

Verwendungszweck
Chase Buffer ist für die Verwendung mit Determine™ In-vitro-Diagnostik-Schnelltests vorgesehen. Chase Buffer ermöglicht bei der Untersuchung von Vollblutproben die Migration von Probe und Konjugat durch die Testvorrichtung. Es ist speziell formuliert und optimiert, um die korrekte Durchführung des Determine™ Tests zu gewährleisten und den Testfluss zu kontrollieren. Es ist für den professionellen Gebrauch und patientennahe Tests und nicht für Selbsttests geeignet.

Das vollständige Verfahren ist in den IFUs der diagnostischen Tests beschrieben:
- Determine™ HIV-1/2 (7D23)
- Determine™ HIV Early Detect (7D28)
- Determine™ HBsAg 2 (7D29)
- Determine™ Syphilis TP (7D24)
- Determine™ HBsAg (7D25)

Halten Sie die Flasche senkrecht, wenn Sie Chase Buffer in das Probenpad geben. Pro Test ist ein Tropfen zu verwenden (eine Flasche Chase Buffer kann für 100 Tests verwendet werden). Tropfen mit Blasenbildung vermeiden, keinen Puffer zur Probe hinzufügen.

ANFORDERUNGEN AN AUSBILDUNG, QUALIFIKATION UND ERFAHRUNG DER BENUTZER
Dieser Chase Buffer ist für die Verwendung durch Fachkräfte im Labor und im patientennahen Bereich, einschließlich Labortechniker, bestimmt. Das geeignete Personal muss über ein hohes Maß an Ausbildung und Erfahrung in der Probenvorbereitung, der Untersuchung und Auswertung der Proben, der Verwaltung aller Vorräte und der Abfallentsorgung gemäß den örtlichen Vorschriften sowie der Erstellung von Berichten verfügen.

Achtung: Essen, trinken, rauchen oder schminken Sie sich nicht, während Sie dieses Produkt verwenden.
Für Patienten/Anwender/Dritte in der Europäischen Union und in Ländern mit identischem Regelwerk (Verordnung 2017/746/EU über In-vitro-Diagnostika): Wenn während der Verwendung dieses Produkts oder als Folge seiner Verwendung ein schwerwiegender Zwischenfall aufgetreten ist, melden Sie dies bitte dem Hersteller und/oder seinem Bevollmächtigten sowie Ihrer nationalen Behörde.

Inhalt
CHASE BUFFER 1 Flasche (2.5 mL) Chase Buffer enthält: Phosphatpufferlösung (20mM pH7.4) mit den Konservierungsmitteln Nipasept™ und A56620 (Sarafloxacin).

Anweisungen zur Lagerung
Verschließen Sie den Chase Buffer, um Verdunstung oder Verschütten zu vermeiden, und lagern Sie ihn bis zum Verfallsdatum bei 2–30 °C.

FR

Usage prévu
Chase Buffer est destiné à être utilisé avec les dispositifs de test rapide pour diagnostic in vitro Determine™. Chase Buffer permet la migration de l'échantillon et du conjugué à travers le dispositif de test lors de l'analyse d'échantillons de sang total. Il est spécialement formulé et optimisé pour garantir que le test Determine™ fonctionne correctement et contrôle le flux de dosage. Il est destiné à un usage professionnel et aux tests au chevet du patient, et non à l'autotest.

Pour la procédure complète, se référer aux modes d'emploi des tests de diagnostic :
- Determine™ HIV-1/2 (7D23)
- Determine™ HIV Early Detect (7D28)
- Determine™ HBsAg 2 (7D29)
- Determine™ Syphilis TP (7D24)
- Determine™ HBsAg (7D25)

Lorsque vous ajoutez Chase Buffer au tampon d'échantillonnage, tenez le flacon verticalement. Une goutte à utiliser par test (un flacon de Chase Buffer peut être utilisé pour 100 tests). Évitez les gouttes avec des bulles, n'ajoutez pas de tampon à l'échantillon.

EXIGENCES EN MATIÈRE DE FORMATION, DE QUALIFICATION ET D'EXPÉRIENCE DES UTILISATEURS
Ce Chase Buffer est conçu pour être utilisé par les professionnels à la fois dans les laboratoires et les environnements au chevet des patients, y compris les techniciens de laboratoire. Le personnel approprié doit avoir un niveau de formation et d'expérience complet dans la préparation, l'exécution et l'interprétation des échantillons, la gestion de toutes les fournitures et l'élimination des déchets conformément aux réglementations locales et la génération de rapports.

Mise en garde: Ne pas manger, boire, fumer ou se maquiller pendant l'utilisation de ce produit.
Pour un patient/utilisateur/tiers dans l'Union européenne et dans les pays ayant un régime réglementaire identique (Règlement 2017/746/UE sur les dispositifs médicaux de diagnostic in vitro) ; si, pendant l'utilisation de ce dispositif ou à la suite de son utilisation, un incident grave s'est produit, veuillez le signaler au fabricant et/ou à son représentant autorisé et à votre autorité nationale.

Contenu
CHASE BUFFER 1 flacon (2.5 ml) Chase Buffer contient : solution tampon phosphate (20mM pH7.4) contenant les conservateurs Nipasept™ et A56620 (sarafloxacine).

Instruction de stockage
Re-bouchonner le Chase Buffer pour éviter toute évaporation ou tout déversement et le conserver à une température comprise entre 2 et 30 °C jusqu'à la date de péremption.

IT

Scopo previsto
Chase Buffer è destinato all'uso con i dispositivi per test diagnostici rapidi in vitro Determine ™. Chase Buffer consente la migrazione del campione e del coniugato attraverso il dispositivo di test durante l'analisi di campioni di sangue intero. È appositamente formulato e ottimizzato per garantire che il test Determine™ funzioni correttamente e controlli il flusso del test. È indicato per l'uso professionale e per test decentralizzati, non per autotest.

Per la procedura completa, fare riferimento alle istruzioni per l'uso del test diagnostico:
- Determine™ HIV-1/2 (7D23)
- Determine™ HIV Early Detect (7D28)
- Determine™ HBsAg 2 (7D29)
- Determine™ Syphilis TP (7D24)
- Determine™ HBsAg (7D25)

Quando si aggiunge il Chase Buffer al tampone per campioni, tenere il flacone in verticale. Utilizzare una goccia per test (un flacone di Chase Buffer può essere utilizzato per 100 test). Evitare le gocce contenenti bolle, non aggiungere tampone al campione.

REQUISITI DI FORMAZIONE, QUALIFICA ED ESPERIENZA DEGLI UTENTI
Questo Chase Buffer è progettato per l'uso da parte di professionisti sia in laboratorio che in ambienti decentralizzati, inclusi i tecnici di laboratorio. Il personale idoneo deve avere un eccellente livello di formazione ed esperienza nella preparazione dei campioni, nell'esecuzione e nell'interpretazione dei campioni, nella gestione di tutte le forniture, nello smaltimento dei rifiuti secondo le normative locali e nella generazione dei rapporti.

Attenzione: non mangiare, bere, fumare o truccarsi durante l'utilizzo di questo prodotto.
Per un paziente/utente/terza parte nell'Unione Europea e in paesi con identico regime normativo (Regolamento 2017/746/UE sui Dispositivi medici per la diagnostica in vitro): se, durante l'uso di questo dispositivo o a seguito del suo utilizzo, si è verificato un incidente grave, segnalarlo al produttore e/o al suo rappresentante autorizzato e alla propria autorità nazionale.

Contenuto
CHASE BUFFER 1 flacone (2.5 ml) di Chase Buffer contiene: soluzione tampone a base di fosfato (20mM pH7.4) contenente i conservanti Nipasept™ e A56620 (sarafloxacina).

Istruzioni per la conservazione
Richiudere il Chase Buffer per evitare l'evaporazione o la fuoriuscita e conservare a 2-30 °C fino alla data di scadenza.

PT

Utilização prevista
O Chase Buffer (solução tampão) destina-se a ser utilizado em testes rápidos de diagnóstico in vitro Determine™.
O Chase Buffer permite a migração da amostra e conjugado através do dispositivo de teste ao testar amostras de sangue total. Foi especialmente desenvolvido e otimizado para assegurar que o teste Determine™ funciona corretamente e controla o fluxo de ensaio. Destina-se a utilização profissional, testes junto ao paciente e não é adequado para autoteste.

Para obter o procedimento completo, por favor, consulte as Instruções de utilização do ensaio de diagnóstico:
- Determine™ HIV-1/2 (7D23)
- Determine™ HIV Early Detect (7D28)
- Determine™ HBsAg 2 (7D29)
- Determine™ Syphilis TP (7D24)
- Determine™ HBsAg (7D25)

Ao adicionar o Chase Buffer ao bloco de amostras, mantenha o frasco na posição vertical. Use uma gota por teste (um frasco de tampão pode ser usado para 100 testes). Evite gotas com bolhas e não adicione tampão à amostra.

REQUISITOS DE FORMAÇÃO, QUALIFICAÇÃO E EXPERIÊNCIA DO UTILIZADOR
O Chase Buffer foi concebido para ser utilizado por profissionais, tanto em laboratório como em ambientes junto do paciente, incluindo técnicos de laboratório. Os profissionais deveram ter um nível consumado de formação e experiência na preparação de amostras, no funcionamento e interpretação de amostras, na gestão de todos os consumíveis e eliminação de resíduos, de acordo com os regulamentos locais e na elaboração de relatórios.

Cuidado: não comer, beber, fumar ou aplicar maquilhagem durante a utilização deste produto.
Para um paciente/utilizador/terceiro na União Europeia e em países com regime regulamentar idêntico (Regulamento 2017/746/UE relativo a dispositivos médicos de diagnóstico in vitro); se, durante a utilização deste dispositivo ou em resultado da sua utilização, tiver ocorrido um incidente grave, informe imediatamente o fabricante e/ou o seu representante autorizado e a respetiva autoridade nacional.

Conteúdo
CHASE BUFFER 1 frasco (2.5 mL) de Chase Buffer contém: solução tampão fosfato (20mM pH7.4) contendo conservantes Nipasept™ e A56620 (sarafloxacina).

Instrução de armazenamento
Voltar a tapar o Chase Buffer para evitar evaporação ou derramamento e armazenar entre 2-30 °C até à data de validade.

Glossary of Symbols / Glossar der Symbole / Glosario de símbolos / Glossaire des symboles / Glossario dei simboli / Glossário de símbolos

Σ 100	Contains sufficient for 100 tests / Enthält genügend Material für 100 Tests / Contenido suciente para 100 pruebas / Contient suffsamment de produit pour 100 tests / Contenuto sufficiente per 100 test / Contém o suficiente para 100 testes
EC REP	Authorized representative in the European Community / Bevollmächtigter in der Europäischen Gemeinschaft / Representante autorizado en la Comunidad Europea / Représentant autorisé dans l' Union européenne / Rappresentante autorizzato nella Comunità Europea / Representante autorizado na Comunidade Europeia
	Importer / Importeur / Importador / Importateur / Importatore / Importador
UDI	Unique Device Identification / Eindeutige Geräteidentifikation / Identificación única del dispositivo / Identification unique du dispositif / Identificazione univoca del dispositivo / Identificação única de dispositivo
IVD	In vitro diagnostic medical device / In-vitro-Diagnostikum / Producto sanitario de diagnóstico in vitro / Dispositif médical de diagnostic in vitro / Dispositivo medico per la diagnostica in vitro / Dispositivo médico de diagnóstico in vitro
CHASE BUFFER	Chase Buffer / Chase Buffer / Chase Buffer / Chase Buffer / Chase Buffer / Chase Buffer
	Manufacturer / Hersteller / Fabricante / Fabricant / Produttore / Fabricante
REF	Catalogue number / Katalognummer / Número de catálogo / Référence / Numero di catalogo / Número de catálogo
	Consult instructions for use / Siehe Gebrauchsanweisung / Consultar las instrucciones de uso / Consulter le mode d' emploi / Consultare le istruzioni per l' uso / Consultar as instruções de utilização
	Device for Near-Patient Testing / Gerät für patientennahe Tests / Dispositivo para pruebas cercanas al paciente / Dispositif pour tests au chevet du patient / Dispositivo per test decentralizzato / Dispositivo para testes junto do paciente
2°C 30°C	Store between 2-30°C / Lagerung bei 2–30 °C / Almacenar entre 2 y 30 °C / Ranger à une température comprise entre 2 et 30 °C / Conservare a 2-30 °C / Armazenar entre 2-30 °C
LOT	Lot Number / Chargennummer / Número de lote / Numéro de lot / Numero di lotto / Número do lote
CE	CE marking according to IVD Medical Devices Regulation (EU) 2017/746 / CE-Kennzeichnung gemäß der IVD-Medizinprodukte-Verordnung (EU) 2017/746 / Marcado CE según el Reglamento sobre los productos sanitarios para diagnóstico in vitro (UE) 2017/746 / Marquage CE conformément au règlement sur les dispositifs médicaux de diagnostic in vitro (UE) 2017/746 / Marchio CE secondo il Regolamento sui dispositivi medici IVD (UE) 2017/746 / Marcação CE de acordo com o Regulamento relativo aos dispositivos médicos para IVD (UE) 2017/746
	Do not use if package is damaged / Nicht verwenden, wenn die Verpackung beschädigt ist / No utilizar si el envase está dañado / Ne pas utiliser si l' emballage est endommagé / Non utilizzare se la confezione è danneggiata / Não utilizar se a embalagem estiver danificada
	Keep away from sunlight / Vor Sonnenlicht schützen / Mantener alejado de la luz solar / Garder à l' abri de la lumière du soleil / Tenere lontano dalla luce solare / Manter afastado da luz solar
	Not for Self- Testing / Nicht für Selbsttest / No apto para autopruebas / N'est pas destiné à l' autotest / Non per autotest / Não adequado para autotestes

