SBio RPR Card Syphilis Test

Rapid Plasma Reagin (RPR) Card Test / Carbon Antigen for Syphilis Testing

REF	90514100	90514250
Σ	100 T	250T

CE

Temperature Limitation	This side up	EC REP Authorised Representative	Xn NaN., R22 S23-46-61
Use by (Last day of stated month)	Consult Instructions for use	CONTROL + Positive control	
		CONTROL - Negative control	Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
Date of Manufacture	REF Catalogue Number	REAGENT Description of reagent	
LOT Batch Number	IVD *In vitro* Diagnostic Medical Device	Σ Contains sufficient for <n> tests	

SUMMARY

Syphilis is a sexually transmitted (venereal) disease caused by the spirochete *Treponema pallidum*. After infection the host forms *Treponemal antibodies to Treponema pallidum*, in addition, the host also forms Non Treponemal antilipoidal antibodies in response to the lipoidal material released from the damaged host cell. These antibodies are traditionally referred to as 'Reagins.'

The Rapid Plasma Reagin (RPR) / Carbon Antigen test is a macroscopic nonTreponemal flocculation test for the detection and quantitation of antilipoidal antibodies. Non-Treponemal tests like SBio RPR Card Syphilis Test are of great value when used for screening and follow up of therapy.

REAGENTS

1. SBio RPR Card Syphilis Test reagent: A particulate carbon suspension coated with lipid complexes.
2. Positive control, reactive with the SBio RPR Card Syphilis Test reagent.
3. Negative control, non reactive with the SBio RPR Card Syphilis Test reagent.

SBio RPR Card Syphilis Test detects antilipoidal antibodies in serum or plasma. As against the conventional V.D.R.L. reagents, test samples do not require heat inactivation.

Each batch of reagent undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE AND STABILITY

Store the reagent at 2-8^{0}C. DO NOT FREEZE. Once opened the shelf life of the reagent vial is as described expiry date on the reagent vial label provided it is not contaminated. Do not use reagents after the expiry date. Avoid exposure to elevated temperatures and air, as the reagent is highly sensitive to denaturation and drying.

PRINCIPLE

During the testing procedure, the specimen, serum or plasma is mixed with the SBio RPR Card Syphilis Test reagent and allowed to react for eight minutes. If antilipoidal antibodies are present in the specimen, they will react with the SBio RPR Card Syphilis Test reagent forming visible black floccules. If antilipoidal antibodies are not present in the specimen, there will be no flocculation.

NOTE

1. In vitro diagnostic reagent for laboratory or professional use only. Not for medicinal use.
2. The reagents contain 0.1% Sodium azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
3. The reagents that are derived from human source have been tested for HBsAg and Anti-HIV antibodies and are found to be non-reactive. However handle the material as if infectious.
4. SBio RPR Card Syphilis Test Carbon Antigen should be gently but thoroughly mixed before testing to disperse the carbon particles uniformly and improve test readability.
5. Performance of the reagent must be verified with positive and negative controls and it is recommended that controls be run with each test series.
6. Accessories provided with the kit only must be used for optimum results.
7. Do not use damaged or leaking reagents.

SAMPLE COLLECTION AND STORAGE

1. No special preparation of the patient is required prior to sample collection by approved techniques. Hemolysed or lipemic samples are not suitable for testing.
2. Fresh serum or plasma should be used for testing.
3. Samples not tested immediately may be stored at 2-8^{0}C for upto 48 hours.
4. Hazy samples should be centrifuged. Use clear supernatant for testing.

MATERIAL PROVIDED WITH THE RPR KIT

1. Carbon Antigen.
2. Positive control, reactive with the reagent.
3. Negative control, non-reactive with the reagent.
4. Disposable slides with eight reaction circles.
5. Disposable sample / control dispensing pipettes.
6. Mixing sticks.
7. Rubber teats.
8. Reagent Dropper for dispensing the Carbon Antigen.

