POCT SYPHILIS CARD (WB)

(Whole Blood/Serum/Plasma)

IMMUNOPAK

Last update 02-2026

Ref. POCT-SYC.108W, 50 Test

INTENDED USE

CARD test for detection of Syphilis in human Whole blood, serum or plasma.

INTRODUCTION

Ultra-sensitive One Step Anti-Syphilis Cassette Test is a rapid and immunochromatographic procedure for the qualitative detection of *Treponemal antibodies* (IgA, IgM, IgG) generated against *Treponema pallidum* antigens (17KDa, 15KDa, 47KDa) in human whole blood /serum or plasma with high sensitivity and specificity. Test results are read visually without any instrument. Purified recombinant syphilis antigens are employed to identify anti-Syphilis antibodies specifically and it also used in detection of congenital syphilis.

PRINCIPLE

Syphilis Rapid Test Device is a qualitative membrane based immunoassay for the detection of TP antibodies (IgA, IgM, IgG) in whole blood / serum or plasma. In this procedure, recombinant syphilis antigen (17KDa, 15KDa, 47KDa) is immobilized in the test line region of the device. After the specimen is added to the specimen well of the device, it reacts with syphilis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized Syphilis antigen. The double antigen test format can detect IgA, IgG and IgM in specimens. If the specimen contains TP antibodies a pink-purple line will appear in the test line region, indicating a positive result. If the specimen does not contain TP antibodies, a pink-purple line will not appear in the test region, indicating a negative result. To serve as a procedural control, an additional line of Goat anti-mouse IgG has been immobilized on the card. If the test is performed correctly, this will result in the formation of pink-purple line upon contact with the conjugate as a control line.

PRESENTATION

	50 Test
Syphilis Test Card	50 Cards
Assay Buffer	1 Bottle
Sample Dropper	50 Droppers
Sterile Lancet	50 Nos.
Alcohol Pad	50 Nos.

PRECAUTION

- For in vitro diagnostic use only.
- Do not use test kit beyond expiry date.
- The test device should not be reused.
- Keep out of the reach of children.
- Do not freeze the Kits.
- Specimen with extremely high concentrations of red blood cells, fibrin should be re-centrifuged before use.

STORAGE AND STABILITY

Syphilis test card should be stored at 2°C-40°C. The card may be stored at room temperature but not exceeding 40°C in the original sealed pouch. The shelf life or expiry of the card is printed on the pouch as well as on the carton label. The test kit should be kept away from direct sunlight, moisture and heat

SPECIMEN COLLECTION & STORAGE

• Whole blood as Specimen

Fresh blood from finger prick/puncture may be used as a test specimen for collection of whole blood as a test specimen; EDTA, heparin or oxalate can be used as a suitable anticoagulant.The specimen should be collected in a clean glass or plastic container, if immediate testing is not possible, then the specimen may be stored at 2°C-8°C for upto 72 hours before testing. Do not use hemolysed clotted or contaminated blood samples for performing the test.

• Serum / plasma as Specimen

For Serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing.

If the specimen is not tested on the day of collection, store the serum specimen in a refrigerator or freezer. Stir and bring the specimens to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

TEST PROCEDURE

1. Bring the specimen and pouch containing the SYPHILIS CARD to room temperature prior to testing.
2. Remove one test card from the pouch and place it on a clean flat surface.

WHOLE BLOOD AS SPECIMEN:

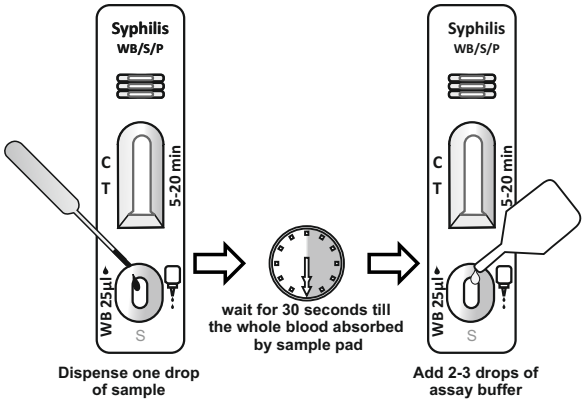
3. With the help of the dropper provided dispense one drop (Approx. 25µl) of anticoagulated or finger prick blood to the sample well, **Wait for few seconds till the Whole blood absorbed by sample pad (Approx. 30 second)**, alternatively 25 µl of whole blood specimen may be delivered in the sample well using a micropipette.(see the figure)
4. Add 2 to 3 drops (60-90 µl) of assay buffer (Diluent) into the sample well of the test device. **(If needed add one more drop of assay buffer).**

SERUM/PLASMA AS SPECIMEN

5. Using the dropper provided, put 2 to 3 drops of serum sample into the sample well. Avoid overflowing.
6. Let the reaction to proceed until the appearance of positive line and control line or upto 20 minutes.
7. Read results within 20 minutes. Strong positive reaction may visible within 5 minutes.

