CHEMBIO SURE CHECK® HIV 1/2

DIAGNOSTIC SYSTEMS, INC.

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 SURE CHECK® HIV 1/2 assay 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.
- The Chembio SURE CHECK® HIV 1/2 assay has not been tested on newborns or children under 13.

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

Intended Use:

The Chembio SURE CHECK® HIV 1/2 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 SURE CHECK® 1/2 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.**

Before you begin:

- Gather 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 pouch.

The following items are needed to do the test:

Contained in the Chembio SURE CHECK® HIV 1/2 kit:

- 1 Product Insert for the Chembio SURE CHECK® HIV 1/2 assay
- 25 Copies of Subject Information Notice
- 25 Disposable Test Stands
- 25 Pouches, each containing:
  1 Test Device with a Test Strip inside
  1 Buffer Cap attached to sampler (~350µL)
  1 Sterile Safety Lancet
  1 Bandage
  1 Desiccant Packet

Materials required but not provided:

- Clock, watch, or other timing device
- Pipettor capable of delivering 2.5µL of sample (for other than fingerstick whole blood or venous whole blood specimens)
- Disposable gloves
- Sterile gauze
- Antiseptic wipes
- Biohazard disposal container
- Collection devices for specimens (other than fingerstick whole blood specimens)
- Chembio® HIV Reactive/Nonreactive Controls (Order No. 60-9549-0)

External Quality Control:

Chembio HIV Reactive/Nonreactive Controls are available separately to use only with the Chembio SURE CHECK® HIV 1/2 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

Interpretation of Test Results

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 Alere if you are unable to get a valid test result upon repeat testing.

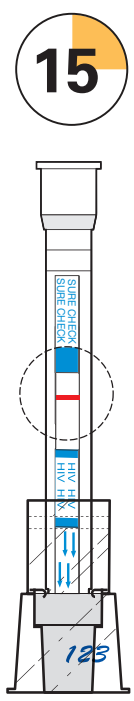
IMPORTANT PROCEDURE NOTE

When inserting the test device into the Buffer Cap, it's important that you push the tip very hard through the foil cover and into the buffer cap until it completely snaps into place. *See reverse for illustration.*

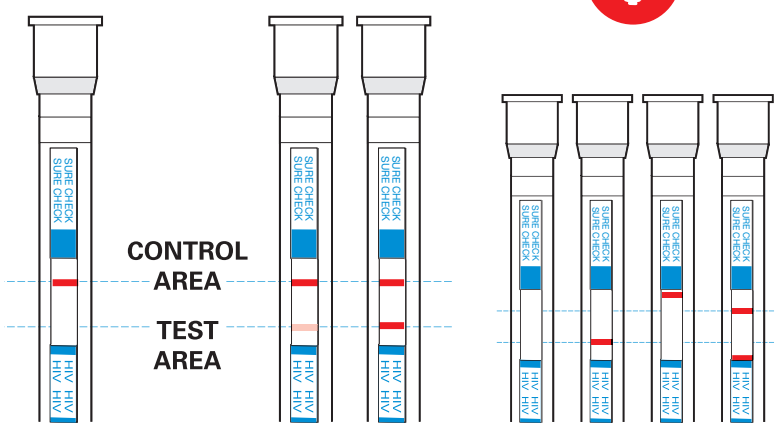
There will be 3 "snaps" when properly seated:

- Snap 1: through foil
- Snap 2: into cap
- Snap 3: seat & seal

Quick Reference – Interpretation of Results



Read result at 15 minutes. *Do not read results after 20 minutes.*



NONREACTIVE
One pink/purple line in the Control area = no HIV antibodies detected in sample.

REACTIVE
Two pink/purple lines - one in the Control area and one in the Test area of any visible color = an HIV Reactive result.

INVALID
A missing Control Line, or a Control Line or Test Line far from the target area is an Invalid result. Repeat testing.

NOTE: the line in test area may not look like the line in control area, one may be darker than other.

ADEQUATE LIGHTING REQUIRED

A test is invalid (there was a problem with the test) if:

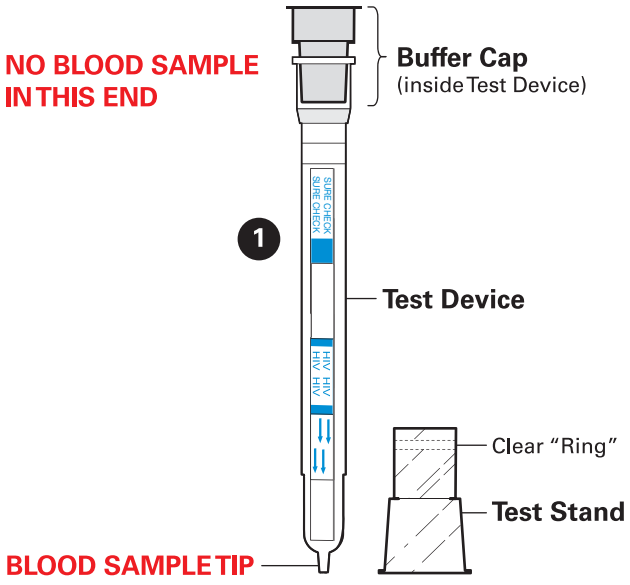
- there is no control line after 15 minutes
- the Control Line is OUTSIDE the Control Area
- the Test Line is OUTSIDE the Test Area (even if Control Line is present)

Repeat the test with a new device. Be sure that the sample is added correctly and the device is pushed all the way into the Buffer Cap.

SEE REVERSE FOR IMPORTANT PRECAUTIONS AND MORE INFORMATION

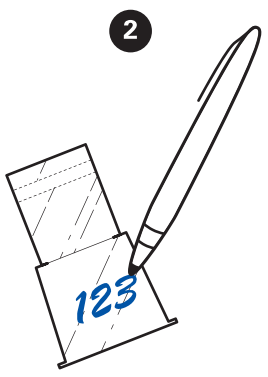
CHEMBIO DIAGNOSTIC SYSTEMS, INC. SURE CHECK® HIV 1/2

Quick Reference – Test Procedure

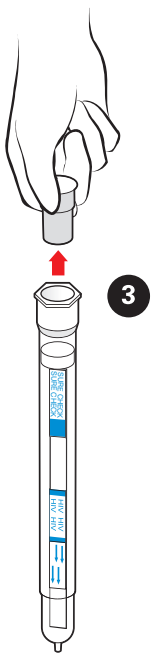


Before you begin,
remove a Chembio SURE CHECK® HIV 1/2 Test Device from its pouch and prepare your work area.

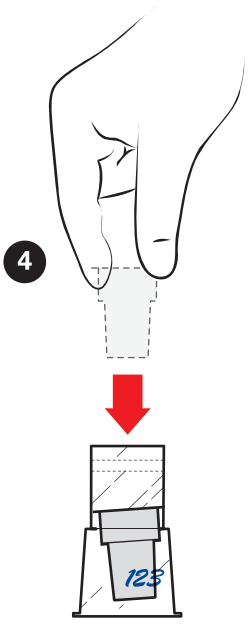
PRIOR TO TESTING, provide the "Subject Information Notice" to the person being tested



Write patient ID on a disposable **Test Stand.**



Pull the foil-covered Buffer Cap out from the top of the Test Device.



On a firm surface, drop the Buffer Cap in the Stand.

Identify these three key testing components: Buffer Cap, Test Device, and Test Stand

