

WHO Prequalification of In Vitro Diagnostics Programme PUBLIC REPORT

Product: SURE CHECK HIV 1/2 Assay
Number: PQDx 0054-006-00

SURE CHECK HIV 1/2 Assay with product code **HIV201 (60-9527-0)**, manufactured by **Chembio Diagnostic Systems, Inc.** Rest-of-World regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 8 December 2014.

Summary of prequalification status for SURE CHECK HIV 1/2 Assay

	Date	Outcome
Status on PQ list	08-Dec-2014	Listed
Dossier assessment	12-Aug-2014	MR
Site inspection(s) of quality management system	27-Nov-2014	MR
Product performance evaluation	31-Oct-2014	MR

MR: Meets Requirements

Report amendments and/or product changes

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

Version	Summary of amendment	Date of report amendment
2.0	Correction of a typographical error.	4-Jun-2018
3.0	Update the “internal finished goods part number for the SURE CHECK HIV 1/2 Assay (Product Code HIV201) from 60-9520-0 to 60-9527-0 to distinguish the WHO Prequalified (Rest-of-World) labelling from the CE Marked labelling.	16-Apr-2020

Intended use:¹

According to the claim of intended use from Chembio Diagnostic Systems, Inc, “*Chembio SURE CHECK® HIV 1/2 assay is a single-use immunochromatographic, rapid test for the detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV 1/2) in fingerstick whole blood, venous whole blood, serum or plasma specimens. The Chembio SURE CHECK® HIV 1/2 assay is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for the statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms. This product is intended for use on patients that are 13 years and above. The product is for professional use by trained health care workers. This product is not intended for blood donor screening*”.

Assay description:

According to the claim of assay description from Chembio Diagnostic Systems, Inc, “*Chembio SURE CHECK HIV 1/2 assay employs a unique combination of a specific antibody binding protein which is conjugated to colloidal gold dye particles and HIV 1/2 antigens which are bound to the solid phase membrane. The specimen - venous or capillary (fingerstick) whole blood, serum or plasma - is applied to the capillary tip of the test device. The sampler is inserted into the Buffer, which is provided in a sealed vial. The Buffer facilitates the lateral flow of the sampler and test reagents and promotes the binding of the antibodies to the antigen. The specimen/buffer mixture migrates along the test strip by capillary action, reconstituting the conjugate. If present, the antibodies bind to the gold conjugated antibody binding protein. In a reactive sample, the dye conjugated-immune complex migrates on the nitrocellulose membrane and is captured by the antigens immobilized in the TEST area producing a pink/purple line. In the absence of HIV 1/2 antibodies, there is no pink/purple line in the TEST area. The sample continues to migrate along the membrane and produces a pink/purple line in the CONTROL area containing Protein A. This procedural control serves to demonstrate that specimen and reagents have been properly applied and have migrated through the device. Results can be read at 15 and 20 minutes from the addition of the Sampler to the Buffer Vial.*”

Test kit contents

Each test kit contains the components to perform 25 tests:

- 1 × Product insert for the SURE CHECK® HIV 1/2 assay
- 1 × Disposable Rack for holding Buffer Vials upright
- 1 × Insert for the Disposable Rack

25 pouches, each containing:

- 1 × Sampler with a test strip inside

¹ This product is one that uses Protein A to detect human IgG antibodies. Protein A is also able to detect other classes of human antibody (IgA, IgD, IgE and IgM) but not as reliably as it does IgG. This product has been prequalified with respect to its ability to detect human IgG antibodies. Any claim to detect other types of antibodies on this kind of product has not been validated based on WHO prequalification requirements.

- 1 × Buffer Vial attached to the sampler (~350 µl)
- 1 × Sterile Lancet
- 1 × Bandage
- 1 × Desiccant Packet

Storage:

The test kit should be stored between 8 °C to 30 °C.

Shelf-life:

24 months.

Warnings/limitations

Refer to current version of manufacturer's instructions for use.

Prioritization for prequalification

Chembio Diagnostic Systems, Inc. submitted an application for prequalification of SURE CHECK HIV 1/2 Assay. Based on the established eligibility criteria, SURE CHECK® HIV 1/2 Assay was given priority for prequalification assessment.

Dossier assessment

Chembio Diagnostic Systems, Inc. submitted a product dossier for SURE CHECK HIV 1/2 Assay as per the WHO guidance document "Instructions for Compilation of a Product Dossier" (PQDx_018 v1). The information submitted in the product dossier was reviewed by WHO staff and external experts (reviewers) appointed by WHO in accordance with the WHO document "Internal Report on the Screening and Assessment of a Product Dossier" (PQDx_009 v2). Based on the product dossier screening and assessment findings, a recommendation was made to accept the product dossier for SURE CHECK HIV 1/2 Assay for prequalification.

Manufacturing site inspection

A comprehensive inspection was performed at the site of manufacture (Medford, USA) of SURE CHECK HIV 1/2 Assay test in October 2014 as per the WHO guidance document "Information for Manufacturers on Prequalification Inspection Procedures for the Sites of Manufacture of Diagnostics" (PQDx_014 v1). The inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality. The manufacturer's responses to the nonconformities found at the time of the inspection were accepted 21 November 2014.

Product performance evaluation

SURE CHECK HIV 1/2 Assay (Chembio Diagnostics System Inc.) was evaluated by the Institute of Tropical Medicine, Antwerp, Belgium, on behalf of WHO in the third quarter of 2014 using serum/plasma specimens. From this evaluation, we drew the following conclusions:

SURE CHECK HIV 1/2 Assay (Chembio Diagnostics System Inc.) is an immunochromatographic assay for the detection of HIV-1/2 antibodies in human serum/plasma and whole blood specimens. A volume of 2.5 µL of serum/plasma specimen is required to perform the assay. This type of assay does not require 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. When using serum or plasma specimens, a precision pipette has to be used to deliver the specimen.

In this limited evaluation on a panel of 1118 clinically-derived specimens, we found an initial sensitivity (95% CI) of 99.8% (98.8% - 100%) and an initial specificity (95% CI) of 99.9% (99.2% - 100%) compared to the reference assays (Vironostika HIV Ag/Ab [bioMérieux] and Enzygnost Anti-HIV 1/2 [Siemens Healthcare Diagnostics]; followed by INNO-LIA HIV I/II Score [Fujirebio]). The final sensitivity (95% CI) was 99.8% (98.8% - 100%) and the final specificity (95% CI) was 99.9% (99.2% - 100%) compared to the reference assays. Lot to lot variation was acceptable.

For eight seroconversion panels, SURE CHECK HIV 1/2 Assay detected on average 0.25 specimens later than the benchmark assay; Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics).

For the mixed titer panel, SURE CHECK HIV 1/2 Assay correctly classified all anti-HIV negative/HIV-1 antigen negative specimens, all anti-HIV positive/HIV-1 antigen positive specimens and all anti-HIV positive/HIV-1 antigen negative specimens of the HIV mixed titer panel in comparison with the expected results. SURE CHECK HIV 1/2 Assay was not able to detect three out of the six anti-HIV indeterminate/HIV-1 antigen positive specimens. The assay did not detect the anti-HIV negative/HIV-1 antigen positive specimen.

For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], SURE CHECK HIV 1/2 Assay detected all specimens.

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

Labelling

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

1. Labels

- **Kit Box Label: 10-6003-2**

- **Pouch (Device) Foil: 10-3519-1**

- **Disposable Rack: 10-6047-1**

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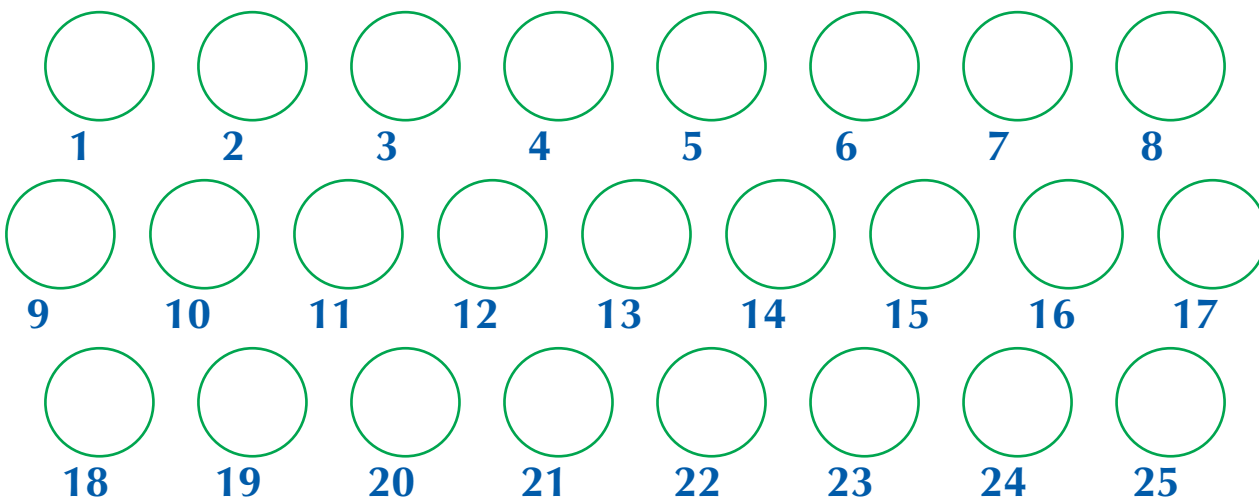
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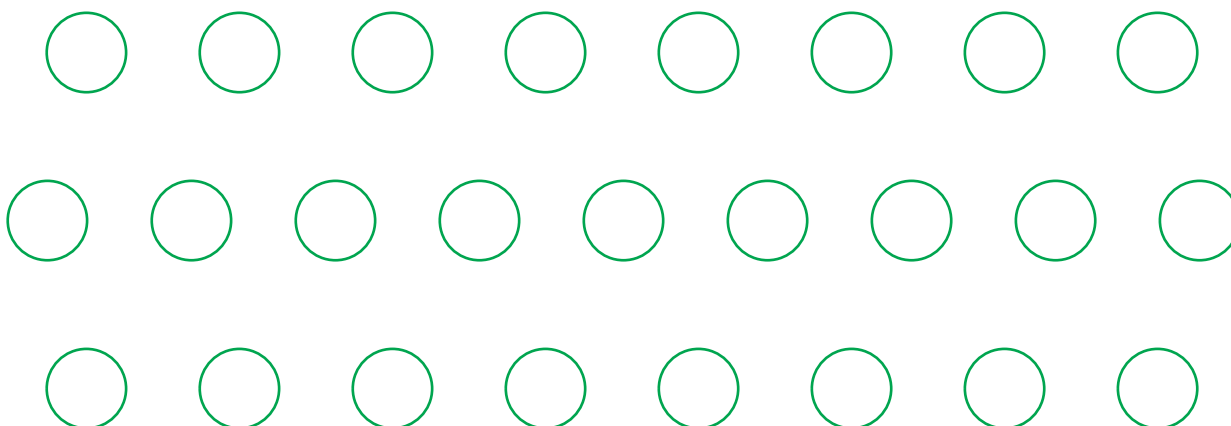
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SPOT AQUEOUS 

(void for glue only)



Rev. 3
10-6047-1



2. Instructions for use²

- **Product Package Insert (IFU): 10-6174-1**

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.

SURE CHECK® HIV 1/2

A Qualitative Screening Test Kit for the Detection of Antibodies to HIV 1/2 in Human Fingertick and Venous Whole Blood, Serum and Plasma

Read this Product Insert completely before using the product. Follow the instructions carefully when performing the test as not doing so may result in inaccurate Test Results.

STORAGE: Store at 8 to 30°C (46 to 86°F)

INTENDED USE

The Chembio SURE CHECK® HIV 1/2 assay is a single-use immunochromatographic, rapid test for the detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV 1/2) in fingertick whole blood, venous whole blood, serum or plasma specimens. The Chembio SURE CHECK® HIV 1/2 assay is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for the statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms. This product is intended for use on patients that are 13 years and above. The product is for professional use by trained health care workers. This product is not intended for blood donor screening.

SUMMARY AND EXPLANATION OF THE TEST

Discovered in 1983, the Human Immunodeficiency Virus is a retrovirus and identified as the etiologic agent for the Acquired Immunodeficiency Syndrome (AIDS), and AIDS related complex [2]. AIDS is characterized by changes in the population of T-cell lymphocytes that play a key role in the immune defense system. In the infected individual the virus causes a depletion of a subpopulation of T-cells, called T-helper cells, which leaves these patients susceptible to opportunistic infections and certain malignancies. The major routes of transmission are sexual contact, exposure to contaminated blood or blood products (including sharing of contaminated syringes and needles) and mother-to-newborn transmission [3-5].

In 2007 there were 2.7 million new HIV infections and 2 million HIV-related deaths. The rate of new HIV infections has fallen in several countries; however, globally these favorable trends are partially offset by increases in new infections in other countries.

As access to treatment has increased over the last ten years, the annual number of AIDS deaths has fallen. Sub-Saharan Africa remains the region most heavily affected by HIV, accounting for 67% of all people living with HIV and for 75% of AIDS deaths in 2007. However, increases in new infections are now occurring in populous countries in other regions, including Indonesia, the Russian Federation, and various high-income countries [6].

The first AIDS cases were reported in the United States in June of 1981 [7]. Since that time, approximately 1.7 million people in the U.S. are estimated to have been infected with HIV, including more than 565,000 who have already died and more than 1.1 million estimated to be living with HIV/AIDS today [8,9].

The HIV virus consists of a genomic RNA molecule protected by a capsid and an envelope. The HIV envelope is the major target for a humoral antibody response. The presence of the virus in patients causes the immune system to elicit the production of antibodies. The detection of these antibodies can be used as a diagnostic tool.

Enzyme Immunoassays (EIAs), Western Blots (WB), Nucleic Acid Amplification Test (NAT) assay and various other test systems are currently available for detection of HIV-1 and HIV-2 infection. The Chembio SURE CHECK® HIV 1/2 assay utilizes immobilized antigens for the detection of antibodies to HIV-1 and HIV-2, and is a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.

BIOLOGICAL PRINCIPLES OF THE TEST

The Chembio SURE CHECK® HIV 1/2 assay employs a unique combination of a specific antibody binding protein which is conjugated to colloidal gold dye particles and HIV 1/2 antigens which are bound to the solid phase membrane. The specimen - venous or capillary (fingertick) whole blood, serum or plasma - is applied to the capillary tip of the test device. The sampler is inserted into the Buffer, which

is provided in a sealed vial. The Buffer facilitates the lateral flow of the sampler and test reagents and promotes the binding of the antibodies to the antigen. The specimen/buffer mixture migrates along the test strip by capillary action, reconstituting the conjugate. If present, the antibodies bind to the gold conjugated antibody binding protein. In a reactive specimen, the dye conjugated-immune complex migrates on the nitrocellulose membrane and is captured by the antigens immobilized in the TEST area producing a pink/purple line. In the absence of HIV 1/2 antibodies, there is no pink/purple line in the TEST area. The specimen continues to migrate along the membrane and produces a pink/purple line in the CONTROL area containing Protein A. This procedural control serves to demonstrate that specimen and reagents have been properly applied and have migrated through the device. Results can be read at 15 and 20 minutes from the addition of the Sampler to the Buffer Vial.

MATERIALS PROVIDED

Each Kit contains the components to perform 25 tests:

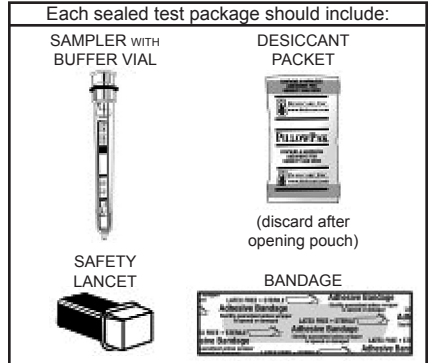
- 1 Product Insert for the SURE CHECK® HIV 1/2 assay
- 1 Disposable Rack for holding Buffer Vials upright
- 1 Insert for the Disposable Rack

25 Pouches, each containing:

- 1 Sampler with a test strip inside
- 1 Buffer Vial attached to the sampler (~350µL)
- 1 Sterile Lancet
- 1 Bandage
- 1 Desiccant Packet

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock, watch, or other timing device
- Pipettor capable of delivering 2.5µL of specimen (for other than fingerstick specimens)
- Disposable gloves
- Sterile gauze
- Antiseptic wipes
- Biohazard disposal container
- Collection devices for specimens other than fingerstick whole blood specimens.



WARNINGS

For *IN VITRO* diagnostic use

1. Read the Product Insert completely before using this assay. Follow the instructions carefully as not doing so may result in inaccurate Test Results.
2. Users of this test should follow the CDC Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other blood borne pathogens.[1]
3. Use of this test Kit with specimen types other than those specifically approved for use with this device may result in inaccurate Test Results.
4. This test should be performed at 18 to 30°C (64 to 86°F). If stored refrigerated, ensure that the pouch is brought to operating temperature before performing testing.
5. The test kit must be stored within the specified storage temperatures of 8 to 30°C (46 to 86°F) to ensure proper performance of the test.
6. An individual infected with HIV-1 and/or HIV-2 who is receiving highly active antiretroviral therapy (HAART) may produce false negative results.

PRECAUTIONS

Safety Precautions

1. Handle the specimens and materials contacting specimens as if capable of transmitting infection.
2. Do not eat, drink or smoke in the area where specimens and kit reagents are handled. Avoid any contact with hands, eyes or mouth during specimen collection and testing.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling specimens.
4. Dispose of all specimens and materials used in the test procedure in a biohazard waste container. Lancets should be placed in a puncture-resistant container prior to disposal. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121°C. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended.

Allow 60 minutes for effective decontamination.

NOTE: Do not autoclave solutions that contain bleach.

5. For additional information on biosafety, refer to “Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other bloodborne pathogens.” [1] and assure accordance with Local, State, Federal or European Regulations. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. Use 10% bleach or other appropriate disinfectant to wipe all spills. The bleach solution should be made fresh each day.
7. The running buffer contains Sodium Azide (0.2%). Avoid skin contact with this reagent. Sodium Azide may react with lead and copper in plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.

HANDLING PRECAUTIONS

1. The Chembio SURE CHECK® HIV 1/2 assay device has a specimen filter in the lower part of the device and an absorbent pad in the upper part of the device within the barrel that encloses the test strip. Confirm the presence of the specimen filter and absorbent pad prior to performing the test. If either is missing, DO NOT USE.
2. Do not use any device if the pouch has been perforated. Do not use the device if the Desiccant Packet is missing.
3. Each device is for single use only.
4. Do not use the reagents beyond the expiration date printed on the pouch. Always check expiration date prior to testing.
5. Do not mix reagents from different lot numbers of Kits.
6. To ensure accurate Test Results, the Sampler must be inserted into the Buffer Vial immediately after the specimen application.
7. Adequate lighting is required to read the Test Results.

STORAGE

The Chembio SURE CHECK® HIV 1/2 assay should be stored in its unopened pouch at 8 to 30°C (46 to 86°F). Do not freeze. Do not open the pouch until you are ready to perform a test. When stored as indicated, test devices are stable until the expiration date marked on the pouch.

SPECIMEN COLLECTION AND PREPARATION

The Chembio SURE CHECK® HIV 1/2 assay is performed on fingerstick whole blood, venous whole blood, serum or plasma specimens. All specimens should be collected, centrifuged (if applicable) and stored following local clinical or laboratory procedures. No special preparation of the patient is necessary prior to collection by approved techniques. Though fresh serum is preferable, specimens may be stored at 4-8°C for up to 24-48 hours in case of delay in testing [10]. Do not use turbid, lipemic and haemolyzed specimens.

Fingerstick Whole Blood: Prepare to perform the fingerstick blood collection procedure. Clean the finger of the person being tested with an antiseptic wipe. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad. Uncap the sterile safety lancet and verify the lancet is unused. Puncture the skin just off the center of the finger and wipe away the first drop with sterile gauze and avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess tissue fluid. Collect the specimen from the second drop touching the Sampler tip of the device to the drop of blood until the Sampler tip is full. Test immediately, following Test Procedure Instructions.

Venous Whole Blood: Draw blood following laboratory procedures for obtaining venous blood. Collect specimen in a tube containing EDTA. Be sure the tube of blood is well mixed.

Serum or Plasma: Draw blood following laboratory procedures for obtaining serum or plasma specimens. Collect specimen in a tube not containing any anticoagulant (serum), and in a tube containing EDTA (plasma). Collect specimen in a clean container following standard laboratory procedures.

Venous whole blood, serum and plasma specimens may be tested immediately after collection. If specimens are not tested immediately, refrigerate them at 4 to 8°C (39 to 46°F) following collection. These specimens should be tested within 48 hours of collection. If specimens are not tested within 48 hours of collection, serum or plasma specimens should be frozen at -20°C (-4°F) or colder in accordance with local clinical or laboratory procedures. **DO NOT FREEZE WHOLE BLOOD!**

SPECIMEN SHIPPING

If specimens are to be shipped, they should be packed in compliance with regulations covering the transportation of etiologic agents. Venous whole blood, serum and plasma specimens should be shipped refrigerated with cold packs or wet ice.

Kit Component Preparation

All components for the Chembio SURE CHECK® HIV 1/2 assay are ready to use as supplied. Follow directions as indicated.

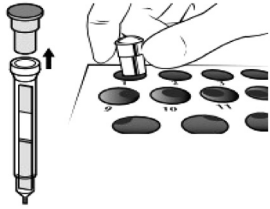


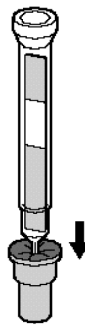
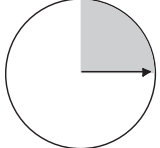
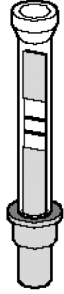
TEST PROCEDURE

If the specimen to be tested is refrigerated, remove it from the refrigerator and allow it to come to a temperature of 18 to 30°C (64 to 86°F) prior to testing.

Fingerstick/Capillary Whole Blood: Obtain a blood drop by finger stick.

Venous Whole Blood: Obtain a venous blood specimen in a tube containing EDTA anticoagulant.

Serum or Plasma: Obtain a serum or plasma specimen following standard laboratory procedure.

<p>1 <u>Open Pouch and remove components.</u> <u>Remove Buffer Vial</u> – separate from top of Sampler and place in Disposable Rack.</p> <p><u>Note:</u> If Desiccant Packet is missing or if absorbent pad (at top of Sampler) is missing, DO NOT USE. Discard device and use a new device.</p>	
<p>2 <u>Specimen Application</u> – For fingerstick whole blood, touch blood drop with Sampler tip until the tip is full.</p> <p style="text-align: center;">Fingerstick example</p>  <p>For Venous whole blood, serum, or plasma, invert Sampler and pipet 2.5 µL of specimen into sampler tip.</p> <p style="text-align: center;">Whole Blood example</p> 	<p>3 <u>Start the test</u> –</p> <ol style="list-style-type: none">1. With buffer vial in rack, firmly press the sampler tip through foil cover.2. Continue pushing to the bottom of the vial until sampler and buffer vial snap together tightly. It will snap 3 times when properly seated. Snap 1: through the foil Snap 2: into Buffer vial Snap 3: seat and seal <p>CAUTION: When inserting tip through foil cover, push firmly to puncture foil, but do not jab into foil cover.</p> 
<p>4 <u>Start timing</u> – wait for 15 minutes.</p> <p>NOTE: the Sampler/ Buffer vial should be kept upright in the Disposable Rack.</p> <p>Check for pink/purple flow in 1 minute.</p> <p>If no pink/purple flow, push test device further down.</p> 	<p>5 <u>Read Test Results</u> – Read the test between 15 and 20 minutes.</p> <p>NOTE: Reactive Test Results (see Interpretation of Test Results Section) may be observed and read earlier than 15 minutes. To verify a Nonreactive Test result, wait the entire 15 minutes after starting the test.</p> <p>Do not read results after 20 minutes.</p> 

QUALITY CONTROL

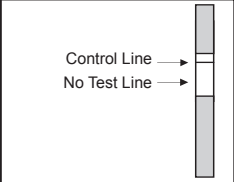
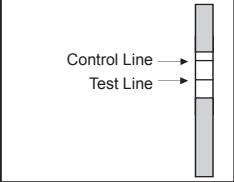
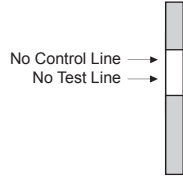
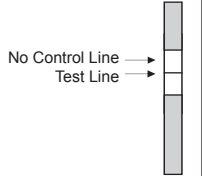
Built-in Control Feature

A pink/purple line will appear in the CONTROL area if the test has been performed correctly and the device is working properly. It serves as a built-in procedural control.

INTERPRETATION OF RESULTS

When the Chembio SURE CHECK® HIV 1/2 assay is properly performed, the appropriate pink/purple lines will become visible. These are:

1. The **Control Line** - which appears closer to the top of the test strip, indicates the presence of specimen and proper hydration and migration of reagents. The control line will become visible in 15 minutes after starting the test regardless of the HIV antibody status of the specimen.
2. The **Test Line** - which appears closer to the bottom of the test strip (below the control line) indicates the presence of HIV-specific antibodies. The test line will only become visible in 15 minutes after starting a valid test when HIV specific antibodies are present at detectable levels in the specimen.

Nonreactive:	One pink/purple line in the CONTROL area, with no line in the TEST area indicates a non-reactive result. A nonreactive result after 15 minutes indicates that there are no detectable HIV antibodies in the specimen. However, this result does not exclude possible infection with HIV.	 <p>Control Line →</p> <p>No Test Line →</p>
Reactive:	Two pink/purple lines, one in the TEST area and one in the CONTROL area indicate a reactive result. The line in TEST area may look different from the line in the CONTROL area. Intensities of the test and control lines may vary. A visible line in the test area, regardless of intensity, is considered reactive.	 <p>Control Line →</p> <p>Test Line →</p>
Invalid Test:	A pink/purple line should always appear in the CONTROL area, whether or not a line appears in the TEST area. If there is no distinct pink/purple line visible in the CONTROL area, the test is invalid. It is recommended that the test be repeated with a new device.	 <p>No Control Line →</p> <p>No Test Line →</p>  <p>No Control Line →</p> <p>Test Line →</p>

PERFORMANCE CHARACTERISTICS

SENSITIVITY

The sensitivity of the Chembio SURE CHECK® HIV 1/2 assay to detect infection with HIV-1 was evaluated using 399 specimens from individuals known to be infected with HIV-1. Specimens were identified as reactive using an FDA Licensed EIA/Western Blot and/or CE Marked EIA/Rapid Test. Of the 399 true positive specimens, the sensitivity for capillary (fingerstick) whole blood was 100% (252/252, 95% CI: 98.6-100%), venous whole blood was 100% (299/299, 95% CI: 98.8-100%), and serum/plasma was 100% (352/352, 95% CI: 99.0-100%). See Table 1.

TABLE 1: Detection of antibody to HIV-1 in specimens from individuals known to be infected with HIV-1

Matrix	Study Population	Specimens	SURE CHECK® HIV 1/2 ASSAY Reactive	FDA Licensed EIA/WB Reactive	CE-Marked EIA/Rapid Test Reactive	True Positive
Capillary (Fingerstick) WB	Positive Specimens from US	252	252	252	252	252
	Positive Specimens from EU	Not tested	Not tested	Not tested	Not tested	Not tested
	TOTAL	252	252	252	252	252
Venous WB	Positive Specimens from US	252	252	252	252	252
	Positive Specimens from EU	47	47	Not tested	47	47
	TOTAL	299	299	252	299	299
Serum	Positive Specimens from US	252	252	252	252	252
	Positive Specimens from EU	100	100	Not tested	100	100
	TOTAL	352	352	252	352	352
Plasma	Positive Specimens from US	252	252	252	252	252
	Positive Specimens from EU	100	100	Not tested	100	100
	TOTAL	352	352	252	352	352

REACTIVITY WITH HIV-1 SPECIMENS FROM VARIOUS GEOGRAPHIC REGIONS

To assess the sensitivity of the SURE CHECK® HIV 1/2 assay for HIV-1 specimens from various geographic regions, 62 serum/plasma specimens representing HIV-1 subtypes A,B,C,D,E,F,G,H,J,K, CRF01_AE, CRF02_AG, CRF03_AB, H/A1, K/CRF09, G/CRF02, CRF01/CRF15. In addition, a total of 7 serum/plasma specimens representing Group O were tested. The SURE CHECK® HIV 1/2 test was able to detect 6 of the 7 Group O specimens evaluated.

