CLIA Complexity: Waived
For Fingerstick Whole Blood and Venipuncture Whole Blood Only

- These instructions are only a Reference Guide. For complete information, refer to the Chembio® HIV 1/2 STAT-PAK® Product Insert.
- Read this Product Insert completely before using the product. Follow the instructions carefully when performing the test as not doing so may result in inaccurate Test Results.
- 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.
- Laboratories using this test must hold a certificate of CLIA Waiver.
- Chembio® HIV 1/2 STAT-PAK® has not been tested on newborns or children under 13.

Intended Use:

The Chembio® HIV 1/2 STAT-PAK® assay is a single-use rapid immunochromatographic test for the qualitative detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in fingerstick whole blood, venous whole blood, serum or plasma specimens. The Chembio® HIV 1/2 STAT-PAK® assay is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for the statistical validation of rapid HIV test results.

FOR IN VITRO DIAGNOSTIC USE

- **THIS IS A RESTRICTED DEVICE.**
- **SALES, DISTRIBUTION AND USE RESTRICTIONS APPLY. SEE CUSTOMER LETTER AND PRODUCT INSERT.**

Continued on reverse...

CHEMBIO DIAGNOSTIC SYSTEMS, INC.

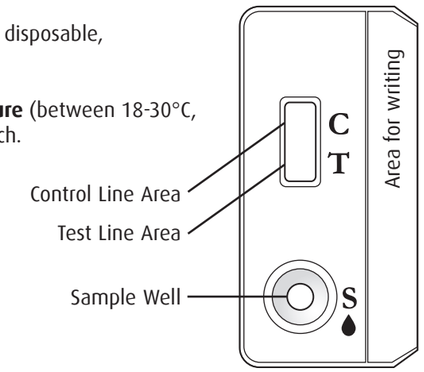
10-6073-1 Rev. 1

CHEMBIO DIAGNOSTIC SYSTEMS, INC. HIV 1/2 STAT-PAK® Test Procedure

Prior to testing, provide the "Subject Information Notice" to the person being tested.

- Gather the material you will need
- Cover your work space with a clean, disposable, absorbent workspace cover.
- Put on your disposable gloves.
- **Let the test reach room temperature** (between 18-30°C, or 64-86°F) before opening the pouch.

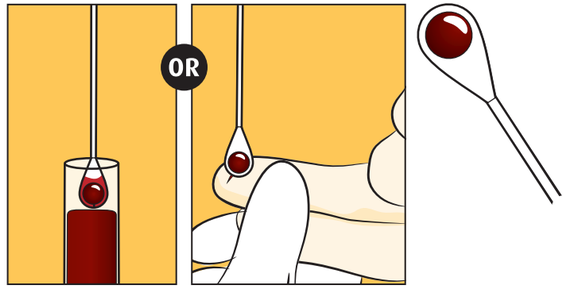
Step 1. Remove the Chembio® HIV-1/2 STAT-PAK® test device from its pouch.



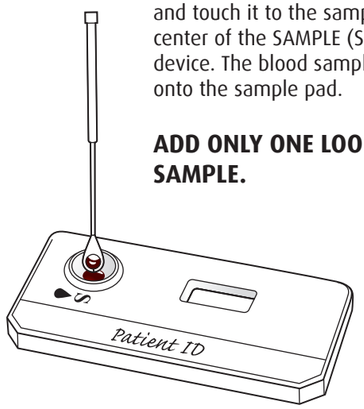
1

Step 2. Obtain a venous or fingertip blood sample according to your normal laboratory practices. After pricking the finger, wipe away the first drop and sample from the second drop.

Touch the sample loop to the drop of blood, allowing the opening of the loop to fill with blood.



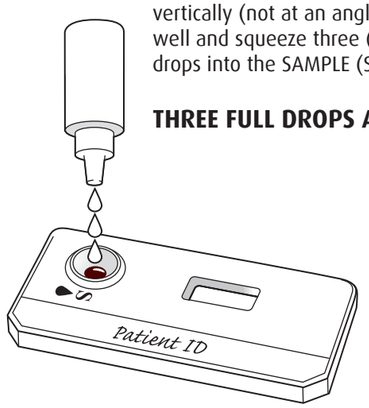
2



Step 3. Point the sample loop down and touch it to the sample pad in the center of the SAMPLE (S) well of the device. The blood sample will flow onto the sample pad.

ADD ONLY ONE LOOP FULL OF SAMPLE.

3



Step 4. Hold the Running Buffer bottle vertically (not at an angle) ABOVE the sample well and squeeze three (3) **FREE FALLING** drops into the SAMPLE (S) well.

THREE FULL DROPS ARE NEEDED.

4

Step 5. Read the test result after 15 minutes.

Do not read results after 20 minutes.

Refer to the INTERPRETATION OF RESULTS Section on the other side to determine the test results.