Advice Line/Infotelefon/Asistencia/Conseil/Assistenza/Rådgivning

For further information, please contact your distributor, or call Abbott Technical Specialists: Europe:
Tel: +44 161 483 9032 Email:EME.TechSupport@abbott.com

Weitere Informationen erhalten Sie von Ihrem Vertreiber oder vom technischen Kundendienst von Abbott: Europa:
Tel: +44 161 483 9032 Email:EME.TechSupoort@abbott.com

Para obtener mas informacion, pongase en contacto con su distribuidor, o llame a los especialistas tecnicos de AbbottEuropa:
Tel: +44 161 483 9032
Correo electronico: EME.TechSupport@abbott.com

Pour de plus amples informations, contactez votre distributeur ou appeler les techniciens specialistes de Abbott: Europa: Europe:
Tel: +44 161 483 9032
Adresse elec.e: EME.TechSupport@abbott.com

Per ulteriori informazioni, contattare il proprio distributore o il servizio di assistenza tecnica di Abbott ai seguenti recapiti:
Europa: Tel: +44 161 483 9032
E-mail: EME.TechSupport@abbott.com

Para informacao adicional, por favor contacte o seu distribuidor, ou ligue para os Tecnicos Especialistas da Abbott: Europa:
Tel: +44 161 483 9032 Email: EME.TechSupport@abbott.com

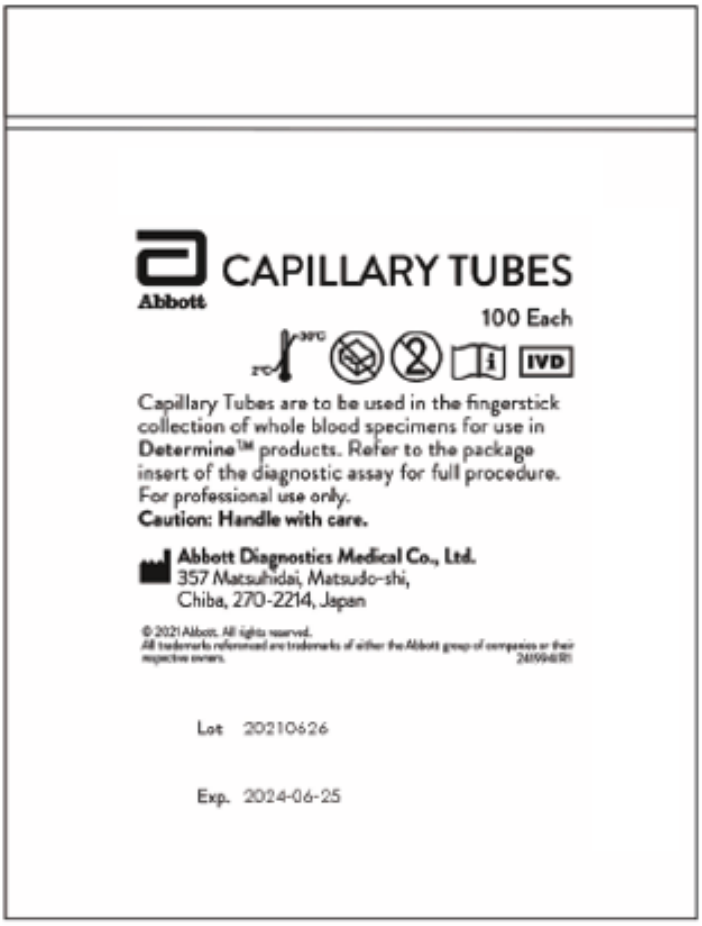
Middle East:Tel: + (965) 2202 2828
Email: EME.TechSupport@abbott.com
Asia Pacific: Tel + (61) 7 3363 7711
Email: AP.TechSupport@abbott.com
Africa: Tel + (27) 10 500 9700
Email: arcis.techsupport@abbott.com
Russia & CIS: Tel:+ (7) 499 403 9512
Email: arcis.techsupport@abbott.com
Latin America: Tel:+ (57) 1 482 4033
Email: LA.TechSupport@abbott.com
Australia: Tel:+ (1) 800 622 642
Email: rapiddx.ANZ.TechSupport@abbott.com

