

MD One Step Syphilis Whole Blood Test



**MEDICAL
DIAGNOSTECH**

Rapid test for the detection of antibodies of *Treponema pallidum* in whole blood

Ref: MDSYPD001, ver 211111

Summary

Syphilis is a curable infection caused by a bacterium called *Treponema pallidum* that is highly infectious. This infection is sexually transmitted, and can also be passed on from mother to fetus during pregnancy. The disease is spread primarily through sexual transmission or intimate contact with an individual who has an open, wet syphilitic sore. Syphilis has three distinct stages in an untreated person. The most severe of the STD's is caused by a pathogen called spirochete *Treponema pallidum* (*Tp*), which is shaped much like a corkscrew, so it can burrow through the skin quite well and get to almost any place in the body. This sore marks the place where the syphilis pathogen entered the skin and body. Within a few weeks, the patient develops a fever, chills, aches, headache, and swollen glands. Occasionally a rash may form. The second stage is called the latent period. This is where the spirochetes invade the bloodstream, usually six to eight weeks after the appearance of the chancre sore. There may not be any symptoms at first. At this stage, the person is no longer contagious, or able to spread the disease, but still has it. The most distinctive characteristic of the secondary stage is the appearance of the rash. If it remains untreated, it goes into the third stage of the disease, where brain damage can occur, as well as blindness, paralysis and disorientation, and damage to blood vessels, allowing clots and aneurysms to form. Due to treatment being available most people do not reach these stages. The MD One Step Syphilis Whole Blood test can quickly aid in the early diagnosis and treatment of the disease.

Principle

The MD One Step Syphilis Whole Blood Test is based on the principle of double antigen sandwich immunoassay for determination of *Tp* antibodies in whole blood. Recombinant antigens TpN 17 and TpN 47 are coated on the solid membrane. There are two coated lines in the result window. One is the test line (T), coated with recombinant antigens, the other is the control line (C), coated with polyclonal antibodies. When the specimen is added to the sample well, the specimen is absorbed into the device by capillary action, mixes with the antigen-dye conjugate, and flows across the pre-coated membrane.

When the *Tp* antibody levels in the specimen are at or above the target cut-off (the detection limit of the test), *Tp* antibodies bind to the antigen-dye conjugate and are captured by recombinant antigens immobilized in the test region (T) of the device and forms Ag-Ab-Ag-Au precipitates. This produces a coloured test band and indicates a positive result.

When the *Tp* antibody levels in the specimen are zero or below the target cut-off, there is no visible coloured band in the test region (T) of the device, and it indicates a negative result.

To serve as a procedure control, a coloured line will appear at the control region (C), if the test has been performed correctly.

Reagents and material provided in the kit

Units	Components
25	Syphilis One Step Whole Blood Test cassette
1	Instruction for use insert
25	Dropper
1	Bottle of buffer solution

Timer required but not provided

Storage conditions and shelf life

The following indications must be adhered to, in order to ensure accurate test performance:

1. Store kits at room temperature or between 4 and 30°C.
2. Store in a dry place, humidity can affect test performance.
3. The test devices must remain pouched until usage.
4. The kits will have a shelf-life of 24 months after manufacturing.
5. Verify the expiration date printed on the kits and pouches.
6. Kits should not be frozen.

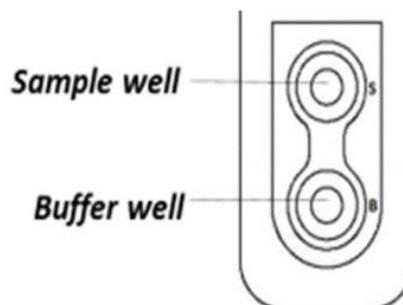
Specimen collection and preparation

1. Select the finger for puncture, usually the side of the fourth finger. Clean the area to be lanced with an alcohol pad. Allow the finger to dry thoroughly.
2. Using a sterile lancet, puncture the skin just off the centre of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of puncture. Avoid squeezing the finger to make it bleed. Wipe away the first drop of blood with an alcohol swab. Allow a new drop of blood to form. If blood flow is inadequate, the subject's finger may have to be gently massaged to produce a droplet of sufficient volume.
3. Touch the end of the capillary tube to the blood until filled to approximately 10 µl (second line). Avoid air bubbles. Whole blood samples collected should be used immediately after collection.

Test Procedure

Allow the device, buffer, and specimen to equilibrate to room temperature (10°C-30°C) prior to testing.

1. Remove a test cassette from the foil pouch by tearing the notch and place it on a level surface.
2. Slowly add 10µl (the second tick mark line) of whole blood to the sample well and then add 4 drops of dilution buffer to the buffer well.
3. As the test begins to work, you will see a purple colour move across the result window in the centre of the test device.
4. Wait for 15 minutes and read the results. **Do not read results after 30 minutes.**



Precautions and warnings

1. For in vitro diagnostic use only.
2. All tests are for single use; do not re-use.
3. Follow the test procedure exactly as shown in this insert to get the most accurate results.
4. Do not open the sealed pouch, unless ready to conduct the test.
5. Verify the expiration date, do not use expired tests.
6. Do not use the test if the pouch is damaged or the seal is broken.
7. Do not eat, drink or smoke while handling specimens and test devices.
8. Wear protective gloves and eye protection while handling specimens.
9. Respect standard procedures to dispose of specimens and potentially contaminated material, in the biohazard container
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Manufactured by:
Medical Diagnostech (Pty) Ltd.
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Interpretation of results

Positive (+)

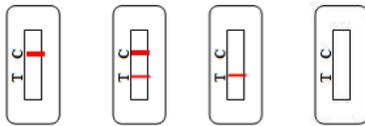
Coloured bands are visible in both the control region and the test region. It indicates a positive result for antibodies of *Tp* in the specimen.

Negative (-)

Only one colour band appears in the control region. No colour band in the test region appears. It indicates that the concentration of the *Tp* antibodies of the specimen is zero or below the detection limit of the test.

Invalid

No visible band at all or test line appears but not the control line. Repeat with a new test kit. If the test still fails, please contact the distributor or the store where you bought the product, with the lot number.



Negative Positive Invalid Invalid

References:

- 1 Braverman PK. *Adolesc Med.* 7(1): 93-98 (1996)
- 2 George R, Pope V, Fears M, Morrill B, Larsen S. *J Clin Lab Immunol.* 50(1): 27-44 (1998)
- 3 Schachter J. *Adolesc Med.* 1(3): 583-596 (1990)
- 4 Zhang S, Liu H, Wang Y, Li Q, He C. *Chinese.* 37(6): 450-453 (2002).

Symbols

IVD	For in-vitro diagnostic use only	For single use only
	Content	Expiry date
LOT	Lot number	Storage temperature

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Limitations of the test

1. This test has been developed for testing whole blood samples only. The performance of this test using other specimens has not been substantiated.
2. As it is with any diagnostic procedure, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.
3. The test is a qualitative screening assay. It is not designed to determine the quantitative concentration of syphilis antibody.

Performance Characteristics

Sensitivity and Specificity

104 serum samples were obtained for testing and then results compared between the MD One Step Syphilis Whole Blood Test kit and the TPPA method. The results of the sensitivity and specificity between the two methods are shown below:

Reagents		TPPA		Total
		Positive	Negative	
One Step Syphilis Whole Blood Test	Positive	53	1	54
	Negative	0	50	50
Total		53	51	104

Sensitivity of One Step Syphilis Whole Blood Test: $53/53 = 100\%$
Specificity of One Step Syphilis Whole Blood Test: $50/51 = 98\%$

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