IMPORTANT NOTE

Do not read results after 30 minutes since serum back flow may cause false results.



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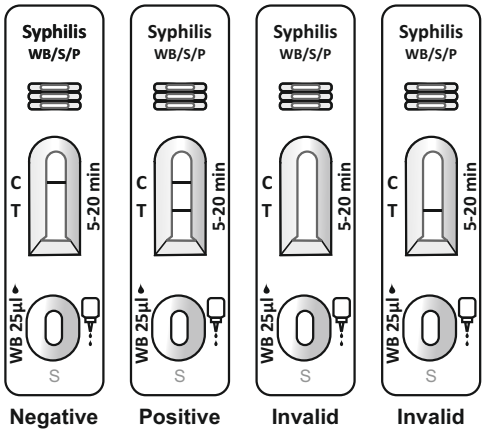
INTERPRETATION OF RESULTS



1. **Negative:** Only one pink-purple line appears on the contro (C) region. No apparent line on the test (T) region .
2. **Positive:** In addition to a pink-purple control (C) line, distinct pink-purple line will also appear in the test (T) region
3. **Invalid:** A total absence of pink-purple line in both regions o no pink-purple line appears on the control (C) region is a indication of procedure error and / or the test reagen deterioration. Repeat the test with a new kit .

SENSITIVITY & SPECIFICITY

To establish the sensitivity and specificity of One-step Syphilis test kit relative to other rates of qualitative whole blood / serum or Plasma Syphilis tests, 305 clinic samples were studied. Another commercially available Qualitative test kit was used to compare with Reckon Diagnostic One-step Syphilis test kit for relative sensitivity and specificity in 305 serum samples. Only 1 sample was discordant, the agreement is 99.67%.

PERFORMANCE CHARACTERISTIC

Syphilis rapid Immunochromatographic test kit from Reckon Diagnostics have been evaluated against an FDA approved RPR and EIA test.

To establish the sensitivity and specificity of Reckon Diagnostic Syphilis test kit, 752 clinic samples were studied. Serum samples were obtained from various sources with their results. Most of the samples were obtained from blood donor institution.
The Details of Data are as under:

A) Clinical Specificity & Sensitivity

Reference		Performance		Reckon Syphilis card Test		Total
Method	Results	Sensitivity	Specificity	Positive	Negative	
FDA approved ELISA	Syphilis Positive	100 %	0 %	150	-	150
Negative Samples	Syphilis Negative	0 %	100 %	-	602	602
Total Samples		100 %	100 %	150	602	752

B) Cross reactivity study

Reckon Syphilis strip test is tested with other diseases/condition which may give cross reactivity with test. The results are mentioned in 9o9wing table and demonstrated that Syphilis strip test showed no cross reactivity with the other diseases samples.

Sample Details	Sample size	Syphilis Reactivity
HIV-1 Positive serum	10	Negative
HIV-2 Positive serum	10	Negative
HBsAg Positive Serum	10	Negative
HCV Positive Serum	10	Negative

C) Precision

a) Within-run precision was determined by using ten replicates of four different specimens. Within-run precision was observed as 100%.

b) Between operator and sites precision was determined by using six replicates of ten different specimens at two different sites and by two different operators. The test showed 100% precision at both sites with both operators.

c) Between-run precision was determined by using four different specimens in three different replicates with three different lots of test devices. Between-run precision was observed as 100%.

LIMITATIONS

1. As with all diagnostic tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. This test kit is for the detection of TP antibodies in whole blood / serum or plasma specimen. This test is for in-vitro diagnostic use only. Neither the quantitative value nor the rate of increase in TP antibodies can be determined by this qualitative test.
3. This kit will only indicate the presence of TP antibodies in the specimen and should not be used as the sole criteria for the diagnosis of TP infection.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of TP infection.
5. Positive result should be confirmed by other confirmatory tests.

REFERENCES

1. Clair FM. Complete genome sequence of Treponema pallidum, the syphilis spirochete, Science 1998; 281 July 375-381.
2. Center for Disease Control. Recommendations for diagnosis and treating Syphilis in HIV - infected patients, MMWR Morb. Mortal Wkly Rep. 1998; 37:601.

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