Trinity Biotech Quick Reference Guide for Syphilis Health Check™ Kit

CLIA Complexity: WAIVED - Fingerstick Whole Blood Specimens Only

Before beginning testing obtain a CLIA Certificate of Waiver. Failure to follow instructions including quality control will result in a high complexity rating and subject to all applicable CLIA requirements for high complexity.

- These instructions are only a reference guide. For complete information please refer to the Package Insert included with the Syphilis Health Check™ Kit.
- Read and follow the instructions including quality control carefully when performing the test. Not doing so may result in inaccurate results.
- Failure to follow the instructions or modification to the test instructions will result in the test no longer meeting the requirements for waived category.
- Before performing the test, 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.

Intended Use

Syphilis Health Check™ is a qualitative rapid membrane immunochromatographic assay for the detection of Treponema pallidum (syphilis) antibodies in human whole blood, serum or plasma. This product can be used as an initial screening test or in conjunction with a non-treponemal laboratory test and clinical findings to aid in the diagnosis of syphilis infection. This test is not intended for use in screening blood or plasma donors.

For *In Vitro* diagnostic use.

The following materials are needed to perform the test.

The Syphilis Health Check™ Kit contains:

a) 20 Test Devices (individually pouched)
b) Diluent (5.0ml)
c) 20 Disposable plastic fixed volume pipettes
1 Package Insert

Materials required but not provided:

• Test site with adequate lighting • Syphilis Health Check™ Kit Controls, catalog number VSC-11-02 • Timer or stopwatch • Biohazard disposal container • Disposable gloves • Adhesive bandages • Sterile Lancet to obtain fingerstick whole blood sample or materials required to obtain a venipuncture whole blood sample • Alcohol wipes and Sterile gauze pads

General Preparation

- All Syphilis Health Check™ Kit components should be stored at 4 - 30°C. Test cassettes should be stored in the sealed pouch. Do not freeze the test kit.
- Check expiration date. The Syphilis Health Check™ Kit is stable until the expiration date stated on the package label. – DO NOT USE PAST EXPIRATION DATE.
- Lay the device on a clean flat surface.
- Label the device with the appropriate patient information / ID.
- Use worksite with adequate lighting.

Test Procedure

Sample Selection and Addition to Device

A. Finger Stick Whole Blood for CLIA Waived samples

Sample Collection

- Using an alcohol wipe, clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad as alcohol will affect the test.
- Using a sterile lancet, capable of producing a 50µl bleed, puncture the skin just off the center of the finger pad. (See picture 1)
- Apply gentle pressure beside the point of the puncture. Wipe away the first drop of blood with a sterile gauze pad. Allow a **second** drop of blood to form. If blood flow is inadequate, the subject's finger may be gently massaged to produce two droplets of sufficient volume.

- Collect the blood into the disposable plastic fixed volume pipette provided in the kit, following the procedure presented below. (See picture 2)
- Hold the pipette bulb gently in a horizontal position to the sample being collected. **This is important, as the specimen may not be adequately drawn in the pipette if the pipette is held in a vertical position.**
- Place the tip of the pipette into the sample, taking care not to squeeze the bulb. Allow the blood to flow into the pipette on its own. Making sure that there are no airbubbles, empty spaces, or gaps in the specimen. Maintain this position until the flow of sample into the pipette has stopped. The sample should fill to the mark on the pipette. (See picture 2) If sample is not collected to the mark, or if air bubbles, empty spaces or gaps are present, the pipette should be safely discarded and another specimen should be collected from another finger by repeating the sample collection process.

Sample Addition

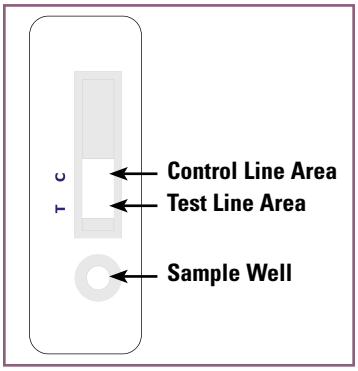
- Holding the pipette vertically, squeeze the bulb until the sample is fully dispensed in to the sample well. If the sample does not fully dispense, cover the small opening at the mark on the pipette with gloved fingers and squeeze the bulb until the sample is fully dispensed. (See picture 3) Allow the sample to absorb into the paper in the sample well. Ensure air bubbles are not introduced into the sample port. Dispose of the pipette in biohazard waste.

Run Sample

- Holding the dropper bottle of diluent in a vertical position, add 4 full drops (200 µl) in the sample well (small circle). One more drop can be added if the sample does not flow down the membrane. DO NOT USE WATER OR OTHER LIQUIDS. (See picture 4)

- Set timer for 10 minutes and set the cassette on a flat surface to incubate at RT (20 - 26ºC).
- Read the results after 10 minutes. The result can be read up to 15 minutes.
- PLEASE NOTE: Do not read after 15 minutes. (See picture 5)

Interpret Result



Read test results after 10 minutes but not after 15 minutes incubation time. If the test is not read between 10-15 minutes repeat test on new device.

Refer to the Interpretation of Results for finger stick Whole Blood Samples section on the back page.

Check if test results are valid. **For a test result to be valid, the sample well must contain full red color AND a control line must also be present. If no red color is seen in the sample well OR there is no control line present, repeat the test with fresh device.**

A positive SHC result is not diagnostic of syphilis without additional testing. A new specimen must be obtained for further testing.

