

# DPP® HIV-Syphilis: Quick Reference Instructions for Fingerstick Whole Blood Cat. No. 65-9502-0

## CLIA Complexity Waived for Fingerstick Whole Blood

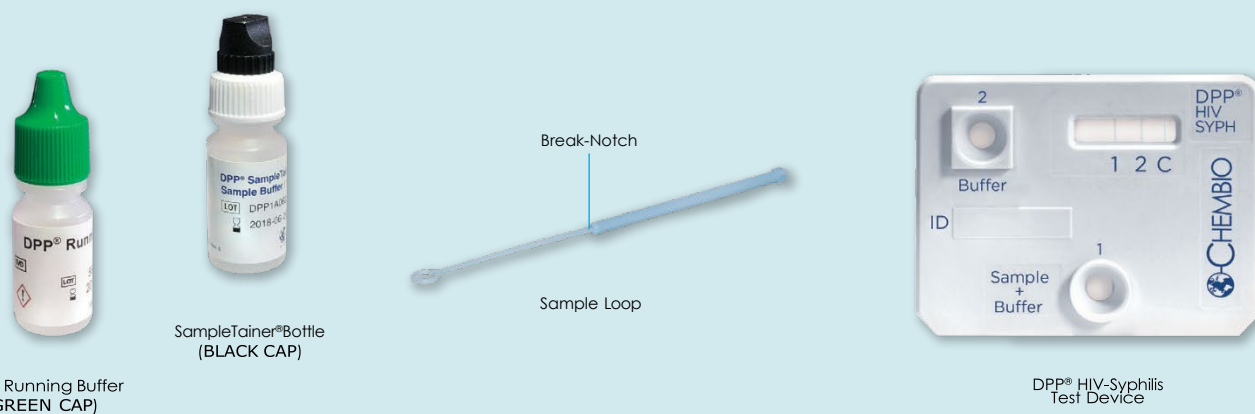
### Before you begin

**Read the complete DPP® HIV-Syphilis Product Insert and the DPP® Micro Reader User Manual before performing the test. Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test. Any modification by the user(s) to the manufacturer's test procedures will result in the test no longer meeting the requirements for waived classification.**

- Cover your work station with a clean, disposable absorbent workplace cover.
- Wear disposable gloves, gown (fluid resistant or impermeable), and eye protection (goggles or face shield).
- Treat all patient samples as potentially infectious.
- Let the test reach room temperature (between 18 to 25°C or 64 to 77°F) before opening pouch.
- Remove the DPP® HIV-Syphilis Test Device from pouch and become familiar with it.

#### CONTACT INFORMATION

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- The results of the DPP HIV-Syphilis Test Device must be interpreted using the DPP Micro Reader (Cat. No. 70-1056-0)



## DPP® HIV-Syphilis Test Procedure for Fingerstick Whole Blood

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



# DPP® HIV-Syphilis: Quick Reference Instructions for Fingertick Whole Blood Cat. No. 65-9502-0

## 1 COLLECT SAMPLE – Fingertick: Perform a fingertick prick as per normal laboratory procedures.



**Recommended  
Collection Sites**

Using an alcohol wipe, clean the finger of the person being tested.

**Note:** Using the middle or ring finger of the non-dominant hand is recommended.

Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad as alcohol will affect the test.

Using a sterile lancet, capable of producing a 50µl bleed, puncture the skin just off the center of the finger pad (see above picture).

Apply gentle pressure beside the point of the puncture. Wipe away the first drop of blood with a sterile gauze pad. Allow a second drop of blood to form. If blood flow is inadequate, the patient's finger may be gently massaged to produce a droplet of sufficient volume. Avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess tissue fluid.



Hold the loop in a horizontal position and bring the loop down on to the blood drop from above to collect the sample.

**Important:** Wait until a large enough drop has formed before collecting fingertick sample. Do not attempt to collect the sample before the blood drop is large enough to fill the loop.



Ensure loop is properly filled with sample (as depicted above) before proceeding to Step 2: Prepare the sample.

If necessary, safely discard the sample loop (in biohazard waste) and repeat the sample collection process.

## 2 PREPARE THE SAMPLE

Insert Sample Loop into DPP SampleTainer Bottle.



SNAP and TWIST the shaft at the BREAK-NOTCH to dislodge loop into the SampleTainer Bottle.



Replace cap on DPP SampleTainer Bottle and SHAKE for 10 seconds.

