SYPHILIS CARD

IMMUNOPAK

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INTENDED USE:
CARD test for detection of Syphilis in 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 serum/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 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 colored line will appear in the test line region, indicating a positive result. If the specimen does not contain TP antibodies, a colored line will not appear in the region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

PRESENTATION:

	50 TEST	**100 TESTS**
Disposable test cards	50 Cards	100 Cards

The Shelf life or expiry of the card is printed on the pouch.

PRECAUTION:
1) For in vitro diagnostic use only.
2) Do not use test kit beyond expiry date.
3) The test device should not be reused.
4) Keep out of the reach of children.
5) Do not freeze the Kits.
6) Specimen with extremely high concentrations of red blood cells, fibrin should be recentrifuged before use.

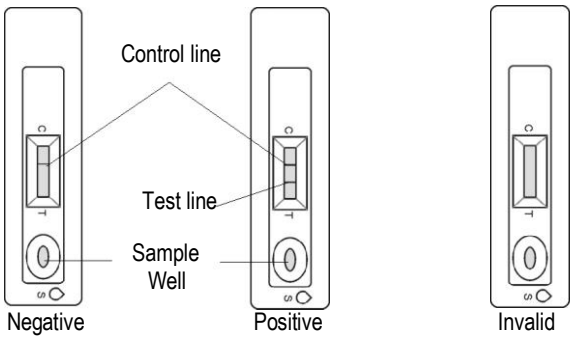
STORAGE AND STABILITY:
The test kit can be stored at temperatures between 4 to 30ºC in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION & PREPARATION:
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 cannot be 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. Remove the test device from its protective pouch (bring the device to room temperature before opening of the pouch to avoid condensation of moisture on the membrane). Label the device with patient or control identifications and use the device as soon as possible.
2. Using the dropper provided put 2-3 (Approx. 30µl) drops of serum sample into the sample well. Avoid overflowing.
3. Wait for 5 to 20 minutes and read results. It is important that the background is clear before the result is read.

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

INTERPRETATION OF RESULTS:



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

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 serum specimen. This test is for in vitro diagnostic use only. Neither the quantitative value not 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.

SENSITIVITY & SPECIFICITY:
To establish the sensitivity and specificity of One-step Syphilis test kit relative to other rates of qualitative serum 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%.

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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3/7, B.I.D.C., Gorwa, Vadodara 390 016 (INDIA)
Web: www.reckondiagnostics.com
Phone: +91·265·2281631
Email: mail@reckondiagnostics.com

RECKON DIAGNOSTICS P. LTD.