WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: DPP® HIV 1/2 Assay
WHO reference number: PQDx 0053-006-00

DPP® HIV 1/2 Assay with product code **65-9506-0**, 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 6 June 2016.

Intended use:
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 EDTA plasma specimens. Chembio DPP® HIV 1/2 Assay is intended for use at point-of-care to aid in the diagnosis of infection with HIV-1 and HIV-2. This test may be used within a validated testing algorithm to determine the HIV serostatus of an individual. When multiple HIV rapid diagnostic tests are available, this assay should be used in appropriate multi-test algorithms.

Assay description:
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 and control) zones in the readout window of the test cassette. To initiate the test, a specimen is collected and applied to SAMPLE+BUFFER Well of the DPP test cassette. The specimen flows along the sample path membrane and is delivered to the test zone of the reagent strip, where specific HIV antigens and a control (Protein A) are immobilized, in the TEST (T) and CONTROL (C) area of the test zone. HIV antibodies, if present in the specimen, bind instantly to the immobilized test antigens, while non-specific IgG binds to the Protein A control. Successful specimen application is indicated by the dissolution of soluble dye lines in the test and control zone. Five minutes after adding the specimen, buffer is added to the BUFFER Well. The buffer hydrates the dried antibody-binding colored conjugate, which migrates to the test zone. If the specimen 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.

Test kit contents:

Component	20 tests (product code 65-9506-0)
DPP® HIV 1/2 Individually Pouched Test Devices with desiccant packet	20
Oral Fluid Swabs	20
Disposable 10µL Sample Loops - BLUE	20
DPP® HIV SampleTainer® – BLACK Cap 1mL, contains sodium phosphate, sodium chloride, EDTA, Tween 20, avidin, and chicken serum, and gentamicin, streptomycin, and sodium azide as preservative.	20 bottles of 1 mL
DPP® HIV Running Buffer – GREEN Cap 6mL, contains sodium phosphate, sodium chloride, EDTA, Tween 20, avidin, chicken serum, and urea, and gentamicin, streptomycin, and sodium azide as preservative.	1 bottle of 6 ml
Product Insert (instructions for use)	1

Items required but not provided:

Item
Consumables: Disposable gloves Antiseptic wipes Sterile Safety Lancet (for fingerstick whole blood specimens) Sterile gauze (for fingerstick whole blood specimens) Collection devices for specimens (other than fingerstick whole blood specimens)
Durables: Laboratory pipette capable of delivering 10µL of sample may be used in lieu of the disposable 10µL sample loop (BLUE) supplied within the kit (for other than fingerstick whole blood specimens) Biohazard disposal container
Equipment: Clock, watch, or other timing device

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

Shelf-life upon manufacture:
24 months.

Warnings/limitations:

1. Individuals infected with HIV-1 and/or HIV-2 who are receiving antiretroviral therapy (ART) and other preventive treatment for HIV may produce false negative results.
2. This test has not been evaluated for newborn screening, cord blood specimens or individuals less than 2 years of age.

Summary of WHO prequalification assessment for DPP® HIV 1/2 Assay

	Date	Outcome
PQ listing	6 June 2016	listed
Dossier review	22 January 2015	MR
Site inspection(s) of quality management system	14 to 16 October 2014	MR
Laboratory evaluation of performance and operational characteristics	29 January 2016	MR

MR: Meets requirements
N/A: Not applicable

Prioritization for prequalification

Based on the established criteria, DPP® HIV 1/2 Assay was given priority for WHO prequalification.

Product dossier assessment

The Manufacturer submitted a product dossier for DPP® HIV 1/2 Assay as per the "Instructions for compilation of a product dossier" (PQDx_018 v1). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The Manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 22 January 2015.

Based on the product dossier screening and assessment findings, the product dossier for DPP® HIV 1/2 Assay meets WHO prequalification requirements.

Manufacturing site inspection

A comprehensive inspection was performed at the site of manufacture (3661 Horseblock Road, Medford, NY, 11763, USA and 91-1, Colin Drive, Holbrook, NY, 11741, USA) of DPP® HIV 1/2 Assay in 14 to 16 October 2014 as per the "Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics" (PQDx_014 v1). The inspection found that the Manufacturer had an acceptable quality

management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality.

The Manufacturer's responses to the nonconformities found at the time of the inspection were accepted on 21 November 2014.

Based on the site inspection and corrective action plan review, the quality management system for DPP® HIV 1/2 Assay meets WHO prequalification requirements.

Laboratory evaluation on serum/plasma specimens

DPP® HIV 1/2 Assay was evaluated by WHO in the second quarter of 2013 using serum/plasma specimens. From this evaluation, we drew the following conclusions:

DPP® HIV 1/2 Assay is an immunochromatographic rapid diagnostic test for the combined detection of HIV-1/2 antibodies in human serum/plasma, oral fluid, venous and capillary whole blood. A volume of 10 µL of specimen is needed to perform the assay for serum/plasma and venous and capillary whole blood. This type of assay requires no sophisticated equipment and can therefore be performed in laboratories with limited facilities and non-laboratory settings. Reading of the results can be done visually i.e. subjectively read.

In this limited evaluation on a panel of 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. The final sensitivity (95% CI) was 100% (99.2% - 100%) and the final specificity (95% CI) was 99.9% (99.2% - 100%) compared to the reference assays. Lot to lot variation was acceptable.

Performance characteristics in comparison with an agreed reference standard: serum/plasma specimens (n=1118)		
	Initial (95% CI)	**Final (95% CI)**
Sensitivity %	99.8% (98.8% - 100%)	100% (99.2% - 100%)
Specificity %	99.9% (99.2% - 100%)	99.9% (99.2% - 100%)
Invalid rate %	0%	
Inter-reader variability %	0.2%	

For eight seroconversion panels, DPP® HIV 1/2 Assay detected on average 0.5 specimens later than the benchmark assay; Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics).

For the mixed titer panel, DPP® HIV 1/2 Assay correctly classified all anti-HIV positive and anti-HIV negative specimens. Six out of the seven anti-HIV indeterminate/HIV-1 antigen positive specimens were detected.

For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], DPP® HIV 1/2 Assay correctly classified 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 0.2%. The invalid rate was 0%.

Additional performance characteristics for serum/plasma specimens	
Sensitivity during seroconversion on 8 seroconversion panels in comparison with a benchmark assay; Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics).	Seroconversion sensitivity index of +0.5, therefore detection is 0.5 specimens later than the benchmark assay
Analytical sensitivity on a mixed titer panel in comparison with an agreed reference standard	24 of 25 specimens were correctly classified.
Lot to lot variation on a dilution panel	Acceptable

Laboratory evaluation on oral fluid specimens

DPP HIV 1/2 Assay (Chembio Diagnostic Systems, Inc.) was evaluated by WHO in 2015 using oral fluid specimens. From this evaluation, we drew the following conclusions:

DPP HIV 1/2 Assay is a qualitative rapid immunochromatographic test for the detection of antibodies to HIV 1/2 in oral fluid, finger stick whole blood, venous whole blood, serum or plasma specimens. A volume of 65 µL of oral fluid (oral fluid in buffer, SampleTainer bottle, 2 drops) is needed to perform the assay. This type of assay requires no sophisticated equipment and can therefore be performed in laboratories with limited facilities and non-laboratory settings. Reading of the results can be done visually i.e. subjectively read.

In this limited evaluation on a panel of 597 clinically-derived specimens, we found an initial sensitivity (95% CI) of 93.9% (87.9% - 97.5%) for specimens from patients on ARV therapy, while the initial sensitivity for specimens from patients not on ARV therapy (95% CI) was 99.1% (94.9% - 100%). The initial specificity (95% CI) was 100% (99.0% - 100%) compared to the reference assays.

Performance characteristics in comparison with an agreed reference standard: oral fluid specimens (n=597)		
	Initial (95% CI)	**Final (95% CI)**
Sensitivity %	*99.1% (94.9% - 100%)	Repeat testing was not conducted
Specificity %	100% (99.0% - 100%)	Repeat testing was not conducted
Invalid rate %	0 %	
Inter-reader variability %	0.2%	

* Specimens collected from individuals not on antiretroviral therapy (ART).

The instructions for use includes a warning that individuals infected with HIV-1 and/or HIV-2 who are receiving antiretroviral therapy (ART) and individuals undergoing preventative treatment for HIV may produce false negative results.

In this study, 0.3% of the results were recorded as indeterminate. Results were interpreted independently by two technicians; the inter-reader variability was 0.2%. The invalid rate was 0%.

Key operational characteristics	
Validated specimen types	Serum, plasma (EDTA), venous whole blood (EDTA), capillary whole blood, oral fluid
Number of steps	4 without precision required
Time to result	15 minutes after buffer is added, if serum, plasma, capillary or venous whole blood. 25 after buffer is added, if oral fluid
Endpoint stability	No more than 25 minutes after buffer is added, if serum, plasma, capillary or venous whole blood. No more than 40 minutes after buffer is added, if oral fluid.
Internal QC	Yes, internal quality control in form of control line for detection of IgG. Test kit controls (for anti-HIV-1/2) were not supplied in the test kit but are available on order from the manufacturer.
In-use stability of reagents	The foil pouch should be opened just before use.

Labelling

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

1. Labels

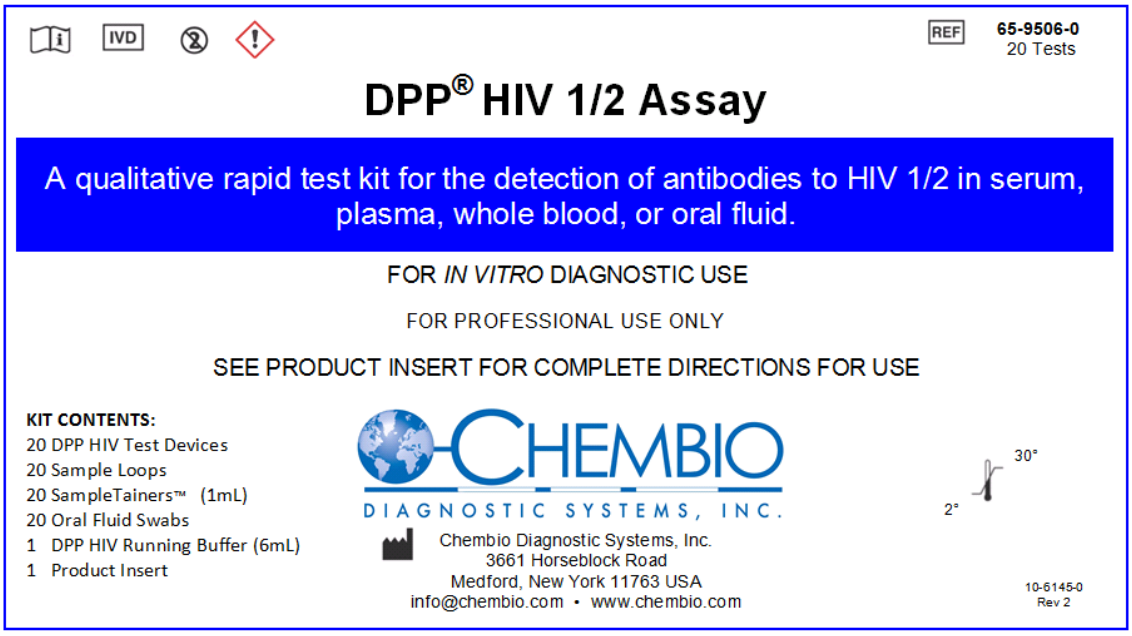

Figure 1. Kit Box Label, P/N: 10-6145-0

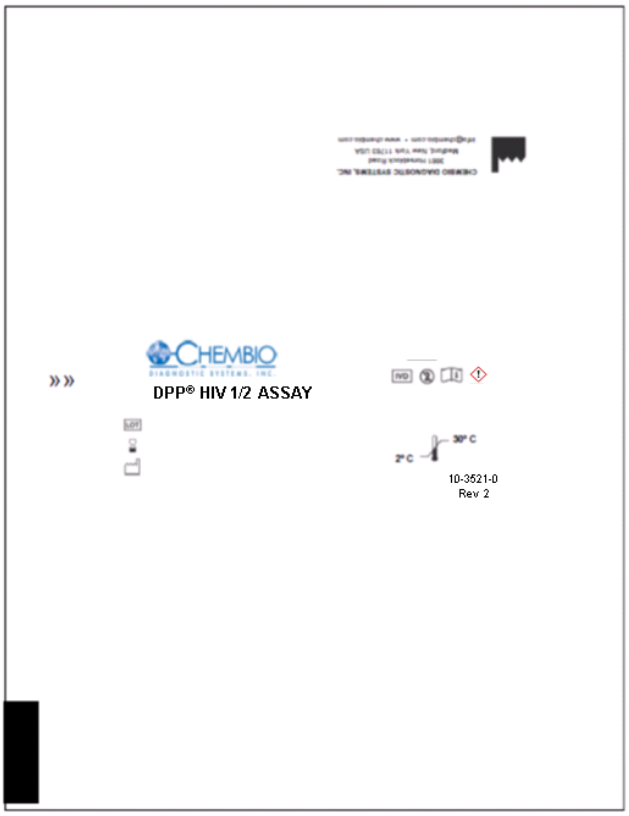

Figure 2. Foil Pouch Label, P/N: 10-3521-0

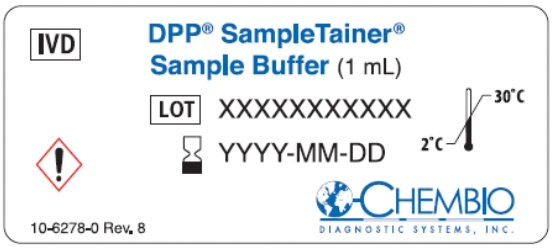

Figure 3. SampleTainer Label, P/N: 10-6278-0

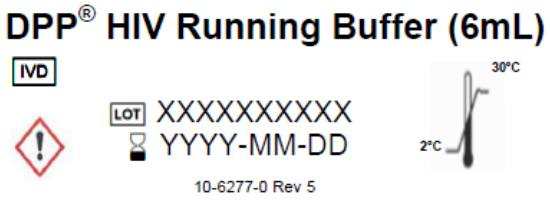

Figure 4. Running Buffer Label, P/N: 10-6277-0

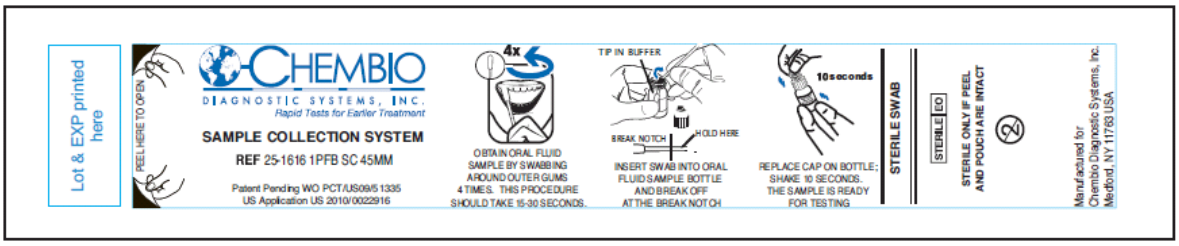

Figure 5. Oral Fluid Swab Label, P/N: 10-2020-2

10 uL Loop w/Break Pt
ID No: 10-4044-0
Lot No: XXXXX

Figure 6. Disposable 10 µL Sample Loop Label: Component of P/N 10-4044-0

2. Instructions for use

CHEMBIO DIAGNOSTIC SYSTEMS, INC.

REF 65-9506-0
20 Test Kit

DPP® HIV 1/2 Assay
FOR *IN VITRO* DIAGNOSTIC USE
FOR PROFESSIONAL USE ONLY

A Qualitative Rapid Test Kit for the Detection of Antibodies to HIV 1/2 in Oral Fluid, Fingerstick Whole Blood, Venous Whole Blood, Serum or Plasma Specimens.

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]

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 EDTA plasma samples. The Chembio DPP HIV 1/2 Assay is intended for use at point-of-care to aid in the diagnosis of infection with HIV-1 and HIV-2. This test may be used within a validated testing algorithm to determine the HIV serostatus of an individual. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms.

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 2012 there were approximately 35 million people living with HIV/AIDS. An estimated 2.3 million people were newly infected with HIV in 2012. In the same year approximately 1.6 million died of AIDS-related illness; 210,000 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 Acid 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 aids in the diagnosis of infection with HIV-1 and HIV-2 at point-of-care.

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 and control) zones in the readout window of the test cassette. To initiate the test, a specimen is collected and applied to SAMPLE+BUFFER Well of the DPP test cassette. The sample flows along the sample path membrane and is delivered to the test zone of the reagent strip, where specific HIV antigens and a control (Protein A) are immobilized, in the TEST (T) and CONTROL (C) area of the test zone. HIV antibodies, if present in the sample, bind instantly to the immobilized test antigens, while non-specific IgG binds to the Protein A control. Successful sample application is indicated by the dissolution of soluble dye lines in the test and control zone. 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 zone. 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.

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MATERIALS PROVIDED

Each kit contains the items to perform 20 tests:
20 DPP HIV 1/2 Individually Pouched Test Devices with Desiccant Packet
20 Oral Fluid Swabs
20 Disposable 10 µL Sample Loops - BLUE
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

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 (BLUE) 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 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 WHO Guidelines for the collection of clinical specimens during field investigation of outbreaks[12] and 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 test has not been evaluated for newborn screening, cord blood specimens or individuals less than 2 years of age.
6. Individuals infected with HIV-1 and/or HIV-2 who are receiving antiretroviral therapy (ART) and individuals undergoing preventative treatment for HIV may produce false negative results.

PRECAUTIONS

SAFETY PRECAUTIONS

1. Handle the samples and materials contacting samples 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] and assure accordance with Local, State, Federal or European Regulations. Follow standard biosafety guidelines for handling and disposal of potentially infective material.

7. The running buffer and the DPP SampleTainer contain 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.

HANDLING PRECAUTIONS

1. Do not use any test device if the pouch has been perforated. .
2. If Desiccant Packet is missing or appears damaged, DO NOT USE. Discard test device and use a new test device.
3. If the Test Window of a device does not contain 2 colored lines, one blue and one green, DO NOT USE. Discard test device and use a new device.
4. Each test device is for single use only.
5. Do not use the test beyond the expiration date printed on the pouch. Always check expiration date prior to testing.
6. Do not mix reagents from different lot numbers of kits.
7. 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. Devices should be run immediately after their pouches are opened. When stored as indicated, test devices are stable until the expiration date marked on the pouch. When stored as indicated, both Running Buffer and SampleTainer components should be stored at 2 to 30 °C (36 to 86 °F) in their original bottles.

SPECIMEN COLLECTION

The Chembio DPP HIV 1/2 Assay can be performed on oral fluid, fingerstick whole blood, venous whole blood, serum or plasma samples. 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 for whole blood, serum and plasma 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[12]. Do not use turbid, lipemic and haemolyzed specimens. Prior to oral fluid collection, ensure that the patient has had nothing by mouth for 30 minutes prior to sampling.

ORAL FLUID

The oral fluid collection system is used to obtain the sample. This consists of an Oral Fluid Swab and a dropper bottle containing Sample Buffer for adding the oral fluid to the test device as shown in Figure 1 below.

Figure 1

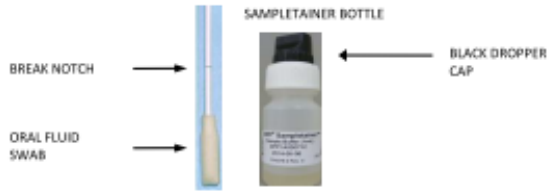

Figure 2

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

Proper oral fluid sample collection is critical. Before collecting the oral fluid sample, label the SampleTainer bottle with the patient ID or identification number, unscrew the WHITE CAP on the Sample Buffer bottle, 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 bottle, such that the swab is touching the bottom of the bottle. Snap the shaft at the break notch to dislodge the swab into the SampleTainer bottle as shown in Figure 3. Replace the BLACK/WHITE CAP assembly onto the bottle and shake the bottle for 10 seconds. Test immediately, following Test Procedure instructions.

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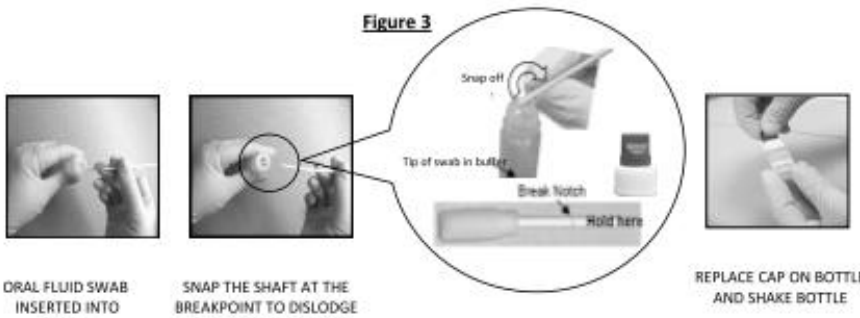
Figure 3



ORAL FLUID SWAB INSERTED INTO BOTTLE

SNAP THE SHAFT AT THE BREAKPOINT TO DISLODGE SWAB INTO THE BOTTLE

REPLACE CAP ON BOTTLE AND SHAKE BOTTLE

FINGERSTICK WHOLE BLOOD

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

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 (BLUE) provided to the drop of blood until the Sample Loop (BLUE) is full as shown in Figure 5.

Insert the filled Sample Loop (BLUE) into the SampleTainer bottle with the BLACK CAP, such that the blue sample loop is touching the bottom of the SampleTainer bottle. Snap and twist the shaft at the break notch to dislodge the blue sample loop into the SampleTainer bottle, as shown in Figure 6.

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

Figure 4

SampleTainer with BLACK CAP

Figure 5

Properly filled Sample Loop

Figure 6

SAMPLETAINER BOTTLE AND BLUE SAMPLE LOOP

BLUE SAMPLE LOOP INSERTED INTO SAMPLETAINERBOTTLE

SNAP AND TWIST THE SHAFT AT THE BREAKPOINT TO DISLODGE LOOP INTO THE SAMPLETAINER BOTTLE

REPLACE CAP ON BOTTLE AND SHAKE SAMPLETAINER BOTTLE

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VENOUS WHOLE BLOOD

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

Dip the Blue Sample Loop into the blood and allow it to fill or use a laboratory pipettor in accordance with standard laboratory procedures to withdraw 10µL of the blood. Pipette the sample or insert the filled Blue Sample Loop into the SampleTainer bottle with the BLACK CAP, such that the blue sample loop is touching the bottom of the SampleTainer bottle.

Snap and twist the shaft at the break notch to dislodge the blue sample loop into the bottle, as shown in Figure 6. Replace the BLACK/WHITE CAP assembly onto the SampleTainer bottle and shake the SampleTainer bottle 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 (serum). Collect plasma samples in tubes containing 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 Blue Sample Loop into the serum or plasma tube and allow it to fill or use a laboratory pipettor in accordance with standard laboratory procedures t to withdraw 10µL of the sample. Pipette the sample or insert the filled Blue Sample Loop into the SampleTainer bottle with the BLACK CAP, such that the blue sample loop is touching the bottom of the SampleTainer bottle.

Snap and twist the shaft at the break notch to dislodge the blue sample loop into the SampleTainer bottle, as shown in Figure 6. Replace the BLACK/WHITE CAP assembly onto the SampleTainer bottle and shake the SampleTainer bottle 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 in accordance with local clinical or laboratory procedures. Using a serum or plasma specimen that has been exposed to more than 2 freeze/thaw cycles is not recommended.

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, plasma and oral fluid specimens should be shipped refrigerated with cold packs or wet ice.

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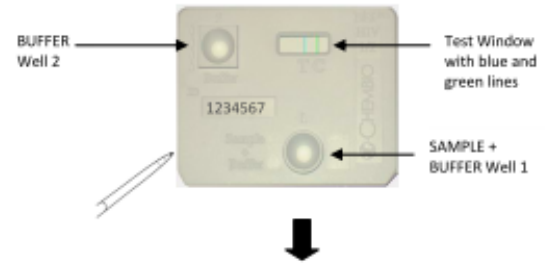
TEST PROCEDURE

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.

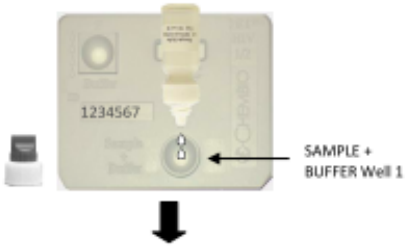
1. Remove the Chembio DPP HIV 1/2 test device from its pouch and place it on a flat surface (it is not necessary to remove the desiccant from the pouch). Label the test device with patient ID or identification number.

   NOTE: If Desiccant Packet is missing, DO NOT USE, discard test device and use a new test device.

   NOTE: The DPP test device should have 2 colored lines in the Test Window; a blue line in the TEST (T) area and a green line in the CONTROL (C) area. If the 2 colored lines are absent, DO NOT USE, discard test device and use a new test device.



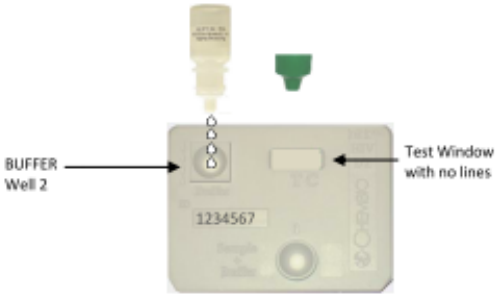
2. Invert the SampleTainer bottle (BLACK CAP), containing the collected sample, and hold it vertically (not at an angle) over the SAMPLE + BUFFER Well 1. Add 2 drops (~65µL) slowly, dropwise, into the SAMPLE + BUFFER Well 1.



3. **Wait 5 minutes.**

   NOTE: The blue and green colored lines should have disappeared from the rectangular Test 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. Reactive Test Results (See Interpretation of Test Results section) may be observed at earlier than 10 minutes, but Nonreactive Test Results cannot be verified until a minimum of 10 minutes have passed. Do not read results after 25 minutes.

   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, SampleTainer bottle (including the Blue Sample Loop or Oral Fluid Swab), and any other test materials into a biohazard waste container.

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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.

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.

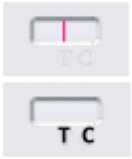
REACTIVE

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 EDTA plasma. Using other types of samples or testing of venipuncture whole blood samples collected using a tube containing an anticoagulant other than 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, CAPILLARY (FINGERSTICK) or VENOUS WHOLE BLOOD, SERUM or PLASMA, 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. Performing fingerstick sample collection when the finger is not completely dry could result in the contamination or dilution of the sample.
8. Results should be read 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. Reactive results should be confirmed by additional testing. The Chembio DPP HIV 1/2 Assay is intended as an aid in the diagnosis of infection with HIV-1/2. HIV and AIDS-related conditions should be established using clinical and/or serological methods.
10. For a reactive result, the intensity of the test line does not necessarily correlate with the titer of antibody in the sample.
11. 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 weeks to several months to reach detectable levels.
12. 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.
13. This assay has not been evaluated for newborn screening, cord blood specimens, or individuals less than 2 years of age.
14. An individual infected with HIV-1 and/or HIV-2 who is receiving antiretroviral therapy (ART) or an individual undergoing preventative treatment for HIV may produce a false negative result.

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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).

PERFORMANCE CHARACTERISTICS

HIV-1 Sensitivity

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.

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

Of the 964 true positive specimens; the sensitivity oral fluid on the DPP Test was 98.9% (95% CI: 98-99.4%) and capillary whole blood (fingerstick) sensitivity was 99.8% (95% CI: 99.2-99.9%), Table 1 and 2, respectively. The sensitivity for serum, venous whole blood and plasma was 99.9% (95% CI: 99.4-99.9%). See Table 3-4.