Chase Buffer

Package Insert

Size: 176 x 250 mm

2.1.4 Capillary Tubes Label (7D2843SET)



2.1.5 Sterile Blood Lancet Label (7D2843SET)

Box Drawing

100mm
96mm
19mm
Instructions for Use
1. Twist Cap
2. Pull Cap
3. Recapping
Do not use lancet if protective cap has been previously removed.
NOTE: If using a lancing device, follow instructions for use of that device.
1. Twist lancet-cap to separate. NOTE: Do not use if cap appears damaged or loose before twisting.
2. Pull off the cap to expose needle tip. Save cap for later use (step 04).
3. Perform lancing procedure using medically accepted aseptic techniques.
4. After procedure, help minimize accidental needle-stick by pressing needle-tip into flat side of the saved cap.
5. Discard used lancets in a suitable container and/or in accordance with local requirements.
Model: I
28 gauge
LOT : 220802T
: 2027-08-01
: 2022-08-02
(01) 06957138607882
(10) 220802T
(17) 270801
(11) 220802
(240) IR28100100
STERILE R Irradiation Sterilization
Single Use Only
Rev# 2024-04-22
Made in China
Litetouch™
Sterile Lancet
medicore™
Austell, GA, USA
1-855-867-2190
100T QTY: 100pcs
Item No: M2721
Tianjin Huahong Technology Co.,Ltd.
A01, Plant B, No.278, Hangkong Road, Tianjin Pilot Free Trade Zone (Air Port Industrial Park), Tianjin, 300308, China
Tel: +86 022-58775333 +86 4008-587-753
Fax: +86 022-58775353
E-mail: huahongsales@163.com

2.2 Instructions for Use (IFU) (7D2843SET)[2]

[2] 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.

DETERMINE™ HIV EARLY DETECT

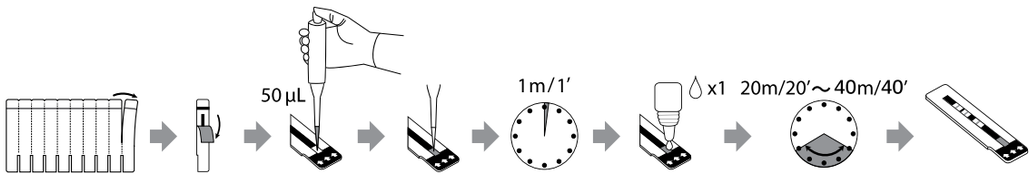
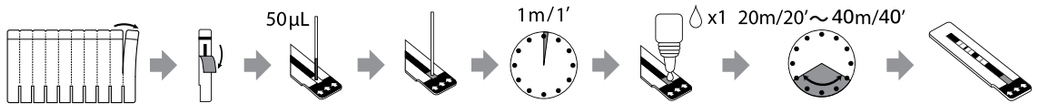
Abbott

January 2025
D10193272 (AA)

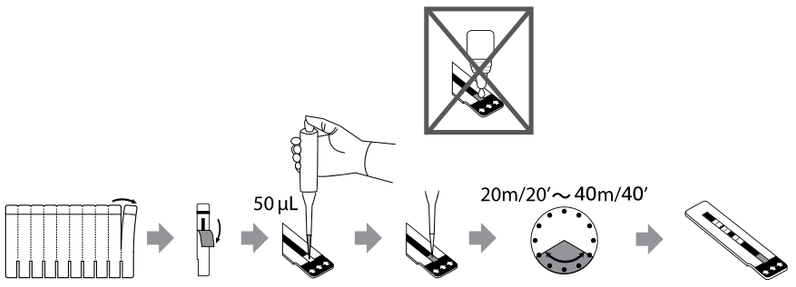
Read Highlighted Changes

REF 7D2843SET

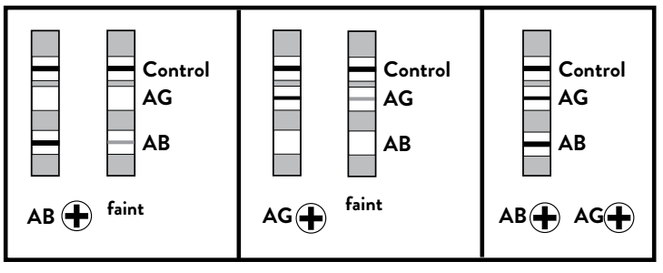
Whole Blood / Sangre Total / Sang Total / Sangue Total

Pipette Pipeta Pipette Pipeta	
Capillary Tubes Tubos capilares Tubes capillaires Tubos Capilares	

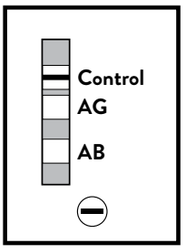
Serum, Plasma / Suero, Plasma / Sérum, Plasma / Soro, Plasma

Pipette Pipeta Pipette Pipeta	

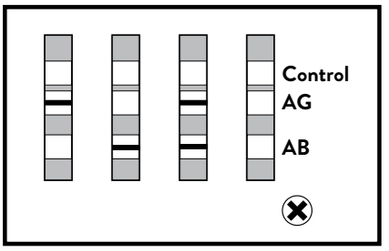
Reactive



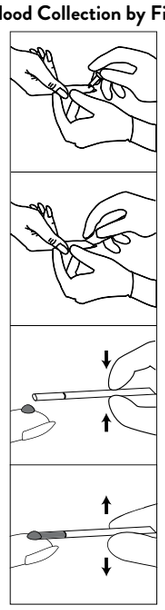
Non-Reactive



Invalid



Whole Blood Collection by Fingerstick



Abbott Diagnostics Medical Co., Ltd.
357 Matsuhidai, Matsudo-shi, Chiba, 270-2214 Japan

EN

January 2025
D10193272 (AA)

This package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are deviations from the instructions in this package insert.

NAME AND INTENDED USE

Determine™ HIV Early Detect is an *in vitro,* visually read, qualitative immunoassay for the detection of antibodies (Ab) to HIV-1 and HIV-2 and the detection of non-immunocomplexed (free) HIV-1 p24 antigen (Ag) in human capillary and venous whole blood, plasma or serum. Therefore, any reactivity on 1) the Ab bar alone 2) the Ag bar alone or 3) both the Ab and Ag bars simultaneously, is considered a reactive result suggestive of infection with HIV. The test is for professional use only and intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection in adults and children over the age of 18 months.

