SURE CHECK® HIV 1/2

CLIA Complexity: Waived

- These instructions are only a Reference Guide. For complete information, refer to the Chembio HIV-1/2 assay Product Insert.
- Read the Product insert completely before using the HIV-1/2 assay
- 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 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 immuno-chromatographic test for the qualitative detection of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2) in fingertip 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 Vivo Diagnostic Use
- This is a restricted device.
- Sales, distribution and use restrictions apply. See customer letter and product insert.

Before you begin:
- Gather materials 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 package.

The following items are needed to do the test:
- Packet: 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
- Pipette capable of delivering 2.5µL of sample (for other than fingertip whole blood or venous whole blood specimens)
- Disposable gloves
- Sterile gauze
- Antiseptic wipes
- Biohazard disposal container
- Collection devices for specimens (other than fingertip 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 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),
- 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 Akuse 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 a 3 “snap” when properly seated.
- Snap 1: Through foil
- Snap 2: into cap
- Snap 3: seal & seal

Quick Reference – Interpretation of Results

NOTE: The lines in test area may not look like the lines in control area, one may be darker then other.

ADDITIONAL INFORMATION REQUIRED

A test is invalid if there was a problem with the test:
- There is no control line after 15 minutes,
- The Control Line is OUTSIDE the control area,
- The Test Line is OUTSIDE the Test Area (down or 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.

MY-3553 (15-3/4 X 9 FLAT, 9 X5-1/4 FOLDED)

Color PROCESS and OVERALL AQUAEUS

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SURE CHECK® HIV 1/2

**Quick Reference - Test Procedure**

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

**BLOOD SAMPLE TIP**

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

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

**Collect FINGERSTICK Sample**

> **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.

**Collect VENIPUNCTURE Sample**

> **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**

> **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

**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)

**Lift here for interpretation of Test results**

**PROOF**

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