ADDITIONAL MATERIAL REQUIRED,

Stop watch, High intensity light source, Isotonic saline, Pipettes, Test tubes, Mechanical rotor at 180 r.p.m. circumscribing a circle 2 cm in diameter on a horizontal plane.

TEST PROCEDURE

Bring reagent and samples to room temperature before testing.

Thoroughly mix the SBio RPR Card Syphilis Test reagent suspension by gentle agitation before testing.

Qualitative Method

1. Pipette one drop (50 µl) of the test specimen, positive and negative controls onto separate reaction circles of the disposable slide using a sample-dispensing pipette.
2. Add one drop of well-mixed SBio RPR Card Syphilis Test reagent next to the test specimen, positive control and negative control by using the reagent dropper provided with the kit. Do not let the dropper tip touch the liquid on the slide.
3. Using a mixing stick mix the test specimen and the SBio RPR Card Syphilis Test reagent thoroughly spreading uniformly over the

entire reaction circle.

4. Immediately start a stopwatch. Rotate the slide gently and continuously either manually or on a mechanical rotor at 180 r.p.m.
5. Observe for flocculation macroscopically at 8 minutes.

Quantitative Method

1. Using isotonic saline prepare serial dilutions of the test sample positive in the qualitative method 1:2, 1:4, 1:8, 1:16,1:32, 1:64, 1:128 and so on.
2. Perform the qualitative test procedure using each dilution as test specimen.
3. The titre is reported as the reciprocal of the highest dilution, which shows a positive test result.

INTEPRETATION OF TEST RESULTS

Qualitative methods

Large and Medium black floccules against white background : Reactive
Small black floccules against white background : Weakly Reactive
No floccules, even grey background : Non reactive

Flocculation is a positive test result and indicates the presence of antilipoidal antibodies in the test specimen.
No Flocculation is a negative test result and indicates the absence of antilipoidal antibodies in the test specimen.

Quantitative Method

The titer of antilipoidal antibodies is the highest dilution of the test sample giving a positive test result.

REMARKS

1. Quantitative procedure must be performed to determine the response to treatment and detect reinfection.
2. False positive reactions occur not infrequently and have been attributed to a variety of acute and chronic conditions.
3. In absence of supporting clinical, historical or epidemiological evidence, reactive results must be confirmed with more specific Treponemal tests.
4. It is strongly recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.
5. Dispose all used and contaminated material as per Standard Biohazard Safety Guidelines.
6. The reagent dropper provided for dispensing the Carbon Antigen should be thoroughly cleaned with distilled water and air dried after use, to ensure that it does not contaminate the reagent during subsequent use.
7. Very slight roughness should be interpreted as a negative test result.

PERFORMANCE CHARACTERISITICS

The results of 100 serum samples obtained with SBio RPR Card Syphilis Test were compared with those obtained using commercial reagent (A) with similar characteristics and another commercial reagent (B) (modified VDRL reagent) with another method.

Test Result	SBio RPR Card Syphilis Test	A	B
Positive	46	46	46
Negative	54	54	54

The results of SBio RPR Card Syphilis Test correlate 100% with both the commercial reagents used for evaluation.
Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of VDRL negative and VDRL positive samples. No variations were found in the outcome of different tests.

WARRANTY

This product is designed to perform as described on the label and the package insert.
The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Pang Born, Mary C., Isolation and purification of serologically active phospholipid from Beef heart, J. Biol. Chem., 1974: 143: 247.
2. J. Venereal Disease Inform., 1946, 27, 169.
3. Mc. Grew B.E. et al, Am. J. Clin. Path., 1968: 50: 52.

Manufactured by:

TULIP DIAGNOSTICS (P) LTD.

Plot Nos. 92/96, Phase II C, Verna Industrial Estate,
Verna, Goa - 403 722, INDIA.
Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh,
Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

Manufactured for:

Singapore Biosciences PTE Ltd.
11 Yishun Street 51, #04-23,The Criterion,
Singapore 767971

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EC REP

CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain