SYPHILIS TEST STRIP (2–30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADSYP2	50 Tests

Intended Use:
The Syphilis Test Strip is a rapid chromatographic immunoassay for the qualitative detection of IgM and IgG antibodies to *Treponema pallidum* (TP) in human whole blood, serum and plasma samples 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. Relatively little is known about the organism in comparison with other bacterial pathogens. According to the Centre for Disease Control (CDC), the number of cases of Syphilis infection has markedly increased since 1985. Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drug users. One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis.
Syphilis is characterised by numerous clinical stages and long periods of latent, asymptomatic infection. Primary Syphilis is defined by the presence of a chancre at the site of inoculation. An antibody response to the TP bacterium can be detected within 4 to 7 days after the chancre appears. The infection remains detectable until the patient receives adequate treatment.

Test Principle:
The test principle of the Syphilis Test Strip assay is a double antigen immunoassay. In the test recombinant Syphilis antigen is applied to the test line of the strip and recombinant Syphilis antigen-conjugated particles are coated near the sample well. The strip is immersed in the sample and the latter begins to migrate where it reacts with the antigen coated particles. Any antibodies to TP will bind to the antigen forming immunocomplexes. The reaction mixture moves chromatographically along the strip and interacts with the Syphilis antigen at the test line. The double antigen test format detects both IgG and IgM in samples. If the sample contains TP antibodies, a coloured band will appear at the test line indicating a positive result. If the sample does not contain TP antibodies, no colour will develop at the test line indicating a negative result. To serve as a procedural control, a coloured line should always appear at the Control line indicating that proper volume of sample has been added and membrane wicking has occurred.

Reagents
The test contains Syphilis antigen coated particles and Syphilis antigen coated on the membrane.

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

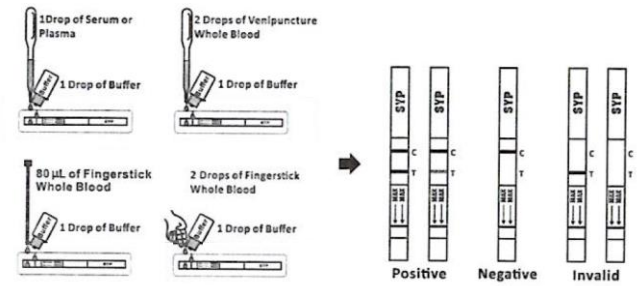
Materials not provided: Timer, sample collection container, centrifuge, lancet, heparinized capillary tubes and dispensing bulb.

Precautions:
For professional *in vitro* diagnostic use only. Do not use after expiry date.
Handle all samples as if potentially infectious and follow local regulations for disposal of samples.
Wear protective clothing including laboratory coat, disposable gloves and safety glasses when conducting the test.
Humidity and temperature can adversely affect results.

Storage and Stability:
Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable until the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze devices. Do not use after the expiry date. The buffer is stable for 6 months after opening.

Sample Collection and Preparation:
The Syphilis Test Strip is intended for use with human whole blood, serum and plasma samples.
To collect finger prick whole blood samples: Clean the finger tip with an alcohol swab. Allow to dry. Massage the hand without touching the puncture site from the hand to the fingertip. Puncture the skin with a sterile lancet and wipe away the first sign of blood. Squeeze the finger to form a rounded drop of blood at the puncture site.
Using a capillary tube: Touch the end of a capillary tube to the blood until filled to approximately 80 µl. Avoid air bubbles. Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the sample area of the test strip.
By falling drops: Position the subject's finger so that the puncture site is just above the strip sample area. Massage and squeeze the finger until 2 drops of whole blood fall onto the sample area.
Whole blood samples collected by finger prick must be used immediately. Whole blood samples collected by venepuncture can be used in the test up to 48 hours if stored at 2 – 8°C. Do not freeze whole blood samples.
Collect serum and plasma samples by separation of blood after standard venepuncture technique. Separate serum or plasma from red blood cells as soon as possible to avoid haemolysis. Only use clear non-haemolysed samples.
Serum and plasma samples can be used in the test up for to up to 3 days when stored at 2 - 8°C or for longer term storage freeze at -20oC or below.
Before testing equilibrate samples completely to room temperature. Frozen samples must be fully thawed and mixed well prior to testing. Avoid repeated freeze-thaw cycles.
If samples are to be transported, pack them in compliance with all applicable regulations for transportation of etiological agents