Note: Handle all blood samples and materials containing blood samples as if capable of transmitting infectious agents. Dispose of all test blood samples and materials used in test procedure in a biohazard waste container.

External Quality Control

Syphilis Health Check™ Controls (product code VSC-11-02) are available separately for use only with the Syphilis Health Check™ Kit. • The Kit Controls are used to verify your ability to perform the test and interpret the test result. • The Positive Control will produce a positive test result and has been manufactured to produce a faint test line. • The Negative Control will produce a negative test result (refer to the Test Results and Interpretation Section). **Note that a red color at the sample well will not be seen if using the Syphilis Health Check™ Controls (product code VSC-11-02).**

Run the Kit Controls under the following circumstances:
Each new operator (an individual who has not run the test for at least two weeks). • Each new kit lot. • Whenever a new shipment of test kits is received. • If the temperature of the test kit storage area falls outside of 4-30°C. • If the temperature of the testing area falls outside of 20 – 26°C. • Monthly, as a continued check on storage conditions. • Whenever problems (storage, operator, or other) are identified at periodic intervals. • As specified in your Quality Assurance program.

If you have any questions regarding Syphilis Health Check™ Kit, or for more information on other Trinity Biotech products please call:

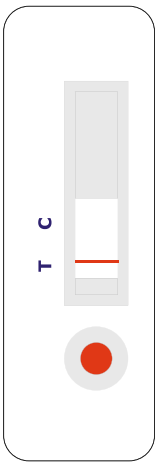
Trinity Biotech USA
Phone: 1-800-325-3424
E-mail: hiv@trinitybiotech.com or visit
www.trinitybiotech.com

If you wish to obtain information on obtaining a CLIA Certificate of Waiver, please call:
Centres for Medicare & Medicaid Services
Phone: 1-877-267-2323 or visit www.cms.hhs.gov/clia/cliaapp.asp

Interpretation for Whole Blood Sample

Invalid Results

For a test to be valid a control line must be present and the sample well must contain full red color.

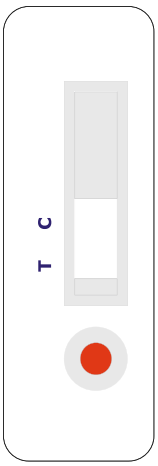


REPORT AS INVALID

- Test line present
- No control line present
- Full red color at Sample Well

No pink/red line appears in the device window adjacent to word "Control" whether or not a pink/red line appears in the device window adjacent to word "Test".

The test should be repeated with a fresh device.

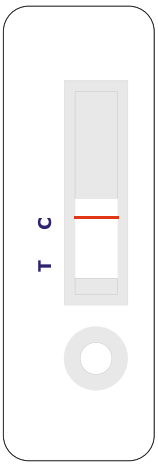


REPORT AS INVALID

- No test line present
- No control line present
- Full red color at Sample Well

No pink/red line appears in the device window adjacent to word "Control" whether or not a pink/red line appears in the device window adjacent to word "Test".

The test should be repeated with a fresh device.

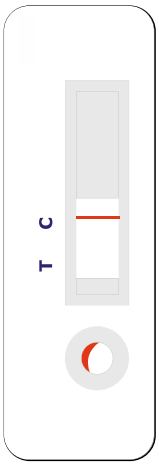


REPORT AS INVALID

- No test line present
- Control line present
- No red color at Sample Well

Red color is not seen in the Sample Well.

The test should be repeated with a fresh device.

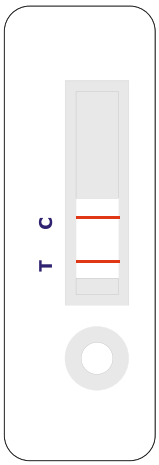


REPORT AS INVALID

- No test line present
- Control line present
- No full red color at Sample Well

Red color is not seen in full sample well. White of sample pad remains.

The test should be repeated with a fresh device.



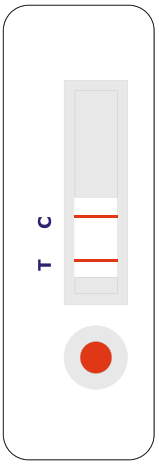
REPORT AS INVALID

- Test line present
- Control line present
- No red color at Sample Well

Red color is not seen in the Sample Well.

The test should be repeated with a fresh device.

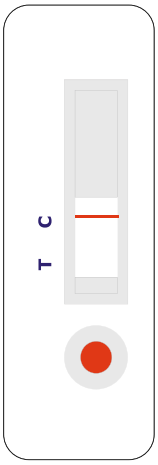
Valid Results



REPORT AS PRELIMINARY POSITIVE

- Test line present
- Control line present
- Full red color at Sample Well

Reactive Test Result
A pink/red line of **any** intensity appears in the device window adjacent to word "Test" AND a second pink/red line of any intensity appears adjacent to word "Control" AND a full red color appears in the Sample Well. This indicates a reactive result that is interpreted as a presumptive Positive for Treponema Pallidum (Syphilis) antibodies.



REPORT AS NEGATIVE

- No test line present
- Control line present
- Full red color at Sample Well

Non-Reactive Test Result
A pink/red line of **any** intensity appears in the device window adjacent to word "Control" AND a full red color appears in the Sample Well, but no pink/red line appears in the device window adjacent to "Test".

This indicates a non-reactive result that is interpreted as Negative for Treponema Pallidum (Syphilis) antibodies.

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