

inSTIcheck™ Syphilis

Rapid Treponema pallidum Test Device

Product Code: ATF-112 or 85226400105

A rapid test for the qualitative detection of antibodies to *Treponema pallidum* in serum or plasma or whole blood.



For professional in vitro test use only.

Warning: A positive result is not useful for establishing a diagnosis of syphilis. In most situations, such a result may reflect a prior treated infection; a negative result can exclude a diagnosis of syphilis except for incubating or early primary disease.

INTENDED USE

The *InSTIcheck*™ Syphilis Test Device is a rapid chromatographic immunoassay for the qualitative detection of antibody to *Treponema pallidum* in serum, plasma or whole blood.

SUMMARY

Syphilis is a sexually transmitted disease caused by the spirochete *Treponema pallidum* (TP). As this organism cannot be cultured on artificial media, the diagnosis of syphilis depends on the correlation of clinical data with the specific antibody demonstrated by serological tests. Serological screening tests for syphilis utilizing the patient's serum, plasma or whole blood and cardiolipin and lecithin as antigens are simple to perform but biological false positive (BFP) reactions occur frequently because the tests use non-treponemal antigens.

Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of syphilis. Primary syphilis is defined by the presence of a chancre at the site of inoculation. The antibodies response to the TP bacterium can be detected within 4 to 7 days after the chancre appears. The infection remains detectable until the patient receives adequate treatment.³ *InSTIcheck*™ type rapid treponema antibody tests are gaining importance as screening as well as confirmatory tests because they detect the presence of antibodies specific to *treponema pallidum*.

PRINCIPLE

The *InSTIcheck*™ Syphilis Test Device is a qualitative, membrane based immunoassay for the detection of antibody to *Treponema pallidum* in serum or plasma or whole blood. The membrane is coated with recombinant antigens on the test area of the device. When a serum or plasma or whole blood specimen is applied to the Sample Well of plastic device, it reacts with recombinant antigen coated colored particle. The mixture then migrates towards the Result Window of device and reacts with the recombinant antigens on the membrane in the test area. If the specimen contains antibodies to *Treponema pallidum*, the colored line will appear in the test area, showing a positive result. The absence of the colored line indicates that the specimen does not contain the anti-*Treponema pallidum* antibodies, showing a negative result. A colored line will always appear at the control area if the test has been performed properly.

REAGENTS

The test device contains recombinant antigen coated colored particle and recombinant antigens coated on the membrane.

PRECAUTIONS

- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as though they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protectors when specimens are assayed.
- Humidity and temperature can adversely affect results.
- To obtain accurate results, you must follow the Package Insert instructions.

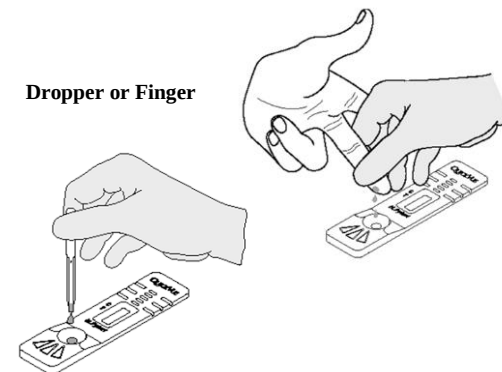
STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4°- 30° C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Do not freeze. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The *InSTIcheck*™ Syphilis Test Device can be performed using either serum or plasma or whole blood.
 - Separate the serum or plasma from blood as soon as possible to avoid hemolysis when serum or plasma is used. Only clear, non-hemolyzed specimens can be used.
 - Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. The plasma or serum may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
 - Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
 - If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.
- [Collection by vein puncture]**
- Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by vein puncture.
 - If specimens are not immediately tested, they should be refrigerated at 2 ~ 8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use. Using the specimen in the long-term keeping more than three days can cause non-specific reaction.
 - When storage at 2 ~ 8°C, the whole blood sample should be used within three days.

Dropper or Finger



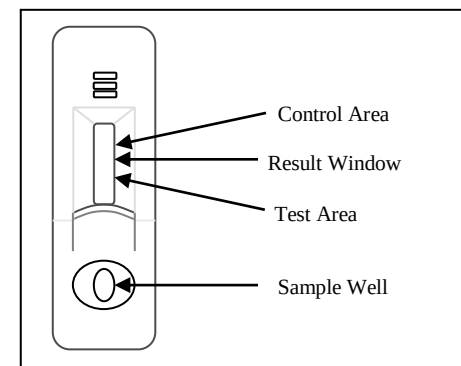
- **Finger Stick Whole Blood:** Prepare to perform the finger stick blood collection procedure. Clean the finger of the person being tested with an antiseptic wipe. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
- Using a sterile lancet, puncture the skin just off the center of the finger and wipe away the first drop with sterile gauze and avoid squeezing the fingertip to hard to accelerate bleeding as this may dilute the blood with excess tissue fluid.
- Collect the sample from the second drop touching the disposable pipette provided to the drop of blood until the narrowed tip is full. Or drop a sample directly from the fingertip as shown above. Test immediately, following Test Procedure Instructions.