SUMMARY AND EXPLANATION OF THE TEST

AIDS (Acquired Immunodeficiency Syndrome) is characterized by changes in the population of T-cell lymphocytes. In an infected individual, the virus causes depletion of CD4 helper T-cells, which leaves the person susceptible to opportunistic infections and some malignancies. The virus that causes AIDS exists as two related types known as HIV-1 and HIV-2. The multiplication of the HIV in the infected cells leads to cell rupture and thus the release of HIV virus particles, which are first detected in the form of HIV RNA and next in the form of HIV antigen.[1,2] This is followed by production of specific antibodies to either HIV-1 or HIV-2.[3,4,5] HIV antigen may become undetectable at this time because of the formation of antibody-antigen complexes.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

Determine HIV Early Detect is an immunochromatographic test for the qualitative detection of free HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2.
Specimen is added to the sample pad. The specimen mixes with biotinylated anti-p24 antibodies and selenium colloid-conjugates coated with recombinant HIV-1, HIV-2 and HIV-1 group O antigens, synthetic HIV-2 peptide and anti p24 mouse monoclonal antibody. This mixture continues to migrate through the solid phase to the immobilized recombinant HIV-1/HIV-1 group O antigens and synthetic HIV-1/HIV-2 peptides at the Antibody (Ab) window, immobilized avidin at the Antigen (Ag) window.
If antibodies to HIV-1 and/or HIV-2 are present in the specimen, the antibodies bind to the selenium colloid-conjugates coated with recombinant HIV-1, HIV-2 and HIV-1 group O antigens and synthetic HIV-2 peptide and to the immobilized recombinant HIV-1/HIV-1 group O antigens and synthetic HIV-1/HIV-2 peptides, forming one red bar at the Ab window site. If antibodies to HIV-1 and HIV-2 are absent, the selenium colloid-conjugates flow past the Ab window and no red bar is formed at the Ab window site.
If free HIV-1 p24 antigen is present in the specimen, the antigen binds to the biotinylated anti-p24 antibodies and the selenium colloid-conjugate coated with anti p24 mouse monoclonal antibody. This complex binds to the immobilized avidin forming a red bar at the Ag window site. If HIV-1 p24 antigen is not present, both the biotinylated anti-p24 antibodies and selenium colloid-conjugate flow past the Ag window and no red bar is formed at the Ag window site.
To ensure assay validity, a procedural control bar is incorporated in the assay device at the Control window.

CONTENTS

Determine HIV Early Detect SET (7D2843SET) (100 Test for testing whole blood samples)

- Determine HIV Early Detect Test Card, 20 cards (containing 5 tests/card)
- Chase Buffer (7D2243) 1 Bottle (2.5 mL) prepared in phosphate buffer. Preservatives: Antimicrobial Agents.
- Capillary Tubes
- Blood Lancet

Materials Required But Not Provided

- Disposable gloves, timing device
- Micropipette capable of delivering 50 µL (other than fingerstick)
- Alcohol swab, clean or sterile gauze pad

WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use.
For professional use only.
Safety data sheet available for professional user on request.

CAUTION: The package insert is placed in the kit box. **DO NOT** put the package insert inside the foil pouch. When handling specimens and reagents, use appropriate biosafety practices[7,8]. These precautions include, but are not limited to the following:

- Wear gloves.
- Do not pipette by mouth.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
- Clean and disinfect all spills of specimens or reagents using suitable disinfectant, such as 0.5% sodium hypochlorite, or other suitable disinfectant.[7,8]
- Decontaminate and dispose of all specimens, used test strips, and other potentially contaminated materials in accordance with local regulations.[7,8]

STORAGE

Store **Determine** HIV Early Detect Test Cards and Chase Buffer at 2°C to 30°C until expiration date.

- When handled and stored as directed, kit components are stable until the expiration date. Do not use kit components beyond expiration date.
- Immediately reseal all unused tests in the foil pouch containing the desiccant by pressing seal from end to end to close.
- Do not use devices that have become wet or if the packaging has become damaged.

SPECIMEN COLLECTION

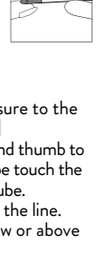
Serum, Plasma, and Whole Blood Collection by Venipuncture.

Use EDTA collection tubes for whole blood and plasma specimens.

- Collect human serum, plasma and whole blood by venipuncture aseptically.
- To obtain serum, separate from the clot. To obtain plasma, separate from the packed cells. Separate specimens as soon as possible to avoid any hemolysis.

Whole Blood Collection by Fingerstick[6] (See Fig.1)

Fig.1



1. Before collecting a fingerstick specimen, place a capillary tube and a lancet on a clean dry surface. After taking a capillary tube, seal to close the plastic bag and store the remaining capillary tubes in the kit box to avoid sunlight.
   Do not use a capillary tube that is dirty or bent.
   Do not touch the open end of the capillary tubes before use.
2. Ask the patient to increase blood circulation by rubbing the hands together.
3. Choose the fingertip of the middle, ring, or index finger (whichever is the least callused). Warm the hand as needed with a warm, moist towel or warm water to increase blood flow.
4. Clean the fingertip with alcohol swab and allow to air-dry. Position the hand, palm-side up. Place the lancet off-center on the fingertip. Firmly press the lancet against the finger and puncture the skin. Dispose of the lancet in an appropriate biohazard sharps container.
5. Wipe away the first drop of blood with a clean or sterile gauze pad.
6. Hold the finger lower than the elbow and apply gentle, intermittent pressure to the base of the punctured finger several times, avoiding the puncture wound.
7. Confirm the location of the line on the capillary tube. Use your index finger and thumb to gently squeeze the body of capillary tube, let the open end of the capillary tube touch the blood bead, gently release the finger - blood will be sucked into the capillary tube.
8. Carefully collect the blood up to the line and do not collect the blood above the line. Reliability of assay results cannot be guaranteed if blood is collected below or above the line.
9. If the sample is not enough to fill up to the line of the capillary tube, apply gentle pressure to the finger again to make a drop of blood and take the blood until the line is reached.
10. Confirm that no air bubble is present in the sample. If an air bubble is present, or if blood is collected below or above the line after completion of collection, discard the capillary tube with the sample and do not use it.
11. Immediately proceed to Testing Procedure 4 for whole blood (fingerstick) samples.

