The Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Treponema Pallidum (TP) in whole blood, serum or plasma to aid in the diagnosis of Syphilis.

**PRECAUTIONS**

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimen is being handled.
- Do not re-use if package is damaged.
- Do not interpret the result after 20 minutes.

**INTENDED USE**

The Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Treponema Pallidum (TP) in whole blood, serum or plasma to aid in the diagnosis of Syphilis.

**SUMMARY**

Treponema Pallidum (TP) is the causative agent of the venereal disease Syphilis. TP is a spirochete bacterium with an outer envelope and a cytoplasmic membrane. It is widely known that the organism is transmitted to human through sexual contact. According to the Center for Disease Control (CDC), the number of cases of Syphilis infection has markedly increased since 1985. Some key factors that have contributed to this increase are the more frequent use of antibiotics and the high incidence of drug resistance among drug users.1 One study reported a substantial epidemiological correlation between the occurrence of syphilis acquisition and transmission of the HIV virus and Syphilis.2 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 incubation period ranges from 10 to 90 days after infection. The chancre is seen in approximately 80-90% of invasive cases. It usually appears at the inoculation site and lasts for about 3 weeks. The chancre often goes unrecognized and is often overlooked by the patient.3,4 The infection remains detectable until the patient receives adequate treatment.5 If the specimen contains TP antibodies, a colored line will appear in the test result. The Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) utilizes a double antigen combination of a Syphilis antigen coated particle and Syphilis antigen immobilized on membrane to detect TP antibodies (IgG and IgM) qualitatively and selectively in whole blood, serum or plasma.

**PRINCIPLE**

The Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunochromatographic test for the detection of TP antibodies (IgG and IgM) in whole blood, serum or plasma. The test procedure consists of two main steps. In the first step, recombinant Syphilis antigen is immobilized on the test line region of the test. After specimen is added to the specimen well of the cassette, it reacts with Syphilis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized Syphilis antigen. The double antigen test format can detect both IgG and IgM in specimens. If the specimen contains TP antibodies, a colored line will appear in the test result, indicating a positive result. If the specimen does not contain TP antibodies, a colored line will not appear in this 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.

**REAGENTS**

- Whole Blood
- Serum or plasma

**PACKAGING CONTENTS**

- Cassette
- Buffer
- Droppers
- Package insert

**SPECIAL INSTRUCTIONS**

1. Wash the hand with soap and warm water or with an alcohol swab. Allow to dry.
2. Place the test, specimen and buffer to reach room temperature (15-30°C) prior to testing.
3. Avoid touching the finger directly to the specimen area.
4. Touch the end of the capillary tube: Fill the capillary tube approximately to the mark on the test area. Remove the test cassette from the sealed package and twist off the vial cap. Do not interpret the result after 20 minutes.

**INTERPRETATION OF RESULTS**

- Positive: Two lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T).

**EXPECTED VALUES**

The Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial TPPA Syphilis test using clinical specimens. There are no significant differences in the results of the Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) compared with the reference results. The results show that the sensitivity and specificity of the Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) is 99.9% and the relative specificity is 99.7%.

**STORAGE AND STABILITY**

- Store in the sealed package either at room temperature or refrigerated (2-30°C).

**BIBLIOGRAPHY**

3. Aral R. Assay performance panel and relative sensitivity and specificity of Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested over a 3-year period using negative, low positive, moderate positive and high positive specimens. The results were correctly identified >99% of the time.