REACTIVITY WITH HIV-1 SEROCONVERSION PANELS

Thirty four HIV-1 seroconversion panels were tested in comparison with CE Marked anti-EIA tests and/or CE Marked rapid test. Each panel consisted of sequential serum/plasma specimens obtained from a single individual during seroconversion. In this study, the SURE CHECK® HIV 1/2 assay detected seroconversion in a similar manner of the comparators; including ELISA's registered in major European countries. At least 40 early seroconversion HIV plasma specimens were tested. The results conform to the state of the art.

DETECTION OF ANTIBODIES TO HIV-2 FROM INDIVIDUALS KNOWN TO BE INFECTED WITH HIV-2

The sensitivity of the Chembio SURE CHECK® HIV 1/2 assay to detect infection to HIV -2 was evaluated using a total of 104 plasma specimens confirmed to be HIV-2 antibody positive by a confirmatory CE Marked Rapid test. The diagnostic sensitivity is determined as 100%.

TABLE 2: Detection of Antibodies to HIV-2 in specimens from individuals known to be infected with HIV-2

Study Population	SURE CHECK® HIV 1/2 ASSAY Reactive	CE-Marked Rapid Test Reactive
Known HIV-2	104	104
TOTAL	104	104

SPECIFICITY

PERFORMANCE OF THE ASSAY WITH INDIVIDUALS PRESUMED TO BE NEGATIVE FOR HIV INFECTION

The specificity of the Chembio SURE CHECK® HIV 1/2 assay was evaluated using serum whole blood and plasma specimens. A total of 2051 HIV negative individual specimens were confirmed negative for HIV-1 infection using confirmatory EIA and/or antigen/antibody test. Of these 2051 specimens that were identified as negative for HIV-1 infection, the specificity for capillary (fingerstick) and venous whole blood was 100% (850/850, 95% CI: 99.6-100%), serum was 99.7% (1048/1051, 95% CI: 99.2-99.9%), and plasma was 99.9% (352/352, 95% CI: 99.7-100%). See Table 3.

TABLE 3: Performance of the SURE CHECK® HIV 1/2 assay with individuals presumed to be negative for HIV

Matrix	Study Population	Specimens	SURE CHECK® HIV 1/2 ASSAY Nonreactive	CE-Marked Rapid Test Reactive	True Negative
<i>Capillary (Fingerstick) WB</i>	Negative Clinical Specimens from US	850	850	850	850
	Negative Blood Donors from EU	Not tested	Not tested	Not tested	Not tested
	Negative Pregnant Women from EU	Not tested	Not tested	Not tested	Not tested
	TOTAL	850	850	850	850
<i>Venous WB</i>	Negative Clinical Specimens from US	850	850	850	850
	Negative Blood Donors from EU	Not tested	Not tested	Not tested	Not tested
	Negative Pregnant Women from EU	Not tested	Not tested	Not tested	Not tested
	TOTAL	850	850	850	850
<i>Serum</i>	Negative Clinical Specimens from US	850	850	850	850
	Negative Blood Donors from EU	Not tested	Not tested	Not tested	Not tested
	Negative Pregnant Women from EU	201	198	201	201
	TOTAL	1051	1048	1051	1051
<i>Plasma</i>	Negative Clinical Specimens from US	850	850	850	850
	Negative Blood Donors from EU	1000	999	1000	999
	Negative Pregnant Women from EU	Not tested	Not tested	Not tested	Not tested
	TOTAL	1850	1849	1850	1850

INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS

To evaluate the influence of unrelated medical conditions or interfering substance on the specificity and sensitivity of the Chembio SURE CHECK® HIV 1/2 assay, 208 specimens representing unrelated medical conditions, and 110 specimens representing potential interfering substances were tested. The specimens were spiked with either saline (Nonreactive) or an HIV-1 reactive serum specimen to a low level of reactivity. All HIV-1 spiked specimens gave reactive results while all unspiked specimens, with the exception of one elevated albumin specimen and 14 syphilis specimens, gave nonreactive results. These specimens were confirmed reactive for HIV via licensed western blot.