Collect FINGERSTICK Sample

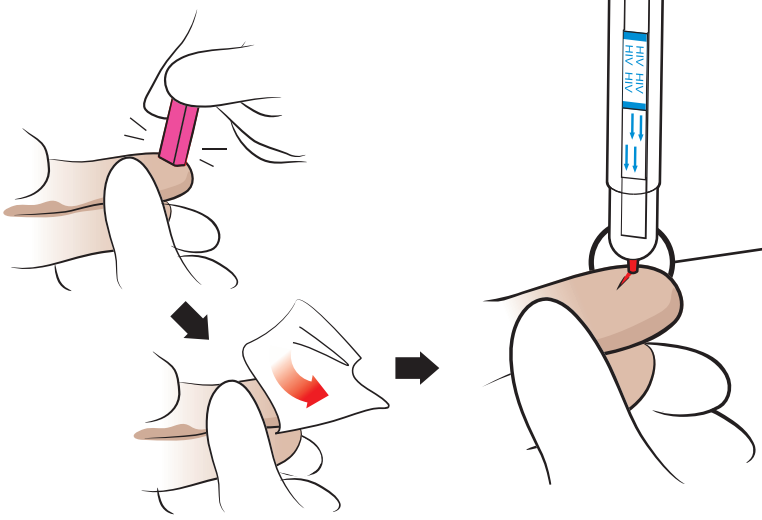
OR

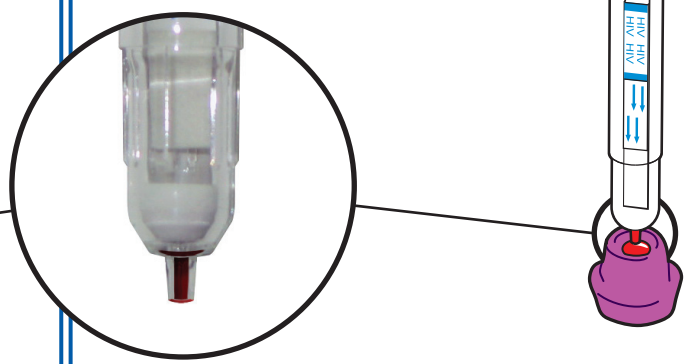
Collect VENIPUNCTURE Sample

5 FINGERSTICK SAMPLE

Draw fingerstick blood sample using the lancet provided.
Wipe away first drop of blood.

Collect second drop of blood, **filling the narrow sampling tip** of the Device as shown.





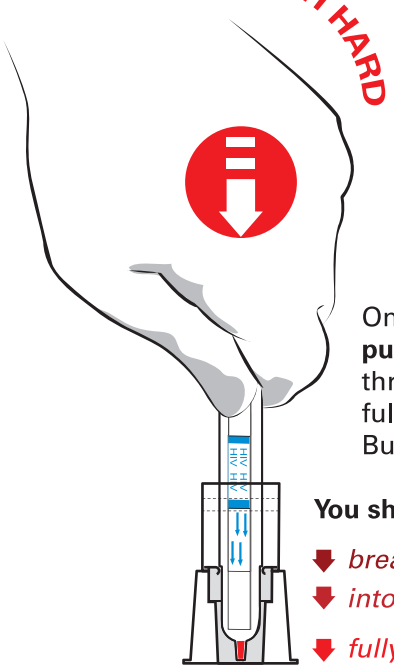
***Example:** sample tip filled with blood sample*

5 VENIPUNCTURE SAMPLE

Collect blood from the tube stopper, using the capillary action of the device to **fill the narrow sampling tip** of the Device.

Start Reaction

6 PUSH HARD



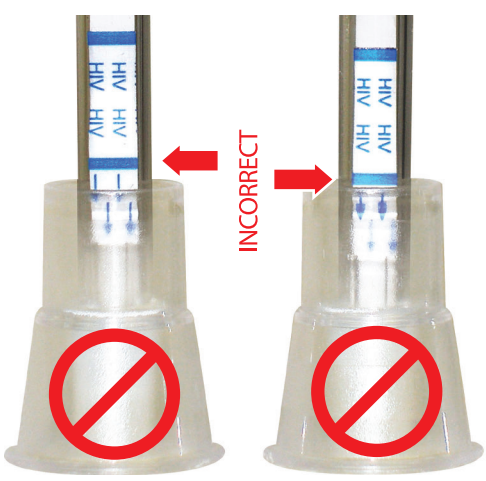
On a firm surface, **push Device HARD** through the foil until fully seated in the Buffer Cap.

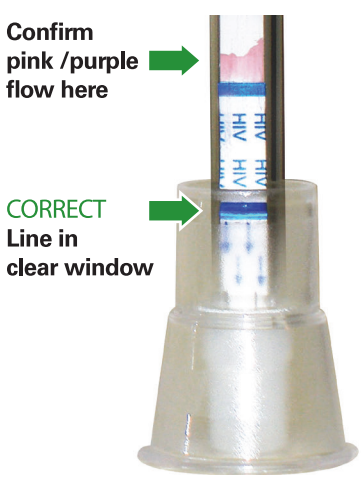
You should feel 3 "snaps:"

- *break foil*
- *into cap*
- *fully seated*

7 CONFIRM TEST DEVICE IS FULLY SEATED

There are 3 push levels, shown below. Push to the 3rd "stop." Look for the blue line in the clear window.





IF YOU DO NOT SEE PINK/PURPLE FLOW WITHIN 3 MINUTES, PUSH AGAIN!! (then start timer)

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Refer to the Package Insert for detailed test procedure information.
For technical assistance call (800) 327-3635
www.chembio.com

Lift here for Interpretation of Test results