SPECIMEN STORAGE

- Store serum and plasma specimens at 2 °C to 8 °C and run the test within 7 days of collection. If testing is delayed more than 7 days, freeze the specimen at -20 °C or colder.
- Avoid repeated freeze/thaw cycles.
- If serum or plasma specimens show particulate matter or turbidity, centrifuge at 10,000g for 5 minutes at room temperature before sampling. Carefully remove the 50 µL test sample from the supernatant. If a lipid layer is formed on the surface of the liquid, ensure to take the sample from the clear liquid below that layer.
- For whole blood collected by venipuncture, store at 2 °C to 8 °C. Do not freeze whole blood specimens. Run the test within 7 days of collection.
- For whole blood collected by fingerstick, test immediately.

TEST PROCEDURE

Remove the desired number of test strips from the 5-test card by bending and tearing at the perforation.
The test is to be performed at 15 °C to 30 °C.

NOTE:

- The lot number and expiration date are printed on the back of each test strip and on the foil pouch.
- After removing the protective foil cover from each test strip, start the assay immediately. At under 80 % or less relative humidity, the test can be used within 30 minutes after removing the protective foil cover.
- For serum or plasma, ensure thorough mixing of sample prior to use. For whole blood sample, mix well by gentle inversion of the tube immediately before testing.
- Running the test in high temperature/low humidity may affect the appearance of the Ag or Ab bar. If the test strip is partially dried and difficult to read at 20 to 40 minutes, the test should be repeated using a new test strip and result read at 20 minutes. When the test strip is partially dried, it appears as mixed white spot and grayish area. At 30 °C/ 20 % RH or low humidity conditions, the test strip dries at 40 minutes.
- If serum or plasma sample does not flow or shows abnormal flow, such as stopping in the middle of the window, centrifuge the specimen and repeat the test with a new test strip.
- Recap and store the Chase Buffer at 2 °C to 30 °C to avoid evaporation or spillage.

CAUTION: Abnormal flow may occur with a whole blood (fingerstick) sample, if the capillary tube is not placed in the middle of the sample pad at an upright (vertical) position. If this occurs, collect a new sample and repeat the test using a new strip.

1. Remove the protective foil cover from each test.
2. **For serum or plasma samples:**
   a. Apply 50 µL of sample (precision pipette) to the sample pad (marked by the arrow symbol).
   b. Wait a minimum of 20 minutes from addition of the sample (up to 40 minutes maximum) and read result.
3. **For whole blood (venipuncture) samples:**
   a. Apply 50 µL of sample (precision pipette) to the sample pad (marked by the arrow symbol).
   b. Wait until the blood is absorbed and there is no droplet on the sample pad (approximately 1 minute), then apply one drop of Chase Buffer to the sample pad, holding the bottle vertically.
   c. Wait a minimum of 20 minutes from addition of the sample (up to 40 minutes maximum) and read result.
4. **For whole blood (fingerstick) samples:**
   a. Squeeze the body of capillary tube expelling the blood onto the sample pad of the test device. Apply all blood in the capillary tube to the sample pad. Do not splash the blood.
   b. Dispose of the used capillary tubes as biohazardous material according to local regulations.
   c. Wait until the blood is absorbed and there is no droplet on the sample pad (approximately 1 minute), then apply one drop of Chase Buffer to the sample pad, holding the bottle vertically.
   d. Wait a minimum of 20 minutes from addition of the sample (up to 40 minutes) and read result.

QUALITY CONTROL

To ensure assay validity, a procedural control is incorporated in the device and is labeled "C". If the control bar does not appear by assay completion, the test result is invalid. Repeat the test using a new test strip. A visible control bar confirms a lateral flow through the membrane.

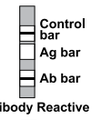
INTERPRETATION OF RESULTS (See pictures)

NOTES:

- Any reactivity on 1) the Ab bar alone 2) the Ag bar alone or 3) both, the Ab and Ag bar simultaneously, is considered a reactive result suggestive of infection with HIV.
- Interpret any visible red bar (even very faint) in the control window as a valid result.
- The test result is reactive even if the Ag or Ab bars appear lighter or darker than the control bar. Any visible red bar, no matter how faint, together with a control bar is interpreted as reactive.
- A test that has a very red background color making the Ag, Ab, and Control bars difficult to read, as can occur with hemolytic specimens, should be considered invalid.
- If an invalid result occurs repeatedly, or for technical assistance, contact your local distributor or call Technical Support.

ANTIBODY REACTIVE
(Two Bars - Control and Ab Bars)

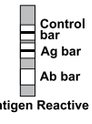
Red bars appear in both the control window (labeled "C") and in the Ab window (labeled "AB") of the strip. Interpret any visible red bar, no matter how faint, in the Ab window as reactive.



Antibody Reactive

ANTIGEN (p24) REACTIVE (Two Bars - Control and Ag Bars)

Red bars appear in both the control window (labeled "C") and in the Ag window (labeled "AG") of the strip. Interpret any visible red bar, no matter how faint, in the Ag window as reactive. The presence of only an antigen response suggests that the infection is at an early stage. Follow up testing may be suggested in order to track the expected future detection of antibodies.



Antigen Reactive

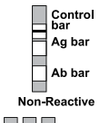
ANTIBODY REACTIVE AND ANTIGEN (p24) REACTIVE (Three Bars - Control, Ab and Ag Bars)

Red bars appear in the control window (labeled "C"), the Ab window (labeled "AB") and the Ag window (labeled "AG") of the strip. Interpret any visible red bar in the Ab and Ag windows as reactive.

Antigen and Antibody Reactive

NON-REACTIVE (One Bar - Control Bar)

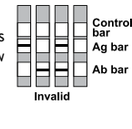
One red bar appears in the control window of the strip (labeled "C"), and no red bar appears in the Ab and Ag windows of the strip (labeled "AG" and "AB").



Non-Reactive

INVALID (No Control Bar)

If there is no red bar in the control window of the strip, and even if a red bar appears in the Ab or Ag window of the strip, the result is invalid. Repeat the test using a new test strip.



Invalid

LIMITATIONS OF THE PROCEDURE

- **Determine** HIV Early Detect is designed to detect antibodies (Ab) to HIV-1 and/or HIV-2 and non-immunocomplexed (free) HIV-1 p24 antigen (Ag), in human serum, plasma and capillary and venous whole blood specimens. Other body fluids or pooled specimens may not give accurate results and should not be used.
- The intensity of the Ab and Ag bars does not necessarily correlate to the titer of antibody and antigen in the specimen, respectively.
- A reactive result for antibodies to HIV-1/2 combined with a non-reactive result for HIV-1 p24 antigen does not preclude the possibility of acute HIV infection.
- Reactivity for both antibody and antigen bar or for antigen reactivity only may be confirmed by 4th generation EIA or NAT where the IVD is indicated as an aid for diagnosis. Antibody reactivity only can also be confirmed by using another HIV Ab RDT. If non-reactive in subsequent testing, retest at least 14 days after the original test is recommended. Follow the local guideline for confirmatory methods if applicable.
- No test provides absolute assurance that a specimen does not contain low levels of HIV-1 p24 antigen and/or antibodies to HIV-1 and HIV-2 such as those present at a very early stage or late stage of HIV infection.
- A non-reactive result for both antibodies to HIV-1/2 and HIV-1 p24 antigen does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2 viruses.
- The absence of Ag bar may occur when all p24 antigen is bound by antibodies. When high levels of antibodies against the p24 antigen are present in the blood after seroconversion,

the antibodies tend to bind to the antigens, forming immunocomplexes. **Determine** HIV Early Detect detects only non-immunocomplexed (free) antigens; it does not detect immunocomplexed (bound) antigens.

- Some known HIV-infected persons taking antiretroviral medication have been shown to produce false negative results when tested by rapid diagnostic tests.[10,11,12]
- Where clinical presentation is inconsistent with the non-reactive **Determine** HIV Early Detect test result, the individual should be re-tested for antibodies to HIV with **Determine** HIV Early Detect at least 14 days after the original test, or with a NAT assay that is indicated for diagnosis.
- Whole blood or plasma specimens containing anticoagulants other than EDTA have not been validated for use with the **Determine** HIV Early Detect and may give incorrect results.
- Infants born to HIV-infected mothers may carry maternal antibodies and will test antibody positive until eighteen months of age, which may not necessarily indicate the true infection status of the new born. The use of HIV- 1 p24 antigen testing to exclude infection in neonates (up to around eighteen months) is not recommended by CDC, because of poor sensitivity, especially in the presence of HIV antibody. Definitive diagnosis of HIV infection in early infancy requires other assays, including HIV nucleic acid test or viral culture.[9]
- Biotin treatment higher than 20mg per day may lead to decreased Ag bar intensity. Biotin concentrations up to 200 ng/mL in serum or whole blood did not impact the sensitivity. There is no impact to Ab bar by biotin.

PERFORMANCE CHARACTERISTICS

SENSITIVITY

Sensitivity was evaluated by testing confirmed HIV antibody positive specimens, commercial seroconversion panels and HIV-1 subtype virus panels.

1. HIV Antibody Positive Specimens:

Table I
HIV Antibody Positive Specimens

Types	Number of Specimens Tested	Reactive by **Determine** HIV Early Detect	Sensitivity
HIV-1	422	422	100.0%
HIV-1 non B subtypes *	56	56	100.0%
HIV-1 group O	4	4	100.0%
HIV-2	100	100	100.0%
HIV**	100	100	100.0%
Total	**682**	**682**	**100.0%**

* Subtypes: A, C, D, F, G, H, J, K, and CRF01-AE, CRF02-AG, CRF03-AB, CRF05-DF, CRF09-A/U, CRF11-cpx

** Specimens collected in Europe

A total of 682 confirmed HIV positive specimens were tested (Table I). The antibody diagnostic sensitivity of **Determine** HIV Early Detect on this population of specimens was calculated to be 100%.

2. HIV Seroconversion Panels: (See Table II on the last page.)

The sensitivity of the **Determine** HIV Early Detect was evaluated using 31 sets of seroconversion panels; each including early seroconversion panel members (98 early samples in total). The results were compared with the results of commercially available CE marked HIV 4th generation rapid immunochromatographic test kit, CE marked HIV 3rd generation rapid immunochromatographic test kit, HIV antibody EIA kit, HIV antigen EIA kit. Additionally, the results of 20 seroconversion panels were compared with the data of CE marked HIV 4th generation kit (Chemiluminescent microparticle immunoassay (CMIA)).

On 28 of 31 panels, **Determine** HIV Early Detect detected HIV infection earlier than a 3rd generation rapid immunochromatographic test kit. On 11 of 31 panels, **Determine** HIV Early Detect detected HIV infection earlier than a rapid 4th generation immunochromatographic test kit.

Detection of six of 20 panels by **Determine** HIV Early Detect was delayed by 1 bleed date when compared to a 4th generation kit (CMIA).

Detection of eight of 31 panels by **Determine** HIV Early Detect was delayed by 1 bleed date when compared to HIV Antigen Kit (EIA).

3. HIV-1 p24 Subtype Antigens:

50 HIV virus panels were prepared by diluting 50 different cultured HIV isolates including HIV-1 group M subtypes: A(4), B(8), C(7), D(5), F(5), G(2), H(1), and CRF01-AE(10), CRF02-AG(2), HIV-1 group O(4) and HIV-2(2) with HIV negative human serum. The **Determine** HIV Early Detect detected all HIV-1 panels and did not detect HIV-2 panels.

4. Analytical Sensitivity of HIV-1 p24 antigen

The analytical sensitivity of the **Determine** HIV Early Detect was evaluated by testing WHO International Standard HIV-1 p24 Antigen (NIBSC code 90/636). The results demonstrated that the test could detect a concentration of 2 IU/mL HIV-1 p24 antigen.

SPECIFICITY

A total of 2509 confirmed negative serum or plasma specimens were tested with the **Determine** HIV Early Detect and the specificity was **Determine**d for the antibody (Ab) bar and for the antigen (Ag) bar (Table III). The specificity was 99.92% for the antibody (Ab) bar and 99.72% for the antigen (Ag) bar.

