REF 65-9500-0
20 Test Kit

DPP® HIV 1/2 Assay

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. Users of this test should follow the CDC Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other bloodborne pathogens.[1]

CLIA Complexity: MODERATE
STORAGE: Store at 2 to 30°C (36 to 86°F)

NAME AND INTENDED USE

The Chembio DPP® HIV 1/2 Assay is a single-use immunochromatographic test for the detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV-1/2) in oral fluid, fingerstick whole blood, venous whole blood, serum, or plasma samples. The Chembio DPP 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.

RESTRICTIONS

1. **Sale of the Chembio DPP HIV 1/2 Assay is restricted to clinical laboratories that have an adequate quality assurance program, including planned systematic activities that provide adequate confidence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional materials.**
2. **The Chembio DPP HIV 1/2 Assay is approved for use only by an agent of a clinical laboratory.**
3. **Test subjects must receive the "Subject Information Notice" prior to specimen collection and appropriate information when test results are provided.**
4. **The Chembio DPP HIV 1/2 Assay is not approved for use to screen blood, plasma, cell or tissue donors.**

SUMMARY AND EXPLANATION

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]

By the end of 2007 there were approximately 33 million people living with HIV/AIDS. An estimated 2.7 million people were newly infected with HIV in 2007. In the same year more than 2 million died of AIDS-related illness; 270,000 of these were children.[6]

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 Amplification Test (NAT) assays and various other test systems are currently available for detection of HIV-1 and HIV-2 infection.[7-11] The DPP® 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 DPP HIV 1/2 Assay employs Chembio's patented DPP (Dual Path Platform) technology and consists of a sample path and a reagent path, which intersect in the antibody detection TEST (T) and CONTROL (C) areas in the readout window of the test cassette. To initiate the test, a specimen is collected and applied to the SAMPLE+BUFFER Well of the DPP test cassette. The sample flows along the sample path membrane and is delivered to the TEST (T) area of the reagent strip, where specific HIV antigens and Protein A are immobilized. HIV antibodies, if present in the sample, bind instantly to the immobilized HIV antigens in the TEST (T) area, while non-specific IgG binds to the Protein A in the CONTROL (C) area. Successful sample application is indicated by the dissolution of soluble dye lines in the TEST and CONTROL areas. Five minutes after adding the sample, buffer is added to the BUFFER Well. The buffer hydrates the dried antibody-binding colored conjugate, which migrates to the TEST (T) area. If the sample contains HIV-1 and/or HIV-2 antibodies, the complex binds to the viral antigens immobilized in the TEST (T) area producing a pink/purple line. In the absence of HIV-1 and HIV-2 antibodies, there is no pink/purple line in the TEST (T) area. The liquid continues to migrate

through the membrane, producing a pink/purple band in the CONTROL (C) area containing Protein A. This procedural control serves to demonstrate that specimen and reagents have been properly applied and have migrated through the device.

MATERIALS PROVIDED

Each kit contains the items to perform 20 tests:

20 Individually Pouched DPP HIV 1/2 Test Devices, each containing:

- 1 DPP HIV 1/2 Test Device containing membrane immobilized with two HIV-1, one HIV-2 synthetic peptides in the TEST (T) area and Protein A in the CONTROL (C) area.
- 1 Desiccant Pouch

20 Copies of Subject Information Notice

20 Oral Fluid Swabs

20 Disposable 10µL Sample Loops

20 DPP HIV SampleTainer™--BLACK Cap

- 1 ml, contains sodium phosphate, sodium chloride, EDTA, Tween 20, avidin, and chicken serum, and gentamicin, streptomycin, and sodium azide as preservative.

1 DPP HIV Running Buffer – GREEN Cap

- 6 mL, contains sodium phosphate, sodium chloride, EDTA, Tween 20, avidin, chicken serum, and urea, and gentamicin, streptomycin, and sodium azide as preservative.

1 Product Insert for the DPP HIV 1/2 Assay

ACCESSORIES AVAILABLE AND REQUIRED

Chembio DPP HIV 1/2 Assay Controls (Catalog# 60-9552-0)

Each package contains:

- 1 DPP HIV-1 Reactive Control (0.5mL)
  Human HIV-1 antibody in human plasma; negative for HIV-1 Ag, HBsAg and anti-HCV antibodies. Preservative: Sodium azide.
- 1 DPP HIV-2 Reactive Control (0.5mL)
  Human HIV-2 antibody in human plasma; negative for HIV-1 Ag, HBsAg and anti-HCV antibodies. Preservative: Sodium azide.
- 1 DPP Nonreactive Control (0.5mL)
  Human plasma; negative for antibodies to HIV and HCV; negative for HBsAg and HIV-1 Ag. Preservatives:Sodium azide
- 1 Product Insert FOR Catalog # 60-9552-0

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock, watch, or other timing device
- Pipettor capable of delivering 10µL of sample may be used in lieu of the disposable 10µL sample loop supplied with the Kit (for other than fingerstick whole blood specimens)
- Disposable gloves
- Sterile gauze (for fingerstick whole blood specimens)
- Antiseptic wipes
- Biohazard disposal container
- Sterile Safety Lancet (for fingerstick whole blood specimens)
- Collection devices (for venous whole blood or serum 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 bloodborne pathogens.[1]
3. Use of this test kit with sample 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. This assay has not been evaluated for newborn screening, cord blood specimens, or individuals less than 2 years of age.
6. An individual infected with HIV-1 and/or HIV-2 who is receiving highly active antiretroviral therapy (HAART) may produce a false negative result.

PRECAUTIONS

SAFETY PRECAUTIONS

1. Handle the samples and materials contacting samples, and kit controls as if capable of transmitting infection.
2. Do not eat, drink or smoke in the area where samples and kit reagents are handled. Avoid any contact between hands, eyes or mouth during sample collection and testing.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling patient samples.
4. Dispose of all samples 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. Use 10% bleach or other appropriate disinfectants to wipe all spills. The bleach solution should be made fresh each day.
6. 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 "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis."[13]

HANDLING PRECAUTIONS

1. If Desiccant Packet is missing, DO NOT USE. Discard Test Device and use a new Test Device.
2. Do not use any Test Device if the pouch has been perforated.
3. Each Test Device is for single use only.
4. Do not use the test 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. Adequate lighting is required to read the test results.

STORAGE AND STABILITY

The DPP HIV 1/2 Test Devices should be stored in unopened pouches at 2 to 30°C (36 to 86°F). Do not freeze. Do not open 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. Both Running Buffer and SampleTainer should be stored at 2 to 30°C (36 to 86°F) in their original bottles.

SPECIMEN COLLECTION

Prior to specimen collection, provide test subjects with Subject Information Notice and pre-test counseling according to CDC Guidelines for Rapid HIV Testing.[14]

The Chembio DPP HIV 1/2 Assay can be performed on oral fluid, fingerstick whole blood, venous whole blood, serum or plasma samples.

ORAL FLUID

The oral fluid collection system is used to obtain the sample. This consists of an Oral Fluid Swab and a SampleTainer (dropper bottle) containing sample buffer for adding the oral fluid to the Test Device as shown in Figure 1 below.

Figure 1

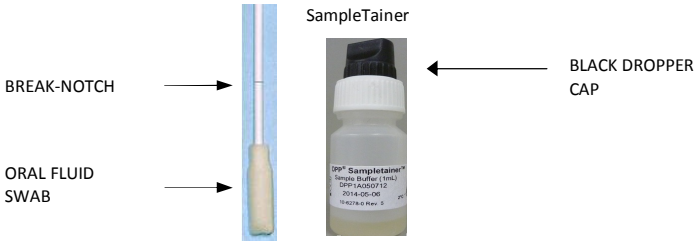
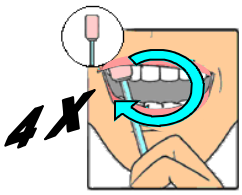


Figure 2



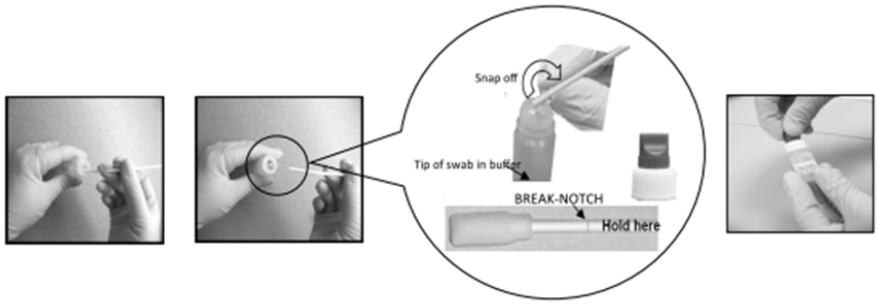
CAUTION: Be sure subject has had nothing by mouth for 30 minutes prior to sampling.

Before collecting the oral fluid sample, label the SampleTainer with the patient ID or identification number, unscrew the WHITE CAP on the SampleTainer, keeping the BLACK CAP screwed onto the white part of the cap. To collect oral fluid, direct the person to insert the Oral Fluid Swab into the mouth above the teeth and against the outer gum as shown in Figure 2 above.

Direct the person to gently swab completely around the outer gums, both upper and lower, four times around. DO NOT allow the person to swab the roof of the mouth, the inside of the cheek or the tongue. This entire procedure should take approximately **15-30 seconds**, but a **minimum of 15 seconds** is recommended.

Insert the Oral Fluid Swab into the SampleTainer, such that the swab is touching the bottom. Snap the shaft at the BREAK-NOTCH to dislodge the swab into the SampleTainer as shown in Figure 3. Replace the BLACK/WHITE CAP assembly onto the SampleTainer and shake for 10 seconds. Test immediately, following Test Procedure instructions.

Figure 3



ORAL FLUID SWAB INSERTED INTO SampleTainer

SNAP THE SHAFT AT THE BREAK-NOTCH TO DISLODGE SWAB INTO THE SampleTainer

REPLACE CAP ON SampleTainer AND SHAKE

FINGERSTICK WHOLE BLOOD

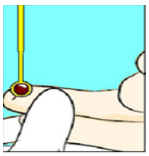
Before collecting the sample, write the sample ID on the SampleTainer with the BLACK CAP. Remove (unscrew) the WHITE CAP keeping the BLACK CAP screwed onto the white part of the cap (Figure 4).

Figure 4

SampleTainer with BLACK CAP

Figure 5

Properly filled Sample Loop



Prepare to perform the fingerstick 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.

Using a sterile lancet, puncture the skin just off the center of the finger and wipe away the first drop of blood with sterile gauze. Avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess tissue fluid.

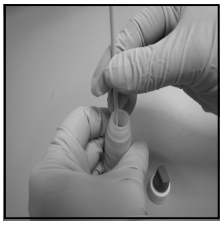
Collect the sample from the second drop, touching the disposable Sample Loop provided to the drop of blood until the Sample Loop is full as shown in Figure 5.

Insert the filled Sample Loop into the SampleTainer with the BLACK CAP, such that the loop is touching the bottom. Snap and twist the shaft at the BREAK-NOTCH to dislodge the loop into the SampleTainer, as shown in Figure 6.

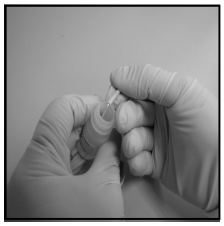
Replace the BLACK/WHITE CAP assembly onto the SampleTainer and gently shake for 10 seconds. Test immediately, following Test Procedure instructions.

Figure 6

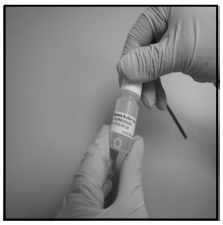
SampleTainer AND SAMPLE LOOP



SAMPLE LOOP INSERTED INTO SampleTainer



SNAP AND TWIST THE SHAFT AT THE BREAK-NOTCH TO DISLODGE LOOP INTO THE SampleTainer



REPLACE CAP ON SampleTainer AND SHAKE

VENOUS WHOLE BLOOD

Draw blood following laboratory procedure for obtaining venous blood. Collect sample in a tube containing citrate, heparin or EDTA. Be sure the tube of blood is well mixed before sampling.

Dip the Sample Loop into the blood and allow it to fill or use a laboratory pipet to withdraw 10µL of the blood. Pipette the sample or insert the filled Sample Loop into the SampleTainer with the BLACK CAP, such that the loop is touching the bottom.

Snap and twist the shaft at the BREAK-NOTCH to dislodge the loop into the SampleTainer, as shown in Figure 6. Replace the BLACK/WHITE CAP assembly onto the SampleTainer and shake for 10 seconds. Test immediately, following Test Procedure instructions.

If tested the same day, venous whole blood may be kept at room temperature. Venous whole blood may be stored for up to 3 days between 2 and 8°C (36 to 46°F) before testing.

DO NOT FREEZE WHOLE BLOOD! Allow refrigerated sample to reach room temperature and mix gently before testing.

SERUM OR PLASMA

Draw blood following laboratory procedure for obtaining serum or plasma samples. Collect serum samples in tubes that do not contain any anticoagulant. Collect plasma samples in tubes containing citrate, heparin, or EDTA. Collect sample in a clean container following standard laboratory procedures. Be sure that the tube of serum or plasma is well mixed before sampling.

Dip the Sample Loop into the serum or plasma tube and allow it to fill or use a laboratory pipet to withdraw 10µL of the sample. Pipette the sample or insert the filled Sample Loop into the SampleTainer with the BLACK CAP, such that the loop is touching the bottom.

Snap and twist the shaft at the BREAK-NOTCH to dislodge the loop into the SampleTainer, as shown in Figure 6. Replace the BLACK/WHITE CAP assembly onto the SampleTainer and shake for 10 seconds. Test immediately, following Test Procedure instructions.

Serum and plasma specimens may be tested immediately after collection. If specimens are not tested immediately, refrigerate them at 2 to 8°C (36 to 46°F) following collection. These specimens should be tested within 3 days of collection. If specimens are not tested within 3 days of collection, serum or plasma specimens should be frozen at -20°C (-4°F) or colder.

SPECIMEN SHIPPING

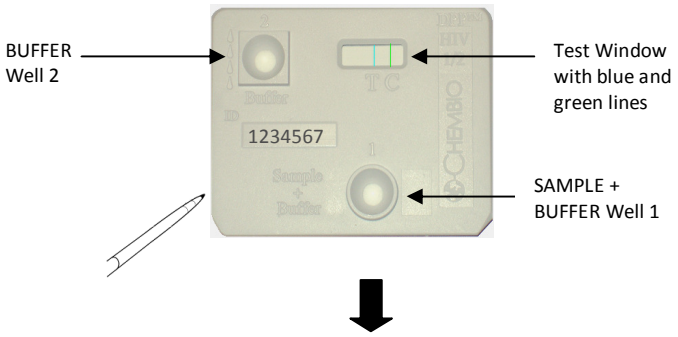
If specimens are to be shipped, they should be packed in compliance with regulations covering the transportation of etiologic agents. Venous whole blood, serum and plasma specimens should be shipped refrigerated with cold packs or wet ice.

TEST PROCEDURE

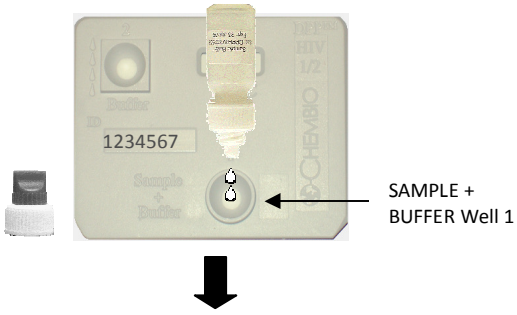
All components for the Chembio DPP HIV 1/2 Assay are ready to use as supplied. Follow directions as indicated. If the sample and / or kit components have been refrigerated, remove them from the refrigerator and allow them to come to a temperature of 18 to 30° C (64 to 86°F) prior to testing.

1. Remove the Chembio DPP HIV 1/2 Test Device from its pouch and place it on a flat surface (it is not necessary to remove the Desiccant Packet from the pouch). Note: If Desiccant Packet is missing, DO NOT USE, discard Test Device and a new Test Device should be used.

   Label the Test Device with patient ID or identification number. Note that the DPP Test Device has 2 colored lines in the Test Window; one is blue and the other is green. If the 2 colored lines are absent, DO NOT USE, discard Test Device and a new Test Device should be used.

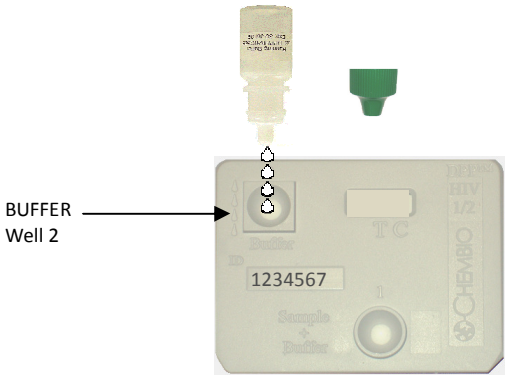


2. Invert the SampleTainer (BLACK CAP), containing the collected sample, and hold it vertically (not at an angle) over the SAMPLE + BUFFER Well 1. Add 2 drops (~65µL) slowly, dropwise, into the SAMPLE + BUFFER Well 1.



3. **Wait 5 minutes.** The blue and green colored lines should have disappeared from the rectangular TEST and CONTROL window. If not, DO NOT USE, discard Test Device and a new Test Device should be used.

   Invert the Running Buffer bottle (Green CAP), and hold it vertically (not at an angle) over BUFFER Well 2. Add 4 drops (~135µL) of Buffer (GREEN CAP) slowly, dropwise, into BUFFER Well 2.



4. **Fingerstick, Venous Whole Blood, Serum or Plasma**
   Read the Test Result between 10 and 25 minutes after the addition of the Running Buffer to BUFFER Well 2. **NOTE**: Discard the used Sample Loop, Test Device, and any other test materials into a biohazard waste container

5 **Oral Fluid**
Test Results are read between 25 and 40 minutes after the addition of the Running Buffer to BUFFER Well 2.

NOTE: Discard the used Test Device, Oral Fluid Swab and any other test materials into a biohazard waste container.

INTERPRETATION OF TEST RESULTS

NONREACTIVE

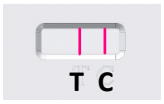
One pink/purple line in the CONTROL (C) area, with no line in the TEST (T) area, indicates a NONREACTIVE Test Result. A NONREACTIVE Test Result means that HIV-1 and HIV-2 antibodies were not detected in the specimen. The Test Result is interpreted as NEGATIVE for HIV-1 and HIV-2 antibodies. However, this does not exclude possible infection with HIV. Follow CDC guidelines to inform the test subject of the Test Result and its interpretation.[13,14]

NONREACTIVE

REACTIVE

Two pink/purple lines, one in the TEST (T) area and one in the CONTROL (C) area, indicate a REACTIVE Test Result. The line in the TEST (T) area may look different from the line in the CONTROL (C) area. Intensities of the Test and Control Lines may vary. Test Result with visible lines in both TEST (T) and CONTROL (C) areas, regardless of intensity, is considered REACTIVE. A Reactive Test Result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The Test Result is interpreted as Preliminary POSITIVE for HIV-1 and/or HIV-2 antibodies. Follow CDC guidelines to inform the test subject of the Test Result and its interpretation.[13,14]

REACTIVE

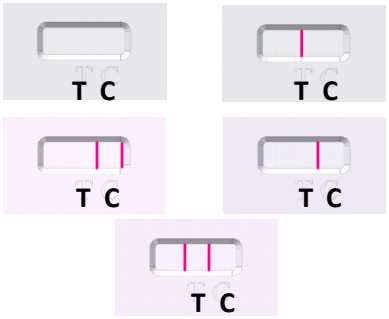


INVALID

A pink/purple line should always appear in the CONTROL (C) area, whether or not a line appears in the TEST (T) area. If there is no distinct pink/purple line visible in the CONTROL (C) area, then the test is INVALID.