Assay Procedure:
1. Bring the device, samples and controls fully to room temperature (15 - 300C) before starting any testing. Remove the test device from the sealed pouch, place it on a clean and level surface and use it immediately.
2. For serum and plasma samples: Take up serum or plasma into a dropper and transfer 1 drop (approximately 40 µl) to the sample area then add 1 drop of buffer (approximately 40 µl) and start the timer. See illustration below.
   For venepuncture whole blood samples: Transfer 2 drops of whole blood (approximately 80 µl) using a dropper or 80 µl whole blood using a pipette to the sample area, then add 1 drop of buffer (approximately 40 µl) and start the timer.
   For finger prick whole blood samples: Fill the capillary tube and transfer approximately 80 µl whole blood to the sample area then add 1 drop of buffer (approximately 40 µl) and start the timer. Or let 2 drops of whole blood (approximately 80 µl) fall onto the sample area then then add 1 drop of buffer (approximately 40 µl) and start the timer.
3. Wait for coloured band(s) to appear. The result should be read at 5 minutes. Do not interpret any 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).
Note: The intensity of the colour in the test line region (T) will vary depending on the concentration of TP antibodies present in the sample. Therefore, any development of colour in the test line region (T) should be considered positive.

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. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Quality Controls:
A procedural control is included in the test in the form of a coloured line developing at the Control line. Its appearance confirms sufficient sample volume added and correct procedural technique.
Quality Controls are not supplied with this kit; however, 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 Test Strip is for *in vitro* diagnostic use only. The test should be used for the detection of TP antibodies in whole blood, serum or plasma samples only. Neither the quantitative value nor the rate of increase in TP antibodies can be determined by this qualitative test.
2. The Syphilis Test Strip will only indicate the presence of TP antibodies in the sample and should not be used as the sole criteria for the diagnosis of TP infection. A confirmed Syphilis diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
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 preclude the possibility of TP infection.

Performance Characteristics:

Sensitivity and Specificity
The Syphilis Test Strip has been compared to a leading commercial TPPA Syphilis test using clinical samples. The results show that the relative sensitivity of the Syphilis Test Strip is >99.9% and the relative specificity is 99.7%.

Method		TPPA		Total Result
Syphilis Test Strip	Results	Positive	Negative	
	Positive	200	1	201
	Negative	0	319	319
Total Result		200	320	520

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

Precision
Intra-Assay
Within-run precision was determined using 10 replicates of four samples: a negative, a low positive, a medium positive and a high positive. The sample results were

correctly identified >99% of the time.

Inter-Assay
Between-run precision was determined in 10 assays using the same four samples. Three different batches of the Syphilis Test Strip were tested 3 on separate days period using the negative and low, medium and high positive samples. The samples were correctly identified >99% of the time.

Cross-reactivity for cross reactivity
The Syphilis Test Strip was tested for cross reactivity by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV, HIV, H. Pylori, MONO, CMV, Rubella and TOXO using samples positive for these pathogens in the Typhoid Device test. The results showed no cross-reactivity.

Interfering Substances
The following potentially interfering substances were added to Syphilis negative and positive samples.

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

None of the substances interfered in the Syphilis Test Strip assay at the concentration tested.

References:

1. Claire M. Fraser. Complete genome sequence of Treponema Pallidum, the Syphilis spirochete, Science 1998;281 July:375-381
2. 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.
3. Aral R. Marx. Crack, sex and STD, Sexually Transmitted Diseases, 1991; 18:92-101
4. J.N. Wasserheit. Epidemiological Synergy: Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases, Sexually Transmitted Diseases 1992; 19:61-77
5. Johnson Phillip C. Testing for Syphilis, Dermatologic Clinic 1994; 12 Jan: 9-17.

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

CE

Prestige Diagnostics UK Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk