Gallup Service Unit

Subject: Point-of-Care Testing: Chembio DPP® HIV-Syphilis System	
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I. Policy

The DPP® HIV-Syphilis System is a single-use rapid, qualitative, multiplex, immunoassay for the detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV-1/2), and or *Treponema pallidum* bacteria (the causative agent of syphilis) in fingerstick, whole blood, potassium-EDTA venous whole blood, or potassium-EDTA plasma specimens. The test is intended to be used with the DPP Micro Reader. The test is intended to be used by trained professionals in point of care settings to aid in the diagnosis of HIV and syphilis infection.

This CLIA-waived procedure is to be performed at the point of care on Fingerstick Whole Blood ONLY.

The Chembio DPP® HIV-Syphilis System is not approved for use to screen blood, blood products, or human cells/tissue/cellular tissue and tissue-based products for HIV and Syphilis.

This test has not been evaluated for newborn screening, cord blood specimens, or individuals less than 2 years of age.

Trained Personnel:

1. All testing in this procedure is performed under either a Provider Performed or Laboratory Waivered Testing CLIA certificate.

2. Point of Care Training Certification: Refer to Point of Care Testing (POCT)/General Policy for the process of certifying staff to perform POCT.

II. Procedure

A. Principle:

The DPP HIV-Syphilis System 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 (1 & 2) and CONTROL (C) areas in the readout window of the test cassette. A specimen mixed with pre-measured buffer is added to Well 1 of the test device. The sample migrates along the sample path membrane and is delivered to the test (1 & 2) area of the reagent strip, where specific HIV antigens, a syphilis recombinant antigen, and Protein A are immobilized. Antibodies to HIV and/or Treponema pallidum (i.e. treponemal antibodies), if present in the sample, bind instantly to the immobilized HIV and/or syphilis antigens in the test (1 & 2) 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 Well 2. The buffer hydrates the dried antibody-binding colored conjugate, which migrates to the test area. The test results are interpreted using the DPP Micro Reader between 10 and 25 minutes after buffer is added to Well 2. The DPP Micro Reader is a reflectance reader for use with the DPP HIV-Syphilis System. The DPP Micro Reader is a portable, battery-powered instrument that uses assay-specific algorithms to analyze the test and control line reflectance to determine the presence or absence of the antibodies to HIV and/or Treponema pallidum in the sample. The reader verifies the presence of the control line and measures color intensity at each of the test line positions. It interprets the results using an algorithm, including assay-specific cut-off values, to report a positive, negative, or invalid result. The results are displayed on the screen at the top of the instrument. **The DPP Micro Reader has been developed to minimize human interpretation errors, therefore the results cannot be visually interpreted by the operator.** The DPP Micro Reader is maintenance-free, not configurable by the user and is operated by a single, multi-function button.

B. Reagents and Material Provided:

1. DPP HIV-Syphilis System kit contains:
    a. 20 DPP HIV-Syphilis Test Devices
    b. 20 Disposable 10 µL Sample Loops with BreakPoint
    c. 20 DPP SampleTainer® Bottles – black cap
    d. 1 DPP Running Buffer – green cap
    e. 1 product insert for the DPP HIV-Syphilis System

2. DPP HIV-Syphilis Rapid Test Control Pack contains:
    a. 1 HIV-1/Syphilis Reactive Control
    b. 1 HIV-2 Reactive Control
    c. 1 Nonreactive Control
    d. 1 product insert for the DPP HIV-Syphilis Rapid Test Control Pack

3. DPP Micro Reader kit contains:
    a. 1 DPP Micro Reader configured for use in the DPP HIV-Syphilis System
    b. 1 DPP Test Device Holder
    c. 1 USB Wall Power Adapter (5v/1000 mA) with cable
    d. 1 microfiber cloth
    e. 1 user manual

C. Materials Required But Not Provided:

1. Timer or stopwatch
2. Disposable gloves
3. Sterile gauze
4. Antiseptic wipes
5. Biohazard disposal container(s)
6. Sterile single-use lancets
7. Eye protection

D. Infection Control:

1. Follow *Gallup Service Unit* policies and procedures for Standard Precautions.
2. Handle the samples, materials contacting samples, and kit controls as if capable of transmitting infection.
3. Wear protective clothing, disposable gloves, and eye protection when handling controls and patient samples.
4. Wash hands thoroughly before and after testing.
5. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in the testing area.
6. In the case of the wash solution contact with eyes, rinse immediately with plenty of water and seek medical advice.
7. Clean and disinfect testing area and/or all spills of specimens or reagents using facility approved disinfectant (follow manufacturer's instructions) or a 10% bleach solution. Bleach solution should be prepared fresh daily.
8. 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.
9. For additional information refer to: CDC "Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other bloodborne pathogens"[3] and "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV Recommendations for Postexposure Prophylaxis."[4] and "Update U.S. Public Health Service Guidelines for Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis"[5].

E. Storage and Stability

1. The DPP HIV-Syphilis test devices and kit components should be stored at 2 to 30°C (36 to 86°F). Do not freeze.
    a. This test should be performed at 18 to 30°C (64 to 86°F). *If stored refrigerated, test devices must be allowed to reach indicated temperature before performing testing.*
    b. Do not open test device pouch until ready to perform test.
    c. When stored properly, test devices are stable until the expiration date marked on the pouch.
    d. Running Buffer and DPP SampleTainer Bottles must be stored in their original containers.
    e. Do not use kit contents beyond labeled expiration date.

2. DPP HIV-Syphilis Rapid Test Control Pack should be stored at 2 to 8°C (36 to 46°F).
    - Do not use beyond the indicated expiration date.
    - Write the open date on each of the Control Vials
    - Recap and store the Control Vials in their original container at 2 to 8°C (36 to 46°F) after each use.

F. Quality Control

1. Internal Quality Control

The DPP Micro Reader verifies the presence of the control line. The control line serves as a built-in internal control and gives confirmation of sample addition and proper test performance.

2. External Quality Control

DPP HIV-Syphilis Reactive/Nonreactive Controls should be should be performed under the following circumstances:

- With each new operator *prior* to performing tests on patient samples
- With the **opening of each new test kit**
- 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 testing facility

External Quality Control Procedure:

PERFORM ONLY ONE CONTROL TEST AT A TIME.
Once the test device has been setup for the first control, you may proceed to start another control test until all 4 control samples have been completed.

1. Label the DPP SampleTainer Bottle with appropriate control information. Ex: HIV1&TP+, HIV2+, NR.

2. Open the DPP SampleTainer Bottle by removing the **white** cap, such that the black cap stays attached to the white cap.

3. Dip the Sample Loop into the Control Vial and allow it to fill.

4. Insert the filled Sample Loop into the DPP SampleTainer Bottle, such that the loop is touching the bottom.

5. Snap and twist the shaft at the *break-notch* to dislodge the loop into the DPP SampleTainer Bottle.

6. Replace the black/white cap assembly onto the DPP SampleTainer Bottle and shake for 10 seconds.

7. Perform test immediately following Patient Test Procedure Instructions.

   If QC fails, operator may repeat QC one time. If QC passes, then patient testing may continue. If QC fails twice, STOP. DO NOT RUN PATIENT TESTS. Contact the POC Coordinator or Laboratory Supervisor.

G. Patient Specimen Collection:

***As a GIMC Point of Care Test, this CLIA-waived procedure is to be performed on Fingerstick Whole Blood ONLY*.**

NOTE: Before collecting the sample, ***write the patient sample ID*** *on the DPP SampleTainer Bottle. Open the bottle by removing the WHITE CAP (keep the black cap attached to the white cap).*

1. To optimize whole blood circulation, warm the hand (wash in warm water or use hand/heel warmer) and massage the finger with a downward motion several times before performing the fingerstick.

2. 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.

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

4. Collect the sample from the second drop, touching the disposable Sample Loop to the drop of blood until the Sample Loop is full.

5. Insert the filled Sample Loop into the DPP SampleTainer Bottle, such that the loop is touching the bottom.

6. Snap and twist the shaft at the *break-notch* to dislodge the Sample Loop into the DPP SampleTainer Bottle.

7. Replace the black/white CAP assembly onto the DPP SampleTainer Bottle and gently shake for 10 seconds.

8. Test immediately following the Patient Test Procedure instructions.

I. Patient Test Procedure:

If stored refrigerated, all components of DPP HIV-Syphilis System kit must come to a temperature of 18 to 30°C (64 to 86°F) prior to testing.

1. Remove the DPP HIV-Syphilis Test Device from its pouch and place it on a flat surface. *Note: If the desiccant packet is missing, DO NOT USE the test device. Discard and open a new pouch.*

2. Label the test device with patient ID.

   Note: The test device has 3 colored lines in the test window. If any or all of the lines are absent, DO NOT USE the test device. Discard and open up a new pouch.

3. Remove the **black** cap on DPP SampleTainer Bottle (keep the white cap with dropper screwed onto the bottle).

4. Invert the DPP SampleTainer Bottle and slowly add 2 drops into Sample + Buffer Well 1. *Be sure to hold the bottle **vertically** when dispensing drops, do not hold at an angle.*

5. Wait 5 minutes. The blue and green colored lines should have disappeared from the test window. *If the lines have **not** disappeared, DO NOT USE the test device. Discard and repeat the test with a new device.*

6. Invert the Running Buffer bottle (green cap) and hold it ***vertically*** over Buffer Well 2. Slowly add 4 drops into Buffer Well 2.

7. Results will be read between 10 – 25 minutes after the addition of the Running Buffer to Buffer Well 2 using the DPP Micro Reader. DO NOT ATTEMPT TO INTERPRET THE RESULTS VISUALLY. **Always use the DPP Micro Reader to obtain results.**

J. Using the DPP Micro Reader

Check to make sure that the window at the bottom of the reader is clean of finger marks and dust or lint before using the reader.

The Reader and Test Device Holder must be on top of the Test Device when reading the device for results to be valid.

1. Connect the DPP Micro Reader to the supplied Test Device Holder (see image below).

   Place the DPP Test Device Holder on a flat surface. Match the reader with the DPP Test Device Holder by inserting the base of the Reader so that the "slanted edge" meets the corresponding "slanted corner" in the Test Device Holder socket. The DPP Micro Reader is secure in the DPP Test Device Holder once a "clicking" sound is heard.

2. Place the DPP Micro Reader and Test Device Holder on top of the Test Device and press the button. The DPP Micro Reader will go through the start-up process:
   1. Self-check will display all segments in the screen
   2. Number of tests remaining will display
   3. "RDY" will display when ready to read results

3. Press the button again and the DPP Micro Reader will show "RUN".
   Results for HIV and treponemal antibodies will be displayed one after the other.

   The results will be displayed for approximately 50 seconds before the DPP Micro Reader turns off.

   To read another test while the previous results are still scrolling, press the button. The DPP Micro Reader will go into "RDY" mode. Place the Reader and Test Device Holder on top of the next test device. Proceed to read results as instructed in step 3 above.

K. Interpretation of Test Results:

NOTE: Do not attempt to interpret results visually, USE DPP Micro Reader.

Display	Result Interpretations
HV.NR TP.NR	Nonreactive for HIV-1 or HIV-2 antibodies Nonreactive for treponemal antibodies
HV.R TP.NR	Reactive for HIV-1 and/or HIV-2 antibodies Nonreactive for treponemal antibodies
HV.NR TP.R	Nonreactive for HIV-1 or HIV-2 antibodies Reactive for treponemal antibodies
HV.R TP.R	Reactive for HIV-1 and/or HIV-2 antibodies Reactive for treponemal antibodies
INV	Invalid result. An invalid test result cannot be interpreted. Repeat the test with a new device. If the repeat is invalid. STOP. Do not continue testing. Call Customer Service at 844-243-6246.

1. HIV Results Interpretation:

   a. A Nonreactive 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.

   b. A Reactive 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.

2. Syphilis Results Interpretation:

   a. A Reactive test result for treponemal antibodies may indicate recent, past, or successfully treated syphilis. Confirmatory testing, in addition to a full clinical evaluation, will need to be performed.

b. A Nonreactive test result means treponemal antibodies were not detected in the specimen, ***however***, this does not exclude incubating or early primary syphilis. Additional testing and full clinical evaluation may be needed if the patient is at high-risk for syphilis.

K. Reporting of Results:

1. Record patient results on worksheets.
2. Patient results MUST be entered into EHR via the POC Lab Entry button.
   a. Select Patient in EHR
   b. Select Visit
   c. POC Lab Entry button will be found under the Visit Elements tab:
      i. Visit Elements → Data Entry menu → Triage Information
   d. Enter all patient information and results. ***Make sure all information is correct.***

      If any errors are observed after the entry has been saved, a new entry must be submitted with all the correct information. An EHR Correction Document must then be submitted to the POC Coordinator to cancel the erroneous entry.

L. Protocol for Informing Status of Test Results:

1. Tester should follow CDC guidelines to inform the patient of the test results.
2. The DPP HIV-Syphilis System test is a preliminary test. Patient shall be informed of this when communicating results and if any further confirmatory testing and/or evaluations are needed.
3. The tester should notify the HIV Nurse Specialist/Provider of Reactive test results for follow-up care (i.e., placing HIV confirmation lab order for patient).
4. HIV Nurse Specialist/Provider will advise patient to go to the lab to have confirmation testing done.
5. HIV Nurse Specialist/Provider will notify the patient of the confirmation test results.

M. Limitations

1. The DPP HIV-Syphilis System must ONLY be used with capillary (fingerstick) whole blood at the point of care. Using other types of samples may not yield accurate results.
2. The DPP HIV-Syphilis System must be used in accordance with the instructions in the product insert to obtain accurate results.
3. Reading test results using the DPP Micro Reader earlier than 10 minutes or later than 25 minutes after the addition of buffer to Buffer Well 2 may yield erroneous results.
4. This test is intended to be used as the first-tier assay in the reverse sequence syphilis screening algorithm to aid in the detection of infection with T. pallidum. A diagnosis of syphilis must be made in the context of treponemal and non-treponemal test results and in conjunction with clinical findings. This test is not intended for use as a confirmatory test in the reverse sequence syphilis screening algorithm.
5. An HIV REACTIVE result using the DPP HIV-Syphilis System suggests the presence of antibodies to HIV-1 and/or HIV-2 in the sample and shall be interpreted as Preliminary Positive for HIV-1 and/or HIV-2 antibodies. The DPP HIV-Syphilis System 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 using clinical and/or serological methods.

6. A NONREACTIVE HIV 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.
7. 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.
8. An individual infected with HIV-1 and/or HIV-2 who is receiving highly active antiretroviral therapy (HAART), PrEP (Pre-exposure prophylaxis), or PEP (Post-exposure prophylaxis) may produce false negative results.
9. This assay has not been evaluated for newborn screening, cord blood specimens, or for screening blood, blood products, tissue or organ donors for HIV and syphilis.
10. Specimens from individuals with Systematic Lupus Erythematosus (SLE), anti-Cytomegalovirus (CMV) IgM antibodies, or anti-Double Stranded DNA (dsDNA) antibodies may cross-react with the treponemal test line, generating false reactive results for treponemal antibodies.

III. References

DPP® HIV-Syphilis System Package Insert 1069070 Rev 3: 09/2020

DPP HIV-Syphilis Rapid Test Control Pack Package Insert 1063310 Rev 3: 06/2019

Centers for Disease Control and Prevention (CDC). Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings. MMWR 1988; 37(24):377-388.

Centers for Disease Control and Prevention (CDC). Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV Recommendations for Postexposure Prophylaxis. MMWR 2001; 50(RR-11):1-42.

Centers for Disease Control and Prevention (CDC). Update U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis. Infection Control and Hospital Epidemiology. 2013 Sep; 34 (9): 875-92.

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