Any line that appears outside of the Control (C) Area or Test (T) Area is an INVALID test. An INVALID test cannot be interpreted. It is recommended that the INVALID test be repeated with a new device.

INVALID



LIMITATIONS OF THE PROCEDURE

1. The Chembio DPP HIV 1/2 Assay must ONLY be used with oral fluid, capillary (fingerstick) or venous whole blood, serum or plasma. Using other types of samples or testing of venipuncture whole blood samples collected using a tube containing an anticoagulant other than citrate, heparin or EDTA may not yield accurate results. For serum samples, collect blood without anticoagulant.
2. The Chembio DPP HIV 1/2 Assay must be used in accordance with the instructions in this product insert to obtain accurate results.
3. Reading test results for CAPILLARY (FINGERSTICK) or VENOUS WHOLE BLOOD, SERUM or PLASMA specimens earlier than 10 minutes or later than 25 minutes after the addition of Running Buffer to BUFFER Well 2 may yield erroneous results.
4. Reading test results for oral fluid specimens earlier than 25 minutes or later than 40 minutes after the addition of Running Buffer to BUFFER Well 2 may yield erroneous results.
5. Do not open the sealed foil pouch until just prior to use.
6. Do not use kit contents beyond labeled expiration date.
7. Ensure finger is completely dry before performing fingerstick.
8. Read results in a well-lit area.
9. A REACTIVE result using the Chembio DPP HIV 1/2 Assay suggests the presence of antibodies to HIV-1 and/or HIV-2 in the sample and the REACTIVE test result is interpreted as Preliminary Positive for HIV-1 and/or HIV-2 antibodies. The Chembio DPP HIV 1/2 Assay is intended as an aid in the diagnosis of infection with HIV-1/2. AIDS-related conditions are clinical syndromes, and their diagnosis can only be established clinically.
10. REACTIVE test results are confirmed by additional testing.

11. A person who has antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus, except that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV.
12. For a REACTIVE result, the intensity of the test line does not necessarily correlate with the titer of antibody in the sample.
13. A NONREACTIVE result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to a recent exposure may take several months to reach detectable levels.
14. This assay has not been evaluated for newborn screening, cord blood specimens, or individuals less than 2 years of age.
15. An individual infected with HIV-1 and/or HIV-2 who is receiving highly active antiretroviral therapy (HAART) may produce a false negative result.

QUALITY CONTROL

BUILT-IN CONTROL FEATURE

The control line serves as a built-in internal control and gives confirmation of sample addition and proper test performance. A pink/purple line will appear in the CONTROL (C) area if the test has been performed correctly and the device is working properly (Please see: Interpretation of Test Results).

EXTERNAL QUALITY CONTROL

Chembio DPP HIV Reactive and Nonreactive Controls (Catalog #: 60-9552-0) are available separately for use with the Chembio DPP HIV 1/2 test. The HIV Controls are used to verify the operator's ability to properly perform the test and to interpret the results. Each Reactive Control will produce a reactive test result and has been manufactured to produce a faint line in the TEST (T) area. The Nonreactive Control will produce a nonreactive test result. Run the controls as described in the Test Procedure section for a serum / plasma sample and follow the directions in the Interpretation of Results section of this product insert. It is the responsibility of each facility using the Chembio DPP HIV 1/2 Assay to establish an adequate quality assurance program to ensure the performance of the device under specific locations and conditions of use.

RUN THE KIT CONTROLS UNDER THE FOLLOWING CIRCUMSTANCES:

- **Each new operator prior to performing tests on patient samples**
- **When opening a new test kit lot**
- **Whenever a new shipment of test kits is received**
- **If the temperature of the test storage area falls outside of 2 to 30°C (36 to 86°F)**
- **If the temperature of the testing area falls outside of 18 to 30°C (64 to 86°F)**
- **At periodic intervals as indicated by the user facility**

If the HIV Control reagents do not produce the expected results, contact Chembio Diagnostic Customer Service at 1-800-327-3635.

PERFORMANCE CHARACTERISTICS

The DPP HIV 1/2 Assay was evaluated in prospective clinical studies at five geographically distinct sites. The specimens were tested from three groups of individuals: Known infected with HIV-1, at high risk for infection with HIV-1, and at low risk for infection with HIV-1. The DPP HIV 1/2 Assay was tested in parallel on oral fluid, fingerstick whole blood, venous whole blood, serum and plasma specimen matrices. The serum/plasma specimens from study subjects were also tested using a licensed Enzyme Immunoassay (EIA). Specimens with discordant results were further tested using licensed Western Blot and/or FDA approved NAT assay.

HIV-1 Sensitivity

ORAL FLUID

The sensitivity of the Chembio DPP HIV 1/2 Assay to detect infection with HIV-1 in oral fluid was evaluated using 868 specimens from individuals known to be infected with HIV-1. All 868 specimens tested repeatedly reactive using an FDA licensed EIA. Of these, 867 specimens tested positive using HIV-1 WB and one tested positive using HIV-1 NAT. Eight hundred sixty (860) out of 868 specimens tested Reactive using the Chembio DPP HIV 1/2 Assay.

In addition, specimens from 976 individuals at high risk for infection with HIV-1 were tested. Of these, 96 specimens tested repeatedly reactive using an FDA licensed EIA, and positive using HIV-1 WB (true positive). On testing these 976 specimens using the Chembio DPP HIV 1/2 Assay, 94 specimens tested Reactive and 882 specimens tested Nonreactive. One specimen tested false reactive and three specimens tested false nonreactive using the Chembio DPP HIV 1/2 Assay.

The sensitivity of the Chembio DPP HIV 1/2 Assay was evaluated using 964 (868 known positives and 96 true positives identified from the high risk population) (see Table 1). Of these, 953 specimens tested reactive using the Chembio DPP HIV 1/2 Assay (860 known positive and 93 high risk). The Chembio DPP HIV 1/2 Assay gave false negative results for 11 specimens (8 known positives and 3 high risk) and one false positive result (high risk) when oral fluid specimens were tested in this study. Of the 11 false negatives, seven were from individuals on HAART. The calculated sensitivity of the Chembio DPP HIV 1/2 Assay for oral fluid specimens in these studies was 953/964 = 98.9% (95% confidence interval 98.0 to 99.4%).

Table 1: Detection of antibody to HIV-1 in oral fluid specimens from individuals known to be infected with HIV-1 and at high risk for infection with HIV-1

True Status	Chembio DPP HIV 1/2 Assay		Total
	Reactive	Nonreactive	
Positive[1]	953	11[2]	964
Negative	1	879	880
Total	954	890	1844

1. Based on repeatedly Reactive test results using an EIA and positive using an FDA-licensed WB or NAT
2. Of these 11 false Negative individuals seven were on HAART.

