



ORAL FLUID Test Procedure

For *IN VITRO* diagnostic use

CLIA Complexity **WAIVED** for oral fluid, fingerstick whole blood, and venous whole blood.

- Before performing testing, all operators **MUST** read and become familiar with Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other blood borne pathogens in Health-Care Settings.
- These instructions are only a Reference Guide for use in CLIA waived settings. Read the complete procedure, including the QC procedure, 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.**

External Quality Control:

A Chembio DPP® HIV 1/2 Rapid Test Control Pack is available separately for use with the Chembio DPP® HIV 1/2 Assay. The HIV Controls are used to verify the operator's ability to properly perform the test and interpret the results. Run the controls as described in the Test Procedure section for a whole blood sample and follow the Interpretation of Results section below. We recommend running controls: • with each new operator • with each new device lot • with each new shipment of devices • if improper device storage is suspected and • at periodic intervals. It is the responsibility of each facility using the Chembio DPP® HIV 1/2 Assay to establish an adequate quality assurance program to ensure the performance of the device in their environment and conditions of use.

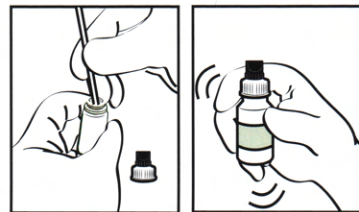
IMPORTANT

Follow the oral fluid sample collection instructions carefully, as not doing so may produce incorrect results.



- Slowly swab upper & lower gums in a circular motion **4 TIMES** for at least **30 SECONDS**.
- **IMPORTANT:** Collection time of 30 seconds is needed for accurate results.
- **DO NOT SWAB** roof of mouth, inside of cheek or tongue.

- Insert Oral Fluid Swab into DPP® SampleTainer® bottle and snap at break notch
- Replace black/white cap and **SHAKE** the DPP® SampleTainer® bottle for at least **10 SECONDS**.



BEFORE YOU BEGIN

- Gather the materials you will need.
- Cover your work space with a clean, disposable absorbent workplace cover.
- Put on disposable gloves.
- Let the test reach room temperature (between 18-30°C or 64-86°F) before opening the pouch.
- Remove the DPP® HIV 1/2 test device from pouch and become familiar with it.

The DPP® HIV 1/2 Assay kit contains:

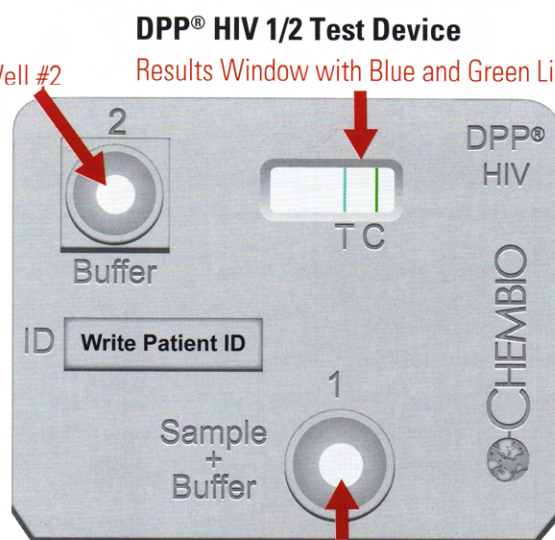
- 20 DPP® HIV 1/2 Individually Pouched Test Devices
- 20 Disposable Sample Loops (10µL)
- 20 Oral Fluid Swabs
- 20 DPP® SampleTainer® Bottles (1mL, Black and White Cap)
- 1 DPP® Running Buffer Bottle (6mL, Green Cap)

Materials required but not provided:

- Clock, watch or other timing device
- Sterile gauze
- Disposable gloves
- Antiseptic wipes
- Biohazard disposal containers
- Sterile Safety Lancet (for fingerstick)
- Collection devices for venous blood

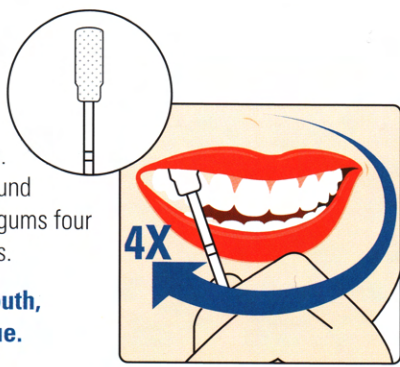


- Before collecting the sample, **write the sample ID on the DPP® SampleTainer® bottle** (with the black and white cap).
- Unscrew the **WHITE CAP** keeping the **BLACK CAP** in place.



1 Obtain Sample

- Insert Oral Fluid Swab into mouth above teeth and against outer gum as shown.
- Gently swab completely around both upper and lower outer gums four times for at least 30 seconds.



DO NOT SWAB: roof of mouth, inside of cheek, or tongue.

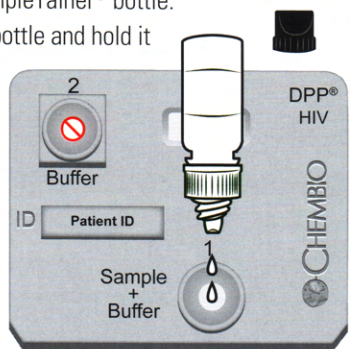
2 Add Sample to DPP® SampleTainer® Bottle



- Insert Oral Fluid Swab into DPP® SampleTainer® bottle with swab resting on bottom of bottle.
- Snap shaft at break notch to release tip of swab into bottle as shown.
- Replace black/white cap assembly onto bottle and shake bottle for at least 10 seconds.

3 Add Sample to Test Device Well #1

- Unscrew the **BLACK CAP** keeping the **WHITE CAP** with the dropper tip on the DPP® SampleTainer® bottle.
- Invert the DPP® SampleTainer® bottle and hold it **VERTICALLY** (not at an angle) over **SAMPLE+BUFFER Well #1**.
- Slowly add 2 **FULL** drops of sample into **SAMPLE+BUFFER Well #1**



Important: Adding less than 2 drops may produce invalid results.

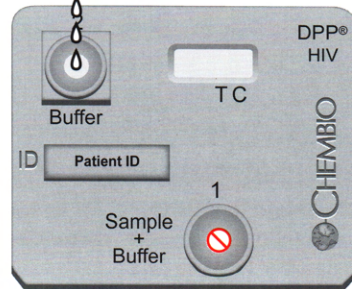
4 Add Running Buffer to Test Device Well #2

- **Five minutes** after adding the sample, add 4 drops of Running Buffer (green cap) into **BUFFER Well #2**. Hold bottle **VERTICALLY**.



Important: Adding less than 4 drops or more than 8 drops of Running Buffer may produce invalid results.

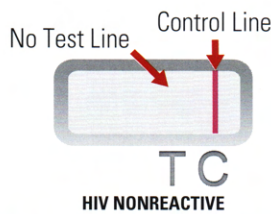
- Read the test result between 25 and 40 minutes after adding Running Buffer to **BUFFER Well #2**. If a test is nonreactive, you **MUST** wait the full 40 minutes to report a nonreactive result.



Wait 5 minutes. After 5 minutes, the blue and green lines should disappear from the Results Window. If they do not disappear, discard test device and repeat the procedure with a new DPP® test device.

Interpretation of Results: ORAL FLUID

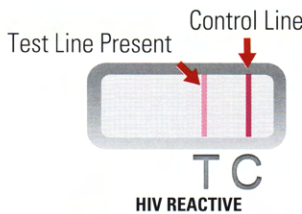
ADEQUATE LIGHTING REQUIRED



NONREACTIVE RESULT

One pink/purple line in the CONTROL (C) area, with no line in the TEST area, is a Nonreactive result. A nonreactive result at **40 minutes** means that HIV antibodies were not detected.

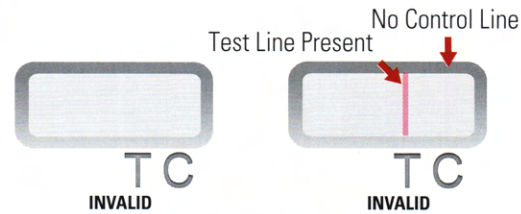
The test result is **NEGATIVE** for HIV antibodies. However, **this does not exclude possible infection with HIV.**



REACTIVE RESULT

A pink/purple line in the CONTROL (C) area, with a line in the TEST area, is a Reactive result. If **ANY VISIBLE LINE** appears in the TEST area and in the CONTROL area, no matter how faint, the result is Reactive. A reactive result **between 25 and 40 minutes** means that HIV antibodies were detected.

A **REACTIVE** test result means that HIV antibodies were detected in the specimen. The test result is **Preliminary POSITIVE** for HIV antibodies.



INVALID RESULTS

If no control line appears, results are invalid whether or not a test line is present.

An **INVALID** test result means there was a problem running the test. The problem could be due to the specimen, the test device or the procedure.

An **INVALID** test result cannot be interpreted. An **INVALID** test should be repeated with a new device.

Contact Chembio Diagnostic Systems if you are unable to get a valid test result upon repeat testing.