Rapid Response™

Syphilis Treponema pallidum Test Cassette
(Serum/Plasma)

REF SYP-12C40 Product Insert

For professional *in vitro* diagnostic use only.

Intended Use

The Rapid Response™ Syphilis Treponema pallidum Test Cassette is a rapid visual immunoassay for the qualitative, presumptive detection of IgM and IgG antibodies to *Treponema Pallidum (TP)* in human serum or plasma specimens. This kit is intended for use as an aid in the diagnosis of syphilis.

Introduction

Treponema Pallidum (TP), a spirochete bacterium with an outer envelope and a cytoplasmic membrane, is the causative agent of the venereal disease syphilis. Although syphilis rates are declining in the United States after an epidemic between 1986 and 1990, the incidence of syphilis in Europe has increased since 1992, especially in the countries of the Russia Federation, where peaks of 263 cases per 100,000 have been reported. In addition, the positive rate of serological test results for syphilis in HIV-infected individuals has been rising recently.

The serological detection of specific antibodies to TP has been long recognized in the diagnosis of syphilis since the natural course of the infection is characterized by periods without clinical manifestations. The antibody response to TP can be detected within 4 to 7 days after the syphilis chancre appears, allowing early detection and diagnosis of syphilis infection.

A variety of antigens have been used in syphilis serological tests, such as Rapid Plasma Cardiolipin (RPR) or VDRL antigen, TP extracts derived from *in vitro* culture or inoculated rabbit testes. However, RPR and VDRL antigens are not treponemal specific, and whole TP extracts are not reproducible and contain a certain amount of contaminating materials such as flagella, which may lead to a nonspecific reaction in assays of test serum.

Principle

The Rapid Response™ Syphilis Treponema pallidum Test Cassette detects IgM and IgG antibodies to *Treponema Pallidum (TP)* through visual interpretation of color development on the internal strip. Specific recombinant TP antigens are immobilized on the test region of the membrane. During testing, the specimen reacts with recombinant TP-specific antigen conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there are sufficient antibodies to *Treponema Pallidum (TP)* in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Precautions

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

Materials

Materials provided

- Individually packed test devices
- Disposable pipettes
- Product insert

Materials required but not provided

- Specimen collection container
- Centrifuge
- Timer

Storage and Stability

- The kit should be stored at 35.6-86°F (2-30°C) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

Collection and Storage of Specimens

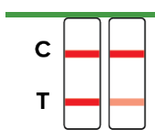
- The Rapid Response™ Syphilis Treponema pallidum Test Cassette is intended for use with human serum or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 35.6-46.4°F (2-8°C) for up to 3 days. For long term storage, specimens should be kept below -4°F (-20°C).
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

Test Procedure

Bring tests, specimens, buffer and/or controls to room temperature (59-86°F; 15-30°C) before use.

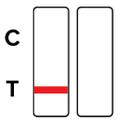
1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
2. Using the provided disposable pipette, transfer 3 drops of specimen (approximately 75 µL) to the specimen well (S) of the device, then start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   As the test begins to work, color will migrate across the membrane.
3. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

Results Interpretation



POSITIVE: Two colored lines appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored line appears in the control region (C). No apparent colored band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

Quality Control

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations

1. The Rapid Response™ Syphilis Treponema pallidum Test Cassette is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of TP antibodies. No meaning should be inferred from the color intensity or width of any apparent bands.
2. The Rapid Response™ Syphilis Treponema pallidum Test Cassette 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.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at anytime rule out the existence of TP antibodies in blood, as antibodies

may be present below the minimum detection level of the test.

4. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Performance Characteristics

Table: Syphilis Rapid Test vs. TPHA

Relative Sensitivity: 99.6% (97.8%-99.9%)*
Relative Specificity: 99.1% (97.5%-99.8%)*
Overall Agreement: 99.3% (98.3%-99.8%)*
*95% Confidence Interval

		Rapid Response™ Syphilis Treponema pallidum Test Cassette		
		+	-	**Total**
TPHA	+	246	1	247
	-	3	343	346
		249	344	593

Bibliography

1. Centers for Disease Control (CDC). Chlamydia trachomatis infections. Policy guidelines for prevention and control. MMWR Morb Mortal Wkly Rep. 1985 Aug 23; 34 Suppl 3: 53S-74S.
2. Tichonova L, Borisenko K, Ward H, Meheus A, Gromyko A, Renton A. Epidemics of syphilis in the Russian Federation: trends, origins, and priorities for control. Lancet. 1997 Jul 19; 350(9072): 210-3.
3. Norgard MV, Chamberlain NR, Swancutt MA, Goldberg MS. Cloning and expression of the major 47-kilodalton surface immunogen of Treponema pallidum in Escherichia coli. Infect Immun. 1986 Nov; 54(2): 500-6.

Glossary of Symbols

Consult instructions for use
Test per Kit
EC REP Authorized Representative
Store between 35.6°F to 86°F
Use by
Do Not Reuse
LOT Lot Number
IVD For *in vitro* diagnostic use only
REF Catalogue #

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