**Quick Reference Instructions**

**ORAL FLUID Test Procedure**

**ORAL FLUID** Test Procedure  
For IN-VITRO diagnostic use

**EXTERNAL QUALITY CONTROL**

- Before performing testing, all operators MUST read and become familiar with the Preliminary Instructions 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 laboratories. 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 to the manufacturer’s test procedures will result in the test no longer meeting the requirements for waived classification.

**BEFORE YOU BEGIN**

- Gather the materials you will need.
- Ensure your work space is clean, disposable absorbent workplace covers.
- Sterile gauze
- Disposable gloves
- Antiseptic wipes
- 20 Disposable Sample Loops (10µL)
- 20 DPP® HIV 1/2 Individually Pouched Test Devices (10µL)
- 1 DPP® Running Buffer Bottle (6mL, Green Cap)
- 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 New Device section for a whole blood sample and follow the Interpretation of Results section below. Perform the controls for a whole blood sample if improper device storage is suspected and at periodic intervals. It is the responsibility of each facility using the DPP® HIV 1/2 Assay to establish an adequate quality assurance program to ensure the performance of the device in its environment and conditions of use.

**Instructions**

1. **Obtain Sample**
   - Insert Oral Fluid Swab into bottle VERTICALLY (not at an angle)
   - Slowly swab upper & lower gums in a circular motion 4 TIMES for at least 10 SECONDS.
   - If no control line appears, results are invalid whether or not a test line is present.
   - A Chembio DPP® HIV 1/2 Rapid Test Control Pack is available separately for use with the 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 New Device section for a whole blood sample and follow the Interpretation of Results section below. Perform the controls for a whole blood sample if improper device storage is suspected and at periodic intervals. It is the responsibility of each facility using the DPP® HIV 1/2 Assay to establish an adequate quality assurance program to ensure the performance of the device in its environment and conditions of use.

2. **Add Sample to DPP® SampleTainer® 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 in place.
   - Insert DPP® SampleTainer® bottle into VERTICAL Wells #1 and #2 of DPP® Test Device Well #1.
   - Slowly add 2 FULL drops of SAMPLE BUFFER (White Cap) the sample into SAMPLE BUFFER Well #1.
   - If no control line appears, results are invalid whether or not a test line is present.
   - 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 and hold bottle VERTICALLY.
   - Read the test result between 25 and 40 minutes after adding Running Buffer to BUFFER Well #2. If a test is non-reactive, you MUST wait the full 40 MINUTES to report a non-reactive result.

**Interpretation of Results: ORAL FLUID**

**ACCUATE LIGHTING REQUIRED**

**WRITE PATIENT ID**

- Make sure there are no droplets of sample or Running Buffer remaining in the sample container.
- Slowly add sample to the test device in a circular motion 4 TIMES for at least 10 SECONDS.
- Insert Oral Fluid Swab into DPP® SampleTainer® bottle and snap shaft at break notch.
- Replace black/white cap assembly onto bottle and shake bottle for at least 10 SECONDS.

**QUIT ADDING SAMPLE**

**WASTE SAMPLE**

**REACTIVITY**

- A pink/purple line in the TEST area, with no line in the CONTROL area, is a Reactive result. A NON-REACTIVE result means that HIV antibodies were not detected.
- The test result is NON-REACTIVE for HIV antibodies. However, this does not exclude possible infection with HIV.

**INACTIVE**

- If no control line appears, results are invalid whether or not a test line is present.
- An INACTIVE result may mean there were a problem during the test. The problem could be due to the specimen, the test device or the procedure. An INACTIVE result cannot be interpreted. An INACTIVE test should be repeated with a new device.

**For problems or questions, please contact Chembio Diagnostic Systems’ Customer Service at 800-327-3635**
**DPP® HIV 1/2 Assay**

**Whole Blood Test Procedure**

For use with 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 whole blood sample and follow the Interpretation of Results section below. We recommend running controls: 1. with each new operator 2. with each new device lot 3. with each new shipment of devices 4. if improper device storage is suspected and 5. 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 inclusiveness of this device in their environment and conditions of use.

**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 whole blood sample and follow the Interpretation of Results section below. We recommend running controls: 1. with each new operator 2. with each new device lot 3. with each new shipment of devices 4. if improper device storage is suspected and 5. 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 inclusiveness of this device in their environment and conditions of use.

**Materials required but not provided:**
- Clock, watch or other timing device
- Disposable gloves
- Antiseptic wipes
- Biohazard disposal containers
- Sterile Safety Lancet (for fingerstick)

**Quick Reference Instructions**

BEFORE YOU BEGIN
- Gather the materials you will need.
- Cover your work space with a clean, disposable absorbent workplace cover.
- Gather the materials you will need.
- Clock, watch or other timing device
- Disposable gloves
- Antiseptic wipes
- Biohazard disposal containers
- Sterile Safety Lancet (for fingerstick)

**DPP® HIV 1/2 Assay includes:**
- 20 DPP® HIV 1/2 Individually Pouched Test Devices
- 20 Disposable Sample Loops (10/4)
- 20 Oral Fluid Swabs
- 20 DPP® SampleTainer® Bottles (1mL, Black and White Cap)
- 1 DPP® Running Buffer Bottle (6mL, Green Cap)

**The DPP® HIV 1/2 Assay includes:**
- 20 DPP® HIV 1/2 Individually Pouched Test Devices
- 20 Disposable Sample Loops (10/4)
- 20 Oral Fluid Swabs
- 20 DPP® SampleTainer® Bottles (1mL, Black and White Cap)
- 1 DPP® Running Buffer Bottle (6mL, Green Cap)

Be sure the test reaches 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.

**Obtain Sample**

1. Finger Stick Blood

Perform a finger stick per your normal laboratory practices.

a. Expose the area of skin for puncture and allow to dry.

b. Insert needle, apply gentle pressure to protect vessel.

2. Venous Whole Blood

Obtain on EDTA or venous blood sample per your normal laboratory practices.

a. Sterilely mix sample and remove stopper from the DPP® SampleTainer® bottle.

b. Snap shaft at break notch to release Sample Loop from the Bottle.

3. Add Sample to DPP® SampleTainer® Bottle

a. Use the BLACK CAP to the BLACK CAP to the BLACK CAP to the SAMPLE/BUFFER Well #1.

b. Add 4 drops of sample into SAMPLE/BUFFER Well #1.

**Important:** Adding less than 2 drops or more than 8 drops of sample may produce invalid results.

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:**

- **FINGER STICK or VENOUS WHOLE BLOOD**

- **NONREACTIVE RESULT**

  A pink line in the CONTROL (C) area, with no line in the TEST (T) area, is a NONREACTIVE result. A nonreactive result means that HIV antibodies were not detected.

  The test result is NONREACTIVE for the HIV antibodies. This does not exclude possible infection with HIV.

- **REACTIVE RESULT**

  A pink line in the CONTROL (C) area, with a line in the TEST (T) area, is a REACTIVE result. An HIV reactive result means that antibodies to HIV were detected.

- **INVALID RESULT**

  An INVALID result means that the HIV antibodies were detected in the specimen. The test result is NONREACTIVE for the HIV antibodies.

For problems or questions, please contact Chembio Diagnostic Systems’ Customer Service at 800-327-3635.