PROCEDURE

Materials Provided

Individually Pouched Test Devices w/ Pipettes
1 Assay buffer bottle

DIRECTIONS FOR USE



Allow test device, assay buffer, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

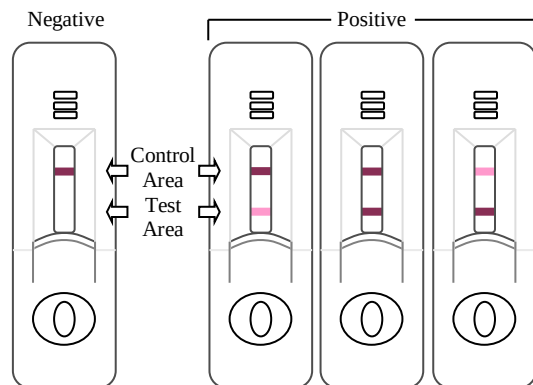
1. Remove the test device from the foil pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Add 20ul (1 drop) of serum or plasma, or 40ul (2 drops) whole blood to the sample well of the test device, then add (2) two

drops of assay buffer (small vial) to the sample well of the device and start the timer.

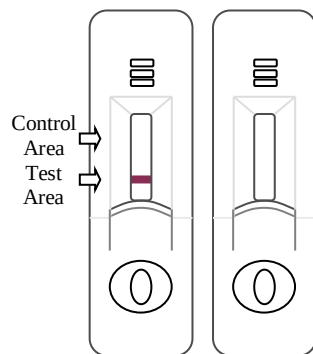
- The test result should be read at 10 minutes. **Discard Test after 30 minutes.**

IMPORTANT: Do not interpret the result after more than 30 minutes. Discard the test device after reading & recording results.

EXAMPLES OF VALID RESULTS



EXAMPLES OF INVALID RESULTS



INTERPRETATION OF RESULTS

POSITIVE: Two bands will appear in the control and test areas, which indicate a positive result for Syphilis. The lines in the TEST (T) area may look different from the line in the CONTROL (C) area. Intensities of the Test and Control Lines may vary. Test Result with visible lines in both TEST (T) and CONTROL (C) areas, regardless of intensity, is considered REACTIVE. A Reactive Test Result means that treponemal antibodies have been detected in the specimen. The Test Result is interpreted as Preliminary POSITIVE for treponemal antibodies.

NEGATIVE: One pink/purple line in the CONTROL (C) area, with no line in the TEST (T) area indicates a NONREACTIVE Test Result. A NONREACTIVE Test Result means that treponemal antibodies were not detected in the specimen. The Test Result is interpreted as

NEGATIVE for treponemal antibodies. However, this does not exclude possible infection with Syphilis.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. A pink/purple line should always appear in the CONTROL (C) area, whether or not a line appears in the TEST (T) area. If there is no distinct pink/purple line visible in the CONTROL (C) area (see diagram), then the test is INVALID. An INVALID test cannot be interpreted. It is recommended that the INVALID test be repeated with a new device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE: The intensity of the red color in the test area will vary depending on the concentration of anti-Treponema pallidum antibodies present in the specimen. However, neither the quantitative value nor the rate of increase in anti-Treponema pallidum antibodies can be determined by this qualitative test.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control area is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

LIMITATIONS

- IMPORTANT NOTE:** Antibody titers to treponemal antigens build gradually, and therefore may not be detected in early primary infection, so a negative treponemal test may not rule out syphilis. On the other hand, once a patient has had syphilis, the specific antibody can remain indefinitely. A positive result therefore may not necessarily indicate active disease, but an earlier infection.
- The *InSTIcheck*TM Syphilis Test Device is for *in vitro* use only. The test should be used for the detection of antibodies to *Treponema pallidum* in specimen.
- The *InSTIcheck*TM Syphilis Test Device will only indicate the presence of antibodies to *Treponema pallidum* in the specimen and **should not be used** as the sole criteria for the diagnosis of *Treponema pallidum* infection.
- For confirmation**, further analysis of the specimens should be performed, such as ELISA and/or western blot analysis. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional follow-up tests using other clinical methods are recommended. A negative result at any time does not preclude the possibility of *Treponema pallidum* infection.

PERFORMANCE CHARACTERISTICS

Accuracy

The *InSTIcheck*TM Syphilis Test Device has been compared with commercial EIA test using clinical specimens.

The *InSTIcheck*TM Syphilis Test Device is highly specific and sensitive for anti- *Treponema pallidum* antibodies compared to a commercial EIA test.

ELISA

	Positive	Negative	Total
Positive	112	1	113
Negative	1	225	226
Total	113	226	339

Relative Sensitivity: 99.1% Relative Specificity: 99.6%

Precision: Intra-Assay

Within-run precision has been determined by using 20 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified 100% of the time.

Precision: Inter-Assay

Between-run precision has been determined by 20 independent assays on the same three specimens: a negative, a low positive and a high positive. Three different lots of the *InSTIcheck*TM Syphilis Test Device have been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 100 of the time.

REFERENCES

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- Young H., Moyes A., Robertson D. H., Screening for treponemal infection by a new enzyme immunoassay. Genitourinary Medicine, 1989, 65:72-78
- Claire M. Fraser. Complete genome sequence of *Treponema Palladium*, the syphilis spirochete. Science (1998) vol. 281 July 375-281.
- Center for Disease Control. Recommendations for diagnosing and treating syphilis in HIV-infected patients. MMWR Morb. Mortal Wkly Rep. (1998) 37; 601

REF IVD

EC REP

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