Considerations for Performing Whole Blood HIV-Syphilis Testing – Waived or NON-waived Testing

CLIA Certificate of Waiver	CLIA Certificate of Accreditation
Waived or Point of Care Test [Patient site/side]	*Moderate-complex or NON-waived Test [CORE LAB]*
Qualified Laboratory Director on CLIA: individual with a minimum of a Bachelor of Science degree	**Qualified Laboratory Director**: Refer to Laboratory Accreditation Organization (TJC, CAP, COLA) of qualified individuals by education and experience
Sample: fingerstick/capillary blood	**Sample**: EDTA-Purple/Lavender Top Tube
Qualified Tester: minimum of a High School Diploma with adequate training & assessed competent	**Qualified Tester**: Medical Laboratory Technician, Clinical Laboratory Scientist with appropriate diplomas, adequate training & assessed competent
Test Kit: contains all supplies to run 20 tests. Does not contain the DP Reader. Catalog #60-9555-0 *[20 Test Devices, 20 disposable 10 µL sample loops with break point, 20 sampletainer bottles, 20 Subject Information Notice Handouts, 1 DPP Running Buffer and 1 Product Insert]*	
Additional Supplies not in test kit: -DP Micro Reader (digital). Catalog #70-1056-0 -Timer or Watch -External Control materials -items for fingerstick (disposable gloves, antiseptic wipes, biohazard disposal container, sterile safety lancet, sterile gauze) -Thermometer to measure Room Temp	**Additional Supplies not in test kit:** -DP Micro Reader (digital) -Timer or Watch -External Control materials -Thermometer to measure Room Temp
Controlled Environment: Test Kit – store at 2-25°C (36-77°F) Testing at Room Temp – 18-25°C (64-77°F) Maintaining the test environment is **very critical** to make sure the test was correctly performed. Testers must follow the manufacturer's instructions!	

PREPARING TO RUN THE TEST

1. Make sure you have the appropriate CLIA Certificate to perform this test.
2. Write the test policy/procedure and have the Laboratory Director on the CLIA certificate review and approve it with signature and date.
3. Review if a consent is required for the HIV screen. The manufacturer states that the consents can be downloaded from the State's website.
4. Review how the test will be performed and that the environment will be maintained as instructed by the manufacturer. Suggest adding the temperature reading to the patient results log.
5. Identify the testers, generate the training/competency assessment form, complete the training and document. Make sure the tester passes the external quality control tests. Training video is here: https://www.youtube.com/watch?v=TuN7IgxZmNI
6. Include into the procedure of how the test results will be reported: onto paper log sheets, verbally called to the ordering medical provider, or entered into the Electronic Health Record using the Point of Care data entry process (if waived test). The core laboratory will report into EHR directly. The documentation system must capture the tester's identity.
7. Define the process of how reactive or positive results will be handled. Will retesting and/or confirmation testing be required? (for waived testing) Who will report the reactive or positive results to the State Health Department/Epidemiology, or local and/or Tribal offices?
8. Will this test be enrolled into a proficiency test program (i.e. American Proficiency Institute that compares your test result against peer laboratories performing the same test and sends you an evaluation report that reflects your scores) for the waived test setting? Core laboratories performing this test as a moderate-complex test should enroll in a proficiency test program.
9. If the test will be done in the **patient home setting**, it is **very important to have a controlled room temperature** and the vehicle should have a biohazardous spill clean-up kit if the laboratory decides

to draw the lavender/purple EDTA blood tubes and transport the tubes to the core laboratory. Transporting samples will require a tracking log sheet to make sure the blood tubes are within the stability range and the time of collection does not exceed the stability time.

Fingerstick Collection

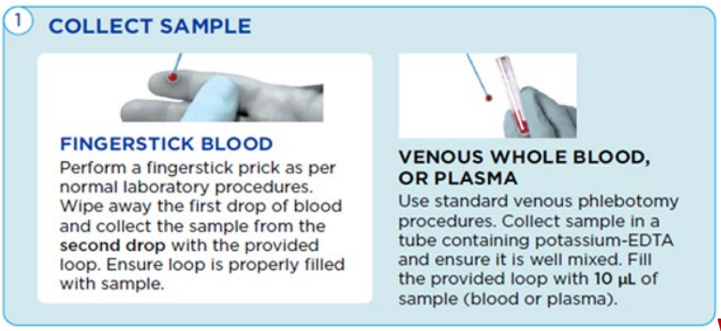
Steps:

- Clean finger with antiseptic wipe
- Allow to dry, or wipe with sterile gauze
- Puncture finger with sterile lancet
- Wipe away first drop of blood with sterile gauze. Avoid squeezing the finger.
- 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.