5

* Before testing, please refer to the complete product insert provided in the test kit.

Quick Reference Instructions*

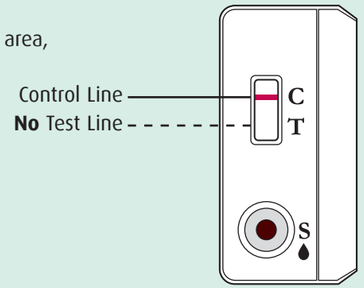
CHEMBIO DIAGNOSTIC SYSTEMS, INC. HIV 1/2 STAT-PAK® Interpretation of Results

ADEQUATE LIGHTING REQUIRED

NONREACTIVE RESULT

One pink/purple line in the CONTROL (C) area, with no line in the TEST (T) area is a **nonreactive** result.

A nonreactive result at 15 minutes means that HIV antibodies were not detected in the sample.

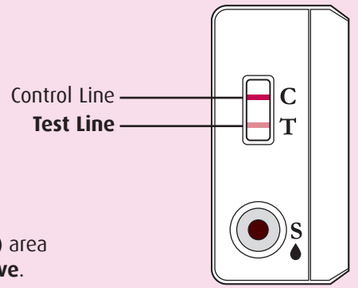


REACTIVE RESULT

Two pink/purple lines – one in the TEST (T) area and one in the CONTROL (C) area – indicate a **reactive** result.

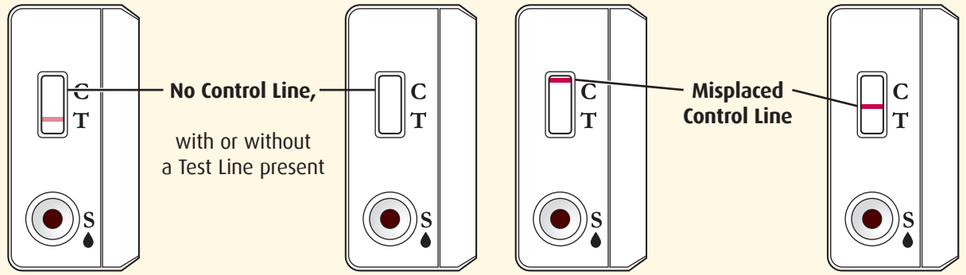
NOTE: The line in TEST (T) area may not look like the line in the CONTROL (C) area. One may be darker than the other.

If **ANY VISIBLE LINE** appears in BOTH the TEST (T) area and in the CONTROL (C) area, the result is **reactive**.



A CONTROL LINE MUST ALWAYS BE PRESENT IN THE CONTROL ZONE (C) FOR THE TEST TO BE VALID.
If there is no control line after 15 minutes, the test is invalid. This means there was a problem with the test. Repeat the test with a new device. Be sure that the sample and 3 drops of Running Buffer are added correctly.

INVALID RESULTS



For technical assistance, please contact Chembio Technical Services at (800) 327-3635

A **NONREACTIVE** Test 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.** However, this does not exclude possible infection with HIV. Follow CDC guidelines to inform the test subject of the Test Result and its interpretation.

A **REACTIVE** Test 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.** Follow CDC guidelines to inform the test subject of the Test Result and its interpretation.

An **INVALID** test result means there was a problem running the test, either related to the specimen or to the Device. **An INVALID test result cannot be interpreted.** It is recommended that the INVALID test be repeated with a new device. Contact Chembio if you are unable to get a valid test result upon repeat testing.

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The following items are needed to do the test:

Chembio® HIV 1/2 STAT-PAK® kit contains:

- 20 STAT-PAK® Individually Pouched Test Devices
- 20 Copies of Subject Information Notice
- 20 Disposable 5µL Sample Loops
- 1 HIV Running Buffer (3.5mL)
- 1 Product Insert for the Chembio® HIV 1/2 STAT-PAK® assay

Materials required but not provided:

- Clock, watch, or other timing device
- Pipettor capable of delivering 5µL of sample may be used in lieu of the disposable 5µL sample loop supplied with the Kit (for other than fingerstick whole blood specimens)
- Disposable gloves
- Sterile gauze (for fingerstick whole blood specimens)
- Antiseptic wipes
- Biohazard disposal container
- Sterile Safety Lancet (for fingerstick whole blood specimens)
- Collection devices for specimens (other than fingerstick whole blood specimens)
- Chembio® HIV Reactive/Nonreactive Controls (Catalog # 60-9549-0)

External Quality Control:

Chembio® HIV Reactive/Nonreactive Controls are available separately to use only with the Chembio® HIV 1/2 STAT-PAK® test. The Controls are used to verify your ability to perform the test and interpret the results. Refer to the Chembio® HIV Reactive/Nonreactive Controls Product Insert for complete instructions.

Run the Kit Controls under the following circumstances:

- 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 8 to 30°C (46 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 user facility.