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	953	11[1]	964
Negative	1	879	880
Total	954	890	1844

1. Of these 11 false negative individuals seven were on ART.

Table 2: Detection of antibody to HIV-1 in Fingerstick (Capillary) 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	962	2	964
Negative	0	880	880
Total	962	882	1844

Table 3: 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	963	1	964
Negative	0	880	880
Total	963	881	1844

Table 4: Detection of antibody to HIV-1 in Plasma & 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	963	1	964
Negative	0	879	879
Total	963	880	1843

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. 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%).

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Table 5: 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	EIA Reactive	True HIV-2 Positive Only[1]
Known HIV-2 Positive	210	210	210	210

1. Confirmation based on results using an HIV-2 WB and not positive on an HIV-1 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 6).

Table 6: Detection of antibody to HIV-2 in oral fluid specimens

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

1. Two out of 10 specimens that 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 (A, A/E, A/D, A/G, AE, AG/B, B/D, C, D, D/A, F, G, G/AG, G/B, H, J, K/C) 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 the 144 HIV-1 Non B Subtype specimens, 143 specimens tested Reactive with the Chembio DPP HIV 1/2 Assay; one subtype D tested false nonreactive. Of the 8 HIV-1 Group O specimens, 8 specimens tested reactive with the Chembio DPP HIV 1/2 Assay.

Seroconversion Panels (Comparison to EIA)

Thirty-three (33) commercial seroconversion panels (serum/plasma) were tested in comparison with state of the art CE Marked anti-HIV EIA assays and/or CE Marked rapid tests. Each panel consisted of sequential serum/plasma specimens obtained from a single individual during seroconversion. In this study, the DPP HIV 1/2 Assay detected seroconversion in a similar manner to 3rd Generation ELISA's registered in major European countries for 23 of the 33 panels evaluated.

Specificity

The specificity of the Chembio DPP HIV 1/2 Assay was evaluated by testing 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 for a total of 1816 HIV-1 negative specimens evaluated.

One specimen from an individual at high risk for infection with HIV-1 was found to be reactive for oral fluid on the DPP Test and ultimately tested as negative for HIV antibodies using WB. The resulting specificity of the DPP HIV 1/2 Assay on oral fluid 99.9% (95% CI: 99.7-99.9%) (see Table 7). The specificity for fingerstick was 100% (95% CI: 99.8-100%) (see Table 8). The resulting specificity of the DPP HIV 1/2 Assay on venous whole blood, serum and plasma was 99.9% (95% CI: 99.7-99.9%) (see Table 9-10).

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Table 7: 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[1]	880[2]	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.

Table 8: Performance of the Chembio DPP HIV 1/2 Assay on fingerstick (capillary) 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
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.

Table 9: 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

Table 10: Performance of the Chembio DPP HIV 1/2 Assay on plasma & 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.

To further assess the specificity of the DPP HIV 1/2 Assay, a total of 1,207 specimens representing HIV Negative Blood Donors from the European Union and 207 HIV Negative Pregnant women from the United States were evaluated. See Table 11.

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

Study Population	Chembio DPP HIV 1/2 Assay	EIA	HIV Rapid Test
Negative Blood Donors (EU)	1000	999	1000
Negative Pregnant Women (US)	207	207	207
Total	1207	999	1207

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, 360 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 12).

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Table 12: 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. 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 60 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 13).

Table 13: 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 Chembio DPP HIV 1/2 Assay according to product insert. A panel of five blinded 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. Results were read semi-quantitatively using a common strip evaluation scale at 10 minutes. A total of 405 data points was taken. Sensitivity was calculated to be 405/405 = 100% with the 95% confidence interval extending from 99.1 to 100%.

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ORDERING INFORMATION

REF 65-9506-0 DPP® HIV 1/2 Assay

For Product Information, Literature and/or SDS please email
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This product insert is similar to the FDA approved Product Insert. The FDA version of the Product Insert is only available in the United States.
Certain language requirements specific to clinical laboratories in the United States have been removed.

SYMBOL LEGEND	
	CONSULT THE MANUAL BEFORE USE
	WARNING
	DO NOT RE-USE
2° 30°	FOR USE WITHIN TEMPERATURE LIMITS
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
LOT	BATCH CODE
REF	PRODUCT CATALOG NUMBER
	MANUFACTURERS IDENTIFICATION
	DATE OF MANUFACTURE
	USE BY DATE