CAPILLARY (FINGERSTICK) WHOLE BLOOD

The sensitivity of the Chembio DPP HIV 1/2 Assay to detect infection with HIV-1 in capillary (fingerstick) whole blood was evaluated using 868 specimens from individuals known to be infected with HIV-1. All 868 specimens tested repeatedly reactive using an FDA licensed EIA. Of these, 867 specimens tested positive using HIV-1 WB and one tested positive using HIV-1 NAT. Eight hundred sixty seven specimens (867) out of 868 tested Reactive using the Chembio DPP HIV 1/2 Assay.

In addition, specimens from 976 individuals at high risk for infection with HIV-1 were tested. Of these, 96 specimens tested repeatedly reactive using an FDA licensed EIA, and positive using HIV-1 WB (true positive). On testing these 976 specimens using the Chembio DPP HIV 1/2 Assay, 95 specimens tested Reactive and 881 tested Nonreactive.

The sensitivity of the Chembio DPP HIV 1/2 Assay was evaluated using 964 specimens (868 known positives and 96 true positive identified from the high risk population). Of these, 962 specimens tested Reactive using the Chembio DPP HIV 1/2 Assay (867 known positive and 95 high risk), (see Table 2). In these studies, the Chembio DPP HIV 1/2 Assay gave false

nonreactive results for one known positive specimen and for one confirmed positive specimen from a high risk individual when capillary whole blood specimens were tested. The calculated sensitivity of the Chembio DPP HIV 1/2 Assay for capillary (fingerstick) whole blood specimens in these studies was 962/964 = 99.8% (95% confidence interval 99.2 to 99.9%).

Table 2: Detection of antibody to HIV-1 in capillary whole blood (fingerstick) specimens from individuals known to be infected with HIV-1 and at high risk for infection with HIV-1

True Status	Chembio DPP HIV 1/2 Assay		Total
	Reactive	Nonreactive	
Positive[1]	962	2	964
Negative	0	880	880
Total	962	882	1844

1. Based on repeatedly Reactive test results using an EIA and positive using an FDA-licensed WB or NAT assay.

VENOUS WHOLE BLOOD

The sensitivity of the Chembio DPP HIV 1/2 Assay to detect infection with HIV-1 in venous whole blood was evaluated using 868 specimens from individuals known to be infected with HIV-1. All 868 specimens tested repeatedly reactive using an FDA licensed EIA. Of these, 867 specimens tested positive using HIV-1 WB and one tested positive using HIV-1 NAT. All these 868 specimens tested Reactive using the Chembio DPP HIV 1/2 Assay.

In addition, specimens from 975 individuals at high risk for infection with HIV-1 were tested. Of these, 96 specimens tested repeatedly reactive using an FDA licensed EIA, and positive using HIV-1 WB (true positive). On testing these 975 specimens using the Chembio DPP HIV 1/2 Assay, 95 specimens tested Reactive and 880 specimens tested Nonreactive.

The sensitivity of the DPP HIV-1/2 Assay was evaluated using 964 (868 known positives and 96 true positives identified from the high risk population). Of these, 963 specimens tested Reactive using the Chembio DPP HIV 1/2 Assay (868 known positive and 95 high risk) (see Table 3). In these studies, the Chembio DPP HIV 1/2 Assay gave false negative results for one confirmed positive specimen from a high risk individual when venous whole blood specimens were tested. The calculated sensitivity of the Chembio DPP HIV 1/2 Assay for venous whole blood specimens in these studies was 963/964 = 99.9% (95% confidence interval 99.4 to 99.9%).

Table 3: Detection of antibody to HIV-1 in venous whole blood specimens from individuals known to be infected with HIV-1 and at high risk for infection with HIV-1

True Status	Chembio DPP HIV 1/2 Assay		Total
	Reactive	Nonreactive	
Positive[1]	963	1	964
Negative	0	879	879
Total	963	880	1843

1. Based on repeatedly Reactive test results using an EIA and positive using an FDA-licensed WB or NAT assay

PLASMA

The sensitivity of the Chembio DPP HIV 1/2 Assay to detect infection with HIV-1 in plasma specimens was evaluated using 868 specimens from individuals known to be infected with HIV-1. All 868 specimens tested repeatedly reactive using an FDA licensed EIA. Of these, 867 specimens tested positive using HIV-1 WB and one tested positive using HIV-1 NAT. All 868 specimens tested Reactive using the Chembio DPP HIV 1/2 Assay.

In addition, specimens from 975 individuals at high risk for infection with HIV-1 were tested. Of these, 96 specimens tested repeatedly reactive using an FDA licensed EIA, and positive using HIV-1 WB (true positive). On testing these 975 specimens using the Chembio DPP HIV 1/2 Assay 95, specimens tested Reactive and 880 tested Nonreactive.

The sensitivity of the Chembio DPP HIV 1/2 Assay was evaluated using 964 specimens (868 known positives and 96 true positives identified from the high risk population). Of these, 963 specimens tested Reactive using the Chembio DPP HIV 1/2 Assay (868 known positive and 95 high risk) (see Table 4). In these studies, the Chembio DDP HIV 1/2 Assay gave false nonreactive results for one confirmed positive specimen from a high risk individual when plasma specimens were tested. The calculated sensitivity of the Chembio DPP HIV 1/2 Assay for plasma specimens in these studies was 963/964 = 99.9% (95% confidence interval 99.4 to 99.9%).

Table 4: Detection of antibody to HIV-1 in plasma specimens from individuals known to be infected with HIV-1 and at high risk for infection with HIV-1

True Status	Chembio DPP HIV 1/2 Assay		Total
	Reactive	Nonreactive	
Positive[1]	963	1	964
Negative	0	879	879
Total	963	880	1843

1. Based on repeatedly Reactive test results using an EIA and positive using an FDA-licensed WB or NAT assay

SERUM

The sensitivity of the Chembio DPP HIV 1/2 Assay to detect infection with HIV-1 in serum specimens was evaluated using 868 specimens from individuals known to be infected with HIV-1. All 868 specimens tested repeatedly reactive using an FDA licensed EIA. Of these, 867 tested positive using HIV-1 WB and one tested positive using HIV-1 NAT. All 868 specimens tested Reactive using the Chembio DPP HIV 1/2 Assay.

In addition, specimens from 976 individuals at high risk for infection with HIV-1 were tested. Of these, 96 specimens tested repeatedly reactive using FDA licensed EIA, and positive using HIV-1 WB (true positive). On testing these 976 specimens using the Chembio DPP HIV 1/2 Assay, 95 specimens tested Reactive and 881 specimens tested Nonreactive.

The sensitivity of the Chembio DPP HIV 1/2 Assay was evaluated using 964 specimens (868 known positives and 96 true positive identified from the high risk population). Of these, 963 specimens tested reactive using the Chembio DPP HIV 1/2 Assay (868 known positive and 95 high risk) (see Table 5). In these studies, the Chembio DPP HIV 1/2 Assay gave false nonreactive results for one confirmed positive specimen from a high risk individual when serum specimens were tested. The calculated sensitivity of the Chembio DPP HIV 1/2 Assay for serum specimens in these studies was 963/964 = 99.9% (95% confidence interval 99.4 to 99.9%).

Table 5: Detection of antibody to HIV-1 in serum specimens from individuals known to be infected with HIV-1 and at high risk for infection with HIV-1

True Status	Chembio DPP HIV 1/2 Assay		Total
	Reactive	Nonreactive	
Positive[1]	963	1	964
Negative	0	880	880
Total	963	881	1844

1. Based on repeatedly Reactive test results using an EIA and positive using an FDA-licensed WB or NAT assay

HIV-2 Sensitivity

The sensitivity of the Chembio DPP HIV 1/2 Assay to detect HIV-2 antibody was determined by testing 210 serum/plasma specimens that were positive for HIV-2 antibodies only. These specimens were obtained from repository sources. A total of 554 specimens from an area endemic for HIV-2 infection were also tested. All specimens reactive by an FDA approved/licensed HIV-1/2 assay were also Reactive with the Chembio DPP HIV 1/2 Assay (see Table 6). The sensitivity of

Chembio DPP HIV 1/2 Assay for detection of antibodies to HIV-2 in these studies was calculated to be 210/210 = 100% (95% confidence interval 98.3 to 100%).

Table 6: Detection of antibody to HIV-2 in known HIV-2 positive specimens and specimens from endemic populations

Study Population	Samples	Chembio DPP HIV 1/2 Assay Reactive	True HIV-2 Positive Only[1]
Known HIV-2 Positive	210	210	210
Endemic Samples	554	201[2]	0
Total	764	411	210

[1] Confirmation based on results using a research use HIV-2 WB and not positive on an HIV-1 WB.

[2] Of these 201 Reactive specimens, 93 were Positive on HIV-1 WB only, 108 were Positive on HIV-1 WB and HIV-2 WB.

Detection of antibody to HIV-2 in oral fluid specimens:

Oral fluid specimens from 11 individuals infected with HIV-2 were collected (one from the United States and 10 from Ivory Coast, Africa). Oral fluid specimens from 11 individuals tested Reactive using the DPP HIV 1/2 Assay. Of these 11, nine specimens were confirmed as infected with only HIV-2 using an HIV-2 specific assay. These specimens were either negative or indeterminate using HIV-1 WB, (see Table 7).

Table 7: Detection of antibody to HIV-2 in oral fluid specimens

Known HIV-2 Individuals from	Number	Chembio DPP HIV 1/2 Assay Reactive	HIV-2 Specific Test on Serum/plasma	HIV-1 Western Blot on serum/plasma		
				Positive	Indeterminate	Negative
Ivory Coast	10	10	10[1]	0	6	4
USA	1	1	1	N/A	N/A	N/A
Total	11	11	11	0	6	4

[1] Two out 10 specimens were dually Reactive for HIV-1 and HIV-2 on an HIV-2 assay were unconfirmed for HIV-1 by HIV-1 Western Blot.

Reactivity with HIV-1 Specimens of Different Virus Subtypes

To assess the ability of the Chembio DPP HIV 1/2 Assay to detect the HIV-1 antibodies directed to different HIV-1 group M subtypes and HIV-1 Group "O", specimens (serum/plasma) from different world wide geographical regions such as Africa (Ghana, Cote d'Ivoire, Mozambique, Uganda, Zimbabwe), Asia (Thailand, China and India), Europe (England, France, Spain and Belgium) and Latin America (Brazil and Argentina) were tested. Of these 204 specimens, 203 specimens tested Reactive with the Chembio DPP HIV 1/2 Assay. One subtype D tested false nonreactive. The results are presented in Table 8.

Table 8: testing HIV-1 Specimens from various Geographic Regions using Chembio DPP HIV 1/2 Assay

HIV Subtype	Number of Specimens	Chembio DPP HIV 1/2 Assay Reactive
A	7	7
AD	3	3
AE	13	13
AG	21	21
B	64	64
B/D	2	2
C	22	22
D	**16**	**15**
F	9	9
G	18	18
H	5	5
J	4	4
K	11	11
O	9	9
TOTAL	204	203

Seroconversion Panels (Comparison to EIA)

Twenty-one commercial seroconversion panels (serum/plasma) were tested. Each panel consisted of sequential collections from a single individual who seroconverted. The table below presents the days elapsed from the date of the initial bleed to the last Nonreactive sample and first Reactive sample (Table 9). Data are presented for two FDA licensed EIA tests and the Chembio DPP HIV 1/2 Assay. In comparing test performance, positive numbers indicate earlier detection of HIV antibodies by the Chembio DPP HIV 1/2 Assay and negative numbers indicate earlier detection of HIV antibodies by EIA. The Chembio DPP HIV 1/2 Assay detected HIV antibodies in 15 out of 21 seroconversion panels as early as EIA 1 and later than EIA 1 in remaining six panels. The Chembio DPP HIV 1/2 Assay detected HIV antibodies earlier than EIA 2 in 11 out of 21 seroconversion panels, as early as EIA 2 in eight out of the remaining 10, and later than EIA 2 in two panels.

Table 9: Testing seroconversion panels using the DPP HIV-1/2 Assay

Panel	EIA 1 and Chembio DPP HIV 1/2 Assay			EIA 2 and Chembio DPP HIV 1/2 Assay		
	EIA 1 Repeatedly Reactive Test Result on Day	Chembio DPP HIV 1/2 Reactive Test Result on Day	Difference in Days to Anti-HIV Reactive Result: EIA minus DPP HIV 1/2	EIA 2 Repeatedly Reactive Test Result on Day	Chembio DPP HIV 1/2 Reactive Test Result on Day	Difference in Days to Anti-HIV Reactive Result: EIA minus DPP HIV 1/2
PRB904	92	92	0	92	92	0
PRB910	26	26	0	26	26	0
PRB914	0	0	0	4	0	4
PRB916	30	30	0	30	30	0
PRB917	65	65	0	72	65	7
PRB919	9	9	0	11	9	2
PRB922	0	4	-4	>11	4	>7
PRB924	35	35	0	>40	35	>5
PRB926	27	27	0	27	27	0
PRB927	33	33	0	40	33	7
PRB928	111	111	0	120	111	9
PRB929	25	28	-3	28	28	0
PRB930	10	10	0	>10	10	>0
PRB933	21	27	-6	27	27	0
PRB934	7	7	0	11	7	4
PRB939	103	103	0	103	103	0
PRB944	14	14	0	16	14	2
PRB952	17	17	0	>21	17	>4
PRB953	10	>10	<0	10	>10	<0
PRB958	15	>17	<-2	15	>17	<-2
PRB959	9	14	-5	14	14	0

Reactivity with HIV-1 Low Titer Panel

A 15-member HIV-1 commercially available low titer panel of serum and plasma specimens was used to evaluate the Chembio DPP HIV 1/2 Assay and the results were compared to FDA licensed HIV-1 EIAs and Western blot (WB). The Chembio DPP HIV 1/2 Assay detected the presence of antibodies to HIV-1 low-titer specimens similarly to licensed HIV EIAs and WB. In no case was the Chembio DPP HIV 1/2 Assay Nonreactive when both licensed EIAs were Repeatedly Reactive or WB was Positive (Table 10).

Table 10: Testing HIV-1 low titer panel using the DPP HIV 1/2 Assay

Panel Member ID	DPP HIV 1/2 Assay	EIA 1	EIA 2	WB
PRB108-1	R	R	R	P
PRB108-2	NR	NR	NR	N
PRB108-3	R	R	R	IND
PRB108-4	R	R	R	P
PRB108-5	R	R	R	P
PRB108-6	R	R	R	IND
PRB108-7	R	R	R	P
PRB108-8	R	R	R	P
PRB108-9	R	R	R	P
PRB108-10	R	R	NR	IND
PRB108-11	R	R	R	P
PRB108-12	NR	R	NR	N
PRB108-13	R	R	NR	IND
PRB108-14	NR	R	NR	N
PRB108-15	R	R	R	IND

R=Reactive, NR=Nonreactive, P=Positive, N=Negative, IND=Indeterminate

Specificity

ORAL FLUID

The specificity of the Chembio DPP HIV 1/2 Assay was evaluated by testing oral fluid specimens from 962 individuals at low risk and 976 individuals at high risk for infection with HIV-1 at five clinical study sites. Samples from 96 high risk and 26 low risk individuals were Repeatedly Reactive on a licensed EIA and Positive on Western Blot and were excluded from the study. Of the remaining 1816 specimens one specimen from an individual at high risk for infection with HIV-1 tested Reactive using DPP HIV 1/2 Assay that tested negative using WB (see Table 11). Based on these studies, the specificity of Chembio DPP HIV 1/2 Assay in oral fluid specimens was calculated to be 1815/1816 = 99.9% (95% confidence interval 99.7 to 99.9%).

Table 11: Performance of the Chembio DPP HIV 1/2 Assay on oral fluid specimens from individuals presumed to be negative for HIV-1 infection

Study Population	Samples	True Negative	Chembio DPP HIV 1/2 Assay Nonreactive
Low Risk	962	936	936
High Risk	976[2]	880	879
Total	1938	1816	1815

[1]Three specimens from high risk group tested Nonreactive using Chembio DPP HIV 1/2 Assay that tested positive using HIV-1 WB.
[2]One specimen from high risk group tested Reactive using Chembio DPP HIV 1/2 Assay that tested negative using HIV-1 WB.

CAPILLARY (FINGERSTICK) WHOLE BLOOD

The specificity of the Chembio DPP HIV 1/2 Assay was evaluated by testing capillary (fingerstick) whole blood specimens from 961 low risk and 976 individuals at high risk for infection with HIV-1 at five clinical study sites. Samples from 96 high risk and 26 low risk individuals were Repeatedly Reactive on a licensed EIA and Positive on Western Blot and were excluded from the study. All the remaining 1815 specimens tested Nonreactive using the Chembio DPP HIV 1/2 Assay (see Table 12). Based on these studies, the specificity of Chembio DPP HIV 1/2 Assay in capillary (fingerstick) whole blood specimens was calculated to be 1815/1815 = 100% (95% confidence interval 99.8 to 100%).

Table 12: Performance of the Chembio DPP HIV 1/2 Assay on capillary whole blood (fingerstick) specimens from individuals presumed to be negative for HIV-1

Study Population	Samples	True Negative	Chembio DPP HIV 1/2 Assay Nonreactive
Low Risk	961	935	935
High Risk	976	880	880
Total	1937	1815	1815

[1]One specimen tested Nonreactive using the Chembio DPP HIV 1/2 Assay and positive using HIV-1 WB

VENOUS WHOLE BLOOD

The specificity of the Chembio DPP HIV 1/2 Assay was evaluated by testing venous whole blood specimens from 961 low risk and 975 individuals at high risk for infection with HIV-1 at five clinical study sites. Samples from 96 high risk and 26 low risk individuals were Repeatedly Reactive on a licensed EIA and Positive on Western Blot and were excluded from the study. Of the remaining 1814 specimens, one specimen from individual at low risk for infection with HIV-1 tested Reactive using the Chembio DPP HIV 1/2 Assay (false positive) that tested negative using HIV-1 WB. One specimen from an individual at high risk for infection with HIV-1 tested Nonreactive (false negative) using DPP HIV 1/2 Assay that tested positive using WB, (see Table 13). Based on these studies, the specificity of Chembio DPP HIV 1/2 Assay in venous whole blood specimens was calculated to be 1813/1814 = 99.9% (95% confidence interval 99.7 to 99.9%).

Table 13: Performance of the Chembio DPP HIV 1/2 Assay on venous whole blood specimens from individuals presumed to be negative for HIV-1 infection

Study Population	Samples	True Negative	Chembio DPP HIV 1/2 Assay Nonreactive[1]
Low Risk	961[1]	935	934
High Risk	975[2]	879	879
Total	1936	1814	1813

[1]One specimen tested Reactive using the Chembio DPP HIV 1/2 Assay that tested negative using HIV-1 WB.
[2]One specimen tested Nonreactive using the Chembio DPP HIV 1/2 Assay that tested positive using HIV-1 WB.

PLASMA

The specificity of the Chembio DPP HIV 1/2 Assay was evaluated by testing plasma specimens from 961 low risk and 975 individuals at high risk for infection with HIV-1 at five clinical study sites. Samples from 96 high risk and 26 low risk individuals were Repeatedly Reactive on a licensed EIA and Positive on Western Blot and were excluded from the study. Of the remaining 1814 specimens, one specimen from individuals at low risk for infection with HIV-1 tested Reactive using the Chembio DPP HIV 1/2 Assay (false positive) that tested negative using HIV-1 WB (see Table 14). One specimen from an individual at high risk for infection with HIV-1 tested Nonreactive using DPP HIV 1/2 Assay (false negative) that tested positive using WB. Based on these studies, the specificity of Chembio DPP HIV 1/2 Assay in plasma specimens was calculated to be 1813/1814 = 99.9% (95% confidence interval 99.7 to 99.9%).

Table 14: Performance of the Chembio DPP HIV 1/2 Assay on plasma specimens from individuals presumed to be negative for HIV-1 infection

Study Population	Samples	True Negative	Chembio DPP HIV 1/2 Assay Nonreactive
Low Risk	961[1]	935	934
High Risk	975[2]	879	879
Total	1936	1814	1813

[1]One specimen tested Reactive using the Chembio DPP HIV 1/2 Assay that tested negative using HIV-1 WB.
[2]One specimen tested Nonreactive using the Chembio DPP HIV 1/2 Assay that tested positive using HIV-1 WB.

SERUM

The specificity of the Chembio DPP HIV 1/2 Assay was evaluated by testing serum specimens from 961 low risk and 976 individuals at high risk for infection with HIV-1 at five clinical study sites. Samples from 96 high risk and 26 low risk individuals were Repeatedly Reactive on a licensed EIA and Positive on Western Blot and were excluded from the study. Of the remaining 1815 specimens, one specimen from an individual at low risk for infection with HIV-1 tested Reactive (false positive) using the Chembio DPP HIV 1/2 Assay that tested negative using HIV-1 WB. One specimen from an individual at high risk for infection with HIV-1 tested Nonreactive (false negative) using DPP HIV 1/2 Assay that tested positive using WB (see Table 15). Based on these studies, the specificity of Chembio DPP HIV 1/2 Assay in serum specimens was calculated to be 1814/1815 = 99.9% (95% confidence interval 99.7 to 99.9%).

Table 15: Performance of the Chembio DPP HIV 1/2 Assay on serum specimens from individuals presumed to be negative for HIV-1 infection

Study Population	Samples	True Negative	Chembio DPP HIV 1/2 Assay Nonreactive
Low Risk	961[1]	935	934
High Risk	976[2]	880	880
Total	1937	1815	1814

[1]One specimen tested Reactive using the Chembio DPP HIV 1/2 Assay that tested negative using HIV-1 WB.
[2]One specimen tested Nonreactive using the Chembio DPP HIV 1/2 Assay that tested positive using HIV-1 WB.

Effect of Unrelated Medical Conditions on Analytical Sensitivity and Specificity

To evaluate the effect of unrelated medical conditions on the performance of the Chembio DPP HIV 1/2 Assay, 370 specimens representing unrelated medical conditions were tested. The specimens were spiked with saline (nonreactive) or an HIV-1 reactive serum specimen or an HIV-2 reactive serum specimen to a low level of reactivity. All HIV-1 and HIV-2 specimens gave Reactive results, while all unspiked samples, with the exception of one Syphilis specimen gave Nonreactive results (see Table 16).

Table 16: Effect of unrelated medical conditions on analytical sensitivity and specificity of the Chembio DPP HIV 1/2 Assay

Description	DPP HIV 1/2 Assay (# Reactive / Total # Tested)		
	Saline	HIV-1 (Weak Reactive)	HIV-2 (Weak Reactive)
Cirrhosis	0/10	10/10	10/10
CMV IgM	0/10	10/10	10/10
EBV IgG	0/10	10/10	10/10
Influenza Vaccination	0/10	10/10	10/10
HBV	0/10	10/10	10/10
HCV	0/10	10/10	10/10
HTLV-I/II	0/10	10/10	10/10
Dialysis	0/10	10/10	10/10
Multiparous	0/10	10/10	10/10
Rheumatoid Factor	0/10	10/10	10/10
Syphilis	1/10[1]	10/10	10/10
Tuberculosis	0/10	10/10	10/10

[1]One specimen reported as a weak Reactive on the DPP HIV 1/2 Assay. Specimen was negative by EIA. This specimen was nonreactive by EIA. An additional 50 specimens from individuals known to be infected with Syphilis gave Nonreactive test results for Chembio DPP HIV 1/2 Assay. All 70 specimens were tested by RPR test for Syphilis infection.

Effect of Potentially Interfering Substances on Analytical Sensitivity and Specificity

To evaluate the effect of potentially interfering substances on the performance of Chembio DPP HIV 1/2 Assay, 300 specimens containing potential interfering substances were tested. The specimens were spiked with saline, an HIV-1 reactive serum specimen or an HIV-2 reactive serum specimen to a low level of reactivity. All HIV-1 and HIV-2 specimens gave Reactive results, while all unspiked samples gave Nonreactive results (see Table 17).

Table 17: Effect of potentially interfering substances on analytical sensitivity and specificity of the Chembio DPP HIV 1/2 Assay

Description	DPP HIV 1/2 Assay (# Reactive / Total # Tested)		
	Saline	HIV-1 (Weak Reactive)	HIV-2 (Weak Reactive)
Hemoglobin Samples, 0.98 – 500 mg/dL	0/10	10/10	10/10
Triglyceride/Triolin, 5.86 – 3,000 mg/dL	0/10	10/10	10/10
Bilirubin Mixed Isomer, 0.04 – 20 mg/dL	0/10	10/10	10/10
Total Protein (HAS), 6.0 – 11.0 g/dL	0/10	10/10	10/10
E. coli, 98 – 50,000 CFU/mL	0/10	10/10	10/10
EDTA, 1.56 – 800 mg/dL	0/10	10/10	10/10
Sodium Citrate, 1.95 – 1,000 mg/dL	0/10	10/10	10/10
Lithium Heparin, 15.63 - 8,000 mg/dL	0/10	10/10	10/10
Sodium Heparin, 15.63 – 8,000 mg/dL	0/10	10/10	10/10
Candida albicans, 44 – 22,500 cells/mL	0/10	10/10	10/10

In a separate study, oral fluid specimens collected from 85 individuals known to be infected with HIV-1 and 85 individuals presumed to be negative for HIV-1 infection were prospectively collected and tested on the Chembio DPP HIV 1/2 Assay.

Information was collected from the participants regarding concurrent diseases or medical conditions, oral pathologies, and other factors. In this study, consumption of alcoholic and non-alcoholic beverages, use of mouthwash, brushing teeth, chewing gum, or smoking tobacco 5 minutes to 24 hours prior to testing did not affect the sensitivity or specificity of the Chembio DPP HIV 1/2 Assay.

REPRODUCIBILITY

Reproducibility was tested at three laboratories using three lots of the Chembio DPP HIV 1/2 Assay. A panel of five blinded (four plasma and one serum) samples 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 laboratory. Testing was performed according to the Product Insert of the Chembio DPP HIV 1/2 Assay. Results were read at 10 minutes. Results were read semi-quantitatively using a common strip evaluation scale. A total of 405 data points was taken. The reproducibility of the Chembio DPP HIV 1/2 Assay was calculated to be 405/405 = 100% (95% confidence interval 99.1 to 100%).

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