Table III
Specificity of Determine HIV Early Detect

Population	Number of Tested Specimens	**Determine** HIV Early Detect					
		Ab bar		Ag bar		Combined Ab and Ag bar	
		Reactive	Non-reactive	Reactive	Non-reactive	Reactive	Non-reactive
Seronegative specimens*	1749	0	1749	2	1747	2	1747
Hospitalized specimens	218	1	217	2	216	3	215
Pregnant women	206	0	206	0	206	0	206
potentially cross-reacting specimens**	336	1	335	3	333	4	332
Total	2509	2	2507	7	2502	9	2500
Specificity (%)		99.92		99.72		99.64	

* Including specimens collected in Europe (300), USA (1299) and Africa (150)

** Disease states other than HIV, and potentially interfering substances: Rheumatoid factor (1), antinuclear antibody, systemic lupus erythematosus, high cholesterol, high total protein, high IgM (1), human anti mouse IgG, other infections (HBV, HCV, acute HAV (1), HTLV I or II, CMV, Toxo IgG, Syphilis, HSV 1/2, varicella zoster virus, influenza A and B, malaria, visceral leishmaniasis, and acute or chronic EBV), Flu vaccinated patients, measles (1), and dialysis patient specimens. Numbers in ( ) indicates number of specimen that showed false positive results.

INTERFERENCE

- 20mg/dL bilirubin, 500mg/dL hemoglobin, 3300mg/dL triglyceride, and 12g/dL protein did not interfere with test results.
- At 15g/dL protein, the test result presented false positive on Ab bar with Ab negative samples. No interference was observed on Ag bar.
- When specimens diagnosed as positive to rheumatoid factor were spiked with p24 antigen, the test result of 2 out of 5 samples presented false negative on Ag bar.

SAMPLE TYPE

Table IV
Antibody sensitivity in matched whole blood (venipuncture and fingerstick), serum and plasma specimens

No. of matched specimens tested	Type of Specimens and No. of Reactive by **Determine** HIV Early Detect (Ab detection)				Correlation between matrices
	Serum	Plasma	Whole Blood venipuncture	Whole Blood fingerstick*	
25	25	25	25	NT	100.0%
25	25	25	25	25	100.0%

NT: not tested *EDTA capillary tubes

Multiple (matched) specimens: Seropositive specimens from a total of 50 individuals from Africa were tested with the **Determine** HIV Early Detect (Table IV). Multiple (matched) specimens, 50 serum specimens, 50 plasma specimens, 50 whole blood (venipuncture) specimens and 25 whole blood (fingerstick) specimens were obtained from the donors in Africa. The results obtained from all specimen matrices showed 100% correlation, demonstrating that **Determine** HIV Early Detect gives identical results for these types of specimen matrices.

Table V
Specificity in matched whole blood (venipuncture and fingerstick), serum and plasma specimens

No. of matched specimens tested	Type of Specimens and No. of Non-reactive by **Determine** HIV Early Detect				Correlation between matrices
	Serum	Plasma	Whole Blood venipuncture	Whole Blood fingerstick*	
25	25	25	25	NT	100.0%
25	25	25	25	25	100.0%

NT: not tested *EDTA capillary tubes

Multiple (matched) specimens: Seronegative specimens from a total of 50 individuals from Africa were tested with the **Determine** HIV Early Detect (Table V). Multiple (matched) specimens, 50 serum specimens, 50 plasma specimens, 50 whole blood (venipuncture) specimens and 25 whole blood (fingerstick) specimens were obtained from the donors in Africa. The results obtained from all specimen matrices showed 100% correlation, demonstrating that **Determine** HIV Early Detect gives identical results for these types of specimen matrices.

Table II
HIV Seroconversion Panels

No	Panel	Days to First Reactive Results				
		Determine™ HIV Early Detect	4th gen rapid test	3rd gen rapid test	4th gen kit (CMIA)*	HIV antigen EIA*
		Ag/Ab	Ag/Ab	Ab	Ag/Ab	Ag
1	PRB943	12	12	19	7	7
2	PRB956	47	50	>50	47	47
3	PRB958	9	15	15	7	7
4	PRB961	27	29	>29	27	27
5	PRB962	14	14	>17	14	14
6	PRB963	17	17	>21	17	17
7	PRB966	48	51	51	44	44
8	PRB967	17	17	17	17	17
9	PRB968	26	26	28	26	26
10	PRB969	70	70	70	63	63
11	PRB970	7	7	14	0	0
12	PRB972	18	18	18	18	18
13	PRB973	11	11	>11	7	7
14	PRB974	9	16	>16	9	9
15	PRB975	14	>14	>14	14	14
16	PRB976	7	7	>9	7	7
17	PRB977	13	13	15	13	13
18	PRB924	26	26	33	NT	26
19	PRB926	7	7	27	NT	7
20	PRB934	0	7	7	NT	0
21	PRB935	28	28	43	NT	28
22	PRB940	7	7	15	NT	7
23	PRB945	13	13	15	NT	13
24	PRB947	9	9	11	NT	9
25	PRB948	23	23	>23	NT	23
26	PRB949**	18	18	>18	NT	18
27	PRB951	11	11	19	NT	8
28	PRB955	7	12	12	NT	3
29	9018	28	35	35	28	28
30	9022	25	32	32	25	25
31	9079	40	42	55	40	40
Total		31	31	31	20	31
Detected earlier than **Determine** HIV Early Detect			0	0	6	8
Detected same day as **Determine** HIV Early Detect			20	3	14	23
Detected later than **Determine** HIV Early Detect			11	28	0	0

* Vendor certificate data, **PRB949 No.5 was not tested. NT: not tested

Advice Line

For further information, please contact your distributor, or call one of the following Abbott Technical Support Care Centers:

Region	Phone	E-Mail Address
Europe	+ (44) 161 483 9032	EME.TechSupport@abbott.com
Middle East	+ (965) 2202 2828	EME.TechSupport@abbott.com
Asia Pacific	+ (61) 7 3363 7711	AP.TechSupport@abbott.com
Africa	+ (27) 10 500 9700	arcis.techsupport@abbott.com
Russia & CIS	+ (7) 499 403 9512	arcis.techsupport@abbott.com
Latin America	+ (57) 601 482 4033	LA.TechSupport@abbott.com

Glossary of Symbols	
	Temperature limit (2°C to 30°C)
	Catalogue number
	Do not reuse
	*In vitro* diagnostic medical device
	Do not use if package is damaged and consult instructions for use
	Keep away from sunlight
	Contains Sufficient for n tests
	Consult instructions for use
	Batch Code
	Use-by date
	Unique device identification
	Manufacturer

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