SYPHILIS DEVICE (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADSYP1	20 Tests

Intended Use:
The Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative, presumptive detection of IgM and IgG antibodies to *Treponema pallidum (TP)* in human whole blood, serum or plasma specimens. This kit is intended for use as an aid in the diagnosis of syphilis.

Summary:

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.

Test Principle:
The Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) detects IgM and IgG antibodies to *Treponema pallidum (TP)* through visual interpretation of colour development on the device test region. During testing, the specimen reacts with recombinant TP-specific antigen conjugated to particles which are pre-coated onto the sample pad of the device. The mixture then migrates through the membrane by capillary action and reacts with specific recombinant TP antigen immobilized on the test region of the membrane. If there are sufficient antibodies to *Treponema pallidum* in the specimen, a coloured band will form at the test region of the membrane. The presence of this coloured band indicates a positive result, while its absence indicates a negative result. The appearance of a coloured 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.

Materials Provided
Individually pouched test devices
Disposable pipettes
Buffer
Instructions For Use sheet

Materials not provided: Timer, specimen collection container, centrifuge

Precautions:

- For professional *in vitro* diagnostic use only.
- Do not use after the expiry 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.

Reagent Preparation and Stability:

- The kit should be stored at 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 equipment, containers or reagents can lead to false results.

Specimen Collection and Storage:

- The Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) is intended for use with human whole blood, serum or plasma specimens only.
- Only clear, non-haemolyzed samples are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid haemolysis.
- Perform testing immediately after specimen collection. Do not leave samples 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, samples should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood samples. Whole blood collected by fingerstick should be tested immediately.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If samples are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, haemolysed, heat treated and contaminated samples may cause erroneous results.

Assay Procedure:

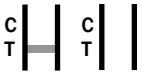
Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

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 1 drop of serum or plasma (approximately 40 µL) to the specimen well (S) of the device, then add 1 drop of buffer (approximately 40 µL) and start the timer.
   OR
   Transfer 2 drops of venepuncture whole blood specimen (approximately 80 µL) to the specimen well (S) of the device with the provided disposable pipette, then add 1 drop of buffer (approximately 40 µL) and start the timer.
   OR
   Allow 2 hanging drops (approximately 80 µL) of fingerstick whole blood specimen to fall into the centre of the specimen well (S) on the device, then add 1 drop of buffer (approximately 40 µL) and 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, you will see colour move across the membrane.
3. Wait for the coloured band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 20 minutes.

Interpretation of Results:

POSITIVE: Two coloured 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 coloured band appears, in the control region (C). No apparent coloured 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 colour in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of colour 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 Controls:

- Internal procedural controls are included in the test. A coloured 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 of the Test:

1. The Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) 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 colour intensity or width of any apparent bands.
2. The Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) 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.

Performance Characteristics

Sensitivity and Specificity

Method		TPPA		Total Results
Syphilis Rapid Test Device	Results	Positive	Negative	
	Positive	200	1	201
	Negative	0	319	319
Total Results		200	320	520

Sensitivity: >99.9% (95% CI*:99.4% - 100%)
Specificity: 99.7% (95% CI*:98.3% - 100%)
Accuracy: 99.8% (95% CI*:98.9% - 100%) *Confidence Intervals

Precision
Intra-Assay
Intra-Assay Precision has been determined by running 10 replicates of four samples: a negative, and a low, a medium and a high positive in a single testing period. The negative, low, medium and high positive samples were correctly identified > 99% of the time.

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Inter-Assay

Inter-Assay Precision has been determined by running 10 separate assays on four samples a negative, and a low, a medium and a high positive. Three different lots of the Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) were tested. The negative, low, medium and high positive samples were correctly identified > 99% of the time.

Cross reactivity

The Syphilis Rapid Test Device has been tested using HBsAg, HBsAb, HbeAg, HBeAb, HBcAb, HCV, HIV, HAMA, RF, H.pylori, CMV, Rubella and Toxo positive samples. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to Syphilis negative and positive specimens:

Acetaminophen	20 mg/dl	Acetylsalicylic Acid	20 mg/dl
Ascorbic Acid	2 g/dl	Bilirubin	1g/dl
Caffeine	20 mg/dl	Gentisic Acid	20 mg/dl
Albumin	2 g/dl	Creatinine	200 mg/dl
Oxalic Acid	600 mg/dl	Haemoglobin	1.1 mg/dl

None of the substances at the concentration tested interfered in the assay.

References:

1. Fraser CM. Complete genome sequence of *Treponema pallidum* the Syphilis spirochete. Science, 1998; 281: 375-381.
2. Centre for Disease Control (CDC). Recommendations for diagnosing and treating Syphilis in HIV infected patients. MMWR Morb Mortal Wkly Rep, 1988; 37: 601.
3. Marx AR. Crack, sex and STD. Sexually Transmitted Diseases, 1991; 18: 92-101.
4. Johnson PC. Testing for Syphilis. Dermatological Clinic, 1994: 12: 9-17.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

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