Prior to specimen collection, provide test subjects with SUBJECT INFORMATION NOTICE (included in test kit) and pre-test counseling according to CDC Guidelines for Rapid HIV Testing.

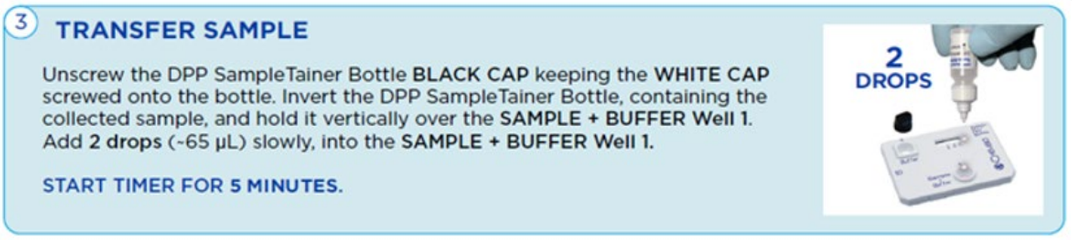
RUNNING THE TEST

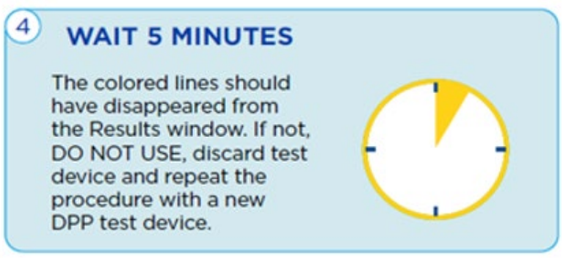
Room Temperature MUST be at 18-25°C (64-77°F)



Waived Test – Fingerstick only!!

If the core laboratory is running the test, then they would use the purple top blood tube.





5 ADD BUFFER

Invert the DPP Running Buffer bottle (**GREEN CAP**) and hold it vertically over **BUFFER Well 2**. Add **4 drops** (~135 µL) slowly, into **BUFFER Well 2**.

START TIMER FOR 10 MINUTES.

6 WAIT 10 MINUTES FOR RESULTS

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

DO NOT ATTEMPT TO INTERPRET RESULTS VISUALLY!!

Always use the DPP Micro Reader to obtain results.

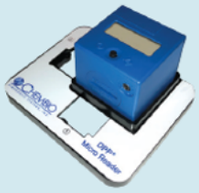
A CLEAN COMPONENTS

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

DPP® Micro Reader DPP® Test Device Holder

B CONNECT TO HOLDER

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. 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 a ***"CLICK"*** is heard.



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

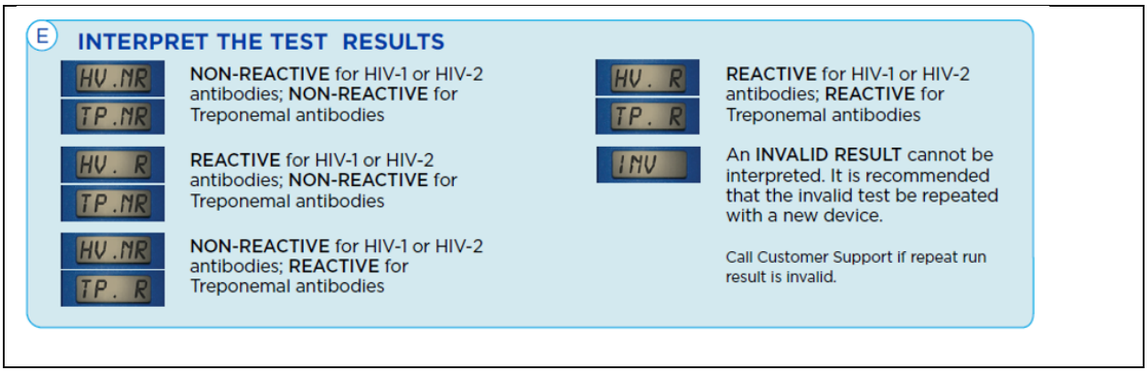
C ACTIVATE

At the time indicated for reading test results, place reader and holder over the test device; press button. The DPP Micro Reader will go through the start-up process.

D START-UP PROCESS

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

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



REPORTING TEST RESULTS	
Waived or Point of Care Test [Patient site/side]	*Moderate-complex or NON-waived Test [CORE LAB]*
-Manual Paper Log sheet with temperature reading -Tester must initial the log -Once returned to facility, can enter results via EHR point of care data entry -Maintain records for 2 years	Core laboratory will follow their own written policies to report the patient test results in their laboratory information system (RPMS Laboratory Package) - Maintain records for 2 years

RUNNING EXTERNAL QUALITY CONTROL MATERIALS

Suggest documenting on appropriate QC Log Sheet that records room temperature reading (Waived Test)

DPP HIV-Syphilis Rapid Test Control Pack (Catalog # 60-9555-0) approx. 50 uses

- **HIV-1/Syphilis Reactive Control -** One Vial containing 0.5 mL of heat inactivated human plasma positive for antibodies to HIV-1 and *T. pallidum*, diluted in normal human plasma. Negative for Hepatitis B surface antigen, Hepatitis C antibody and HTLV I/II antibodies.
- **HIV-2 Reactive Control** - One Vial containing 0.5 mL of heat inactivated human plasma positive for antibodies to HIV-2, diluted in normal human plasma. Negative for Hepatitis B surface antigen, Hepatitis C antibody, HTLV I/II antibodies and treponemal antibodies.
- **Non-reactive Control** – One vial containing 0.5 mL of normal human plasma negative for antibodies to HIV-1, HIV-2 and *T. pallidum*. Negative for Hepatitis B surface antigen, Hepatitis C antibody and HTLV I/II antibodies.
- 1 Product Insert for the DPP HIV-Syphilis Rapid Test Control Pack

Refrigerated storage at 36 to 46ºF (2 to 8° C)
4-month shelf life from date of manufacture

Frequency Run the kit controls under the following circumstances:

- With each new operator prior to performing tests on patient specimens
- 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.

NOTE: If the test site receives 10 boxes of new test kits and all have the same lot number/expiration date, only one box will need to be checked with the external QC materials.

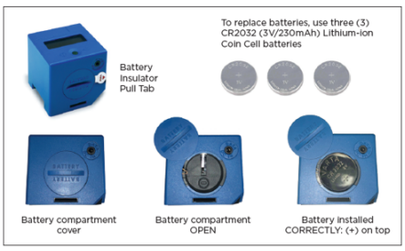
Utilize sample loop or pipette to transfer 10 ul of control material to DPP SampleTainer® bottle and perform test as you would a patient sample.

EXPECTED QC RESULTS:

- HIV-1/Syphilis Reactive Control — HV. R / TP. R
- HIV-2 Reactive Control — HV. R / TP.NR
- Non-reactive Control — HV.NR / TP.NR

DPP Micro Reader:

- Battery replacement
- Power cable (does not charge batteries)
- 3000 read limit
  - < 50 tests displays “REORDER” after the count
  - 0 tests remaining device is disabled and displays “EXPIRED-REORDER” after the count
- Error Code 0x12
  - The device could not read
  - Follow the instructions, verify that the window under the reader is clean, that the reader and the cartridge are correctly positioned in the holder and read the test again.



TROUBLESHOOTING

Possible Causes of Issues/Errors:

- Failure to wipe away first drop of blood
- Not enough sample picked up with transfer loop
- Incorrect amount of buffer
- Using reagents from different lot numbers of kits - “mixing reagents”
- Micro Reader
  - Not flat on adapter
  - Lens dirty
- Individuals infected with HIV-1 and/or HIV-2 who are receiving highly active antiretroviral therapy (HAART), PrEP (Pre-exposure prophylaxis) or PEP (Postexposure prophylaxis) may produce false negative results.

Written Policy or Test Procedure should have the name of the person(s) to contact for assistance in troubleshooting. The technical phone number to call Chem Bio is 1-844-243-6246; info@chembio.com ; www.chembio.com

Reference: DPP HIV-Syphilis Instructions for Use, Chem Bio Diagnostics Systems, Inc. Medford, NY, Rev 7, January 2023

Compiled by Arlinda.Lee@ihs.gov Phoenix Area IHS Area Laboratory Consultant & National Laboratory Professionals Council Chair