**Note:** Make sure that the cap is tightly screwed on.



## 3 TRANSFER SAMPLE

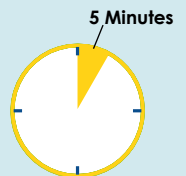
Unscrew the DPP SampleTainer Bottle BLACK CAP keeping the WHITE CAP screwed onto the bottle. Invert the DPP SampleTainer Bottle, containing the collected sample, and hold it vertically over the SAMPLE + BUFFER Well 1. Add 2 drops slowly, into the SAMPLE + BUFFER Well 1.

**START TIMER FOR 5 MINUTES**



## 4 WAIT 5 MINUTES

The colored lines should have disappeared from the Results window. If not, DO NOT USE, discard test device and repeat the procedure with a new DPP test device.



## 5 ADD BUFFER

Invert the DPP Running Buffer bottle (GREEN CAP) and hold it vertically over BUFFER Well 2. Add 4 drops slowly, into BUFFER Well 2.

**START TIMER**



## 6 WAIT 10 MINUTES FOR RESULTS

Read results 10-25 minutes from the addition of DPP Running Buffer to BUFFER (Well 2).



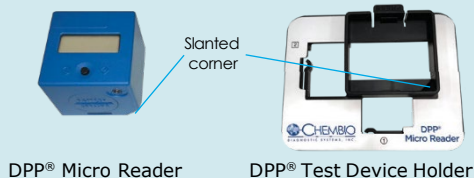
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## Instructions for Using the DPP® Micro Reader for Reading the Results

**DO NOT ATTEMPT TO INTERPRET RESULTS VISUALLY. ALWAYS USE THE DPP® MICRO READER TO OBTAIN RESULTS.**

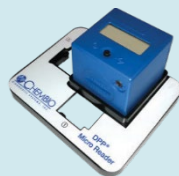
### A CLEAN COMPONENTS

Ensure the reader has working batteries and is clean. Remove any dust or debris from bottom camera window using the enclosed microfiber cloth.



### B CONNECT TO HOLDER

Match the Reader with the DPP Test Device Holder by inserting the base of the Reader so the "slanted edge" meets the corresponding "slanted corner" in the Test Device Holder socket. The assembly is secure once you feel it snap into place and a "CLICK" is heard.



DPP® Micro Reader correctly seated in DPP® Test Device Holder

### C ACTIVATE

The Reader/Test Device Holder assembly must be on top of the Test Device and on a flat surface when reading the device, for results to be valid.

After 10 minutes from the addition of DPP Running Buffer to BUFFER (Well 2), read test results by placing the reader and holder over the test device; press button on the Reader.



### D START-UP PROCESS

The DPP Micro Reader will go through the startup process:

- Displays LCD segments
- Number of remaining tests available
- Display "RDY"; Ready to read



### E Run the Reader

Press the button again; the DPP Micro Reader will show "RUN".



See next section to interpret the test results.

### F INTERPRET THE TEST RESULTS



NON-REACTIVE for HIV<sub>1</sub> or HIV<sub>2</sub> antibodies; NON-REACTIVE for Treponemal antibodies



REACTIVE for HIV<sub>1</sub> or HIV<sub>2</sub> antibodies; NON-REACTIVE for Treponemal antibodies



NON-REACTIVE for HIV<sub>1</sub> or HIV<sub>2</sub> antibodies; REACTIVE for Treponemal antibodies



REACTIVE for HIV-1 or HIV-2 antibodies; REACTIVE for Treponemal antibodies



An INVALID RESULT cannot be interpreted. It is recommended that the invalid test be repeated with a new device.

Call Customer Support if repeat run result is invalid.

## External Quality Control

Chembio DPP HIV-Syphilis Test Control Pack (catalog #: 60-9555-0) are available separately. Each package contains:

- HIV-1/Syphilis Reactive Control: produces an HIV and syphilis reactive test result when read using the DPP Micro Reader
- HIV-2 Reactive Control: produces an HIV reactive and syphilis nonreactive test result when read using the DPP Micro Reader
- Non-reactive Control: produces a non-reactive test result for HIV and Syphilis when read using the DPP Micro Reader

Test each control individually. For running the controls using the Sample Loop, dip the Sample Loop into the control vial and allow it to fill. After this step, follow instructions for testing patient sample from Step 2 above.

### CHEMBIO RECOMMENDS 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 25°C (36 to 77°F)
- If the temperature of the testing area falls outside of 18 to 25°C (64 to 77°F)
- At periodic intervals as indicated by the user facility

**Ordering Information:**  
Cat No.  
65-9502-0  
60-9555-0  
70-1056-0

**Description**  
DPP® HIV-Syphilis  
DPP® HIV-Syphilis Rapid Test Control Pack  
DPP® Micro Reader for Use with  
DPP® HIV-Syphilis

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