

Treponema Pallidum cassette



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For professional <i>in vitro</i> diagnostic use only		

TREPONEMA PALLIDUM

A rapid test for the qualitative, presumptive detection of IgM and IgG antibodies to *Treponema Pallidum* (TP) in human serum or plasma

ONE STEP

PRINCIPLE

The LINEAR Treponema Pallidum 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.

REAGENT COMPOSITION

Syphilis test device, contains protein A coated particles and syphilis antigen coated on the membrane.

INTERPRETATION OF RESULTS

REF 4275240 40 Syphilis test device
40 Disposable specimen droppers

STORAGE AND STABILITY

Store at 2-30°C.

The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The LINEAR Treponema Pallidum 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 2-8°C for up to 3 days. For long term storage, specimens should be kept below -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, hemolyzed, heat treated and contaminated specimens may cause erroneous results.

MATERIAL REQUIRED

- Timer.
- Specimen collection container.
- Centrifuge (for plasma only)

PROCEDURE

Allow test device, buffer, serum or plasma specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

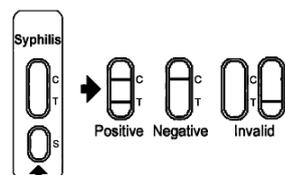
- Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
- Using the provided disposable pipette, transfer 3 drops of specimen (approximately 75 µL) to the 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.

- Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS



POSITIVE: Two colored bands 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 band 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:

- 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.
- 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.

CLINICAL SIGNIFICANCE

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 Cardioliipin (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.

ANALYTICAL PERFORMANCE

Table: *Treponema Pallidum* cassette vs. TPHA

		Syphilis Rapid Test		Total
		+	-	
TPHA	+	246	1	247
	-	3	343	346
		249	344	593

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**

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use 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.

LIMITATIONS OF THE TEST

1. The LINEAR *Treponema Pallidum* 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 LINEAR *Treponema Pallidum* 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 any time 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.

REFERENCES

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