TABLE 4: Chembio SURE CHECK® HIV 1/2 assay reactivity against specimens from unrelated medical conditions or containing potential interfering substances

Description	Chembio SURE CHECK® HIV 1/2 ASSAY	
	Saline (nonreactive)	HIV-1/2 (reactive)
Cirrhosis	20/20	20/20
CMV IgM	20/20	20/20
Recent flu vaccination (6 Mo.)	11/11	11/11
HBV	21/21	21/21
HCV	19/19	19/19
HTLV 1	11/11	11/11
HTLV 2	10/10	10/10
Multiparous	9/9	9/9
Myeloma	10/10	10/10
Rheumatoid Factor	10/10	10/10
Syphilis	15/29 ¹	29/29
Tuberculosis	38/38	38/38
Albumin 1.3 – 1.9 g/dL	9/10 ²	10/10
Elevated Bilirubin 1.1 - 8.2 mg/dL	10/10	10/10
Citrate	10/10	10/10
DNA 211 - 1041	10/10	10/10
EDTA	10/10	10/10
Hemolyzed	10/10	10/10
Heparin	10/10	10/10
Icteric	10/10	10/10
Protein 6.0 – 8.2 g/dL	10/10	10/10
Elevated Triglycerides 304 – 389 mg/dL	10/10	10/10

¹ Fourteen specimens were confirmed reactive, using a licensed WB assay

² One specimen was confirmed as containing HIV antibodies by using a licensed WB assay

REPRODUCIBILITY

Reproducibility was tested at three independent sites using three lots of the Chembio SURE CHECK® HIV 1/2 assay. A panel of five blinded specimens representing nonreactive, low reactive HIV-1, low reactive HIV-2, high reactive HIV-1 and high reactive HIV-2 were run on three separate days by three separate technicians at each site. Testing was done according to the product insert of the Chembio SURE CHECK® HIV 1/2 assay. Results were read at 15 minutes. Results were read semi-quantitatively using a common strip evaluation scale. A total of 405 data points were taken. There was 100% accuracy (405/405) across all parameters. Weak and strong reactive discrimination for both HIV-1 and HIV-2 was also consistent across all parameters.

SPECIMEN MATRIX EQUIVALENCY

Specimens collected from four geographically distinct clinical sites were tested on the Chembio SURE CHECK® HIV 1/2 assay. Four specimen matrices were collected from over 1,000 participants: capillary whole blood from a fingerstick, venous whole blood collected in EDTA, serum and plasma (collected in

EDTA anticoagulant). Specimens were “same day” fresh and tested in parallel on the SURE CHECK® HIV 1/2 assay ≤1 day after sampling. The data obtained during the clinical study showed 100% agreement among matrices.

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ORDERING INFORMATION

REF HIV201 SURE CHECK® HIV 1/2



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SYMBOL LEGEND	
	CONSULT THE MANUAL BEFORE USE
	CAUTION, CONSULT THE ACCOMPANYING DOCUMENTS
	DO NOT RE-USE
	FOR USE WITHIN TEMPERATURE LIMITS
	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	BATCH CODE
	PRODUCT CATALOG NUMBER
	MANUFACTURERS IDENTIFICATION
	DATE OF MANUFACTURE
	USE BY DATE

Disposable Rack Package Insert: 10-6236-1

DISPOSABLE SURE CHECK® HIV 1/2 RACK

AS DESCRIBED IN THE **SURE CHECK HIV 1/2** PRODUCT INSERT, THE BARREL CONTAINING THE TEST STRIP SHOULD BE HELD VERTICALLY TO ENSURE PROPER PERFORMANCE. IN ORDER TO FACILITATE THE POSITIONING OF THE TEST DEVICE, A DISPOSABLE CARDBOARD RACK IS PROVIDED.

- 1.) TO ASSEMBLE THE RACK:
 - a. PUSH GENTLY ON THE LONG EDGES OF THE CARDBOARD TOWARDS THE CENTERLINE OF THE RACK.
 - b. FOLD THE ENDS IN TO STABILIZE THE RACK.

- 2.) TO RUN THE TEST:
 - a. PLACE THE BUFFER VIAL WITH THE FOIL END UP IN ONE OF THE POSITIONS IN THE RACK.
 - b. AFTER COLLECTING THE BLOOD OR SERUM SAMPLE INTO THE SAMPLER TIP OF THE BARREL, INSERT THE TIP OF THE BARREL FIRMLY INTO THE BUFFER VIAL PIERCING THE FOIL ALLOWING THE BUFFER SOLUTION TO MOVE ONTO THE TEST STRIP.

USE A FRESH WELL FOR EACH TEST.

AFTER ALL 25 WELLS HAVE BEEN USED THE RACK SHOULD BE DISPOSED OF AS BIOHAZARDOUS WASTE.

COMPLETE DIRECTIONS FOR USE ARE GIVEN IN THE ENCLOSED SURE CHECK HIV 1/2 ASSAY PRODUCT INSERT.

10-6236-1 Rev. 1
March 2014

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