

# RPR CARBON ANTIGEN

PRODUCT CODE: SYRPR025/SYRPR050  
SYRPR100/SYRPR500



SYRPR025	SYRPR050	SYRPR100	SYRPR500
25 TESTS	50 TESTS	100 TESTS	500 TESTS
STORE AT 2-8°C			
INSTRUCTIONS FOR USE			
FOR IN-VITRO DIAGNOSTIC USE ONLY			

- For In Vitro Diagnostics Use Only
- Lot Number
- Catalogue Number
- Storage Temperature
- Expiry Date (Year / Month)
- Warning, Read Enclosed Documents
- Instructions For Use
- Manufactured By

## RPR CARBON ANTIGEN

### SYPHILIS

#### Principle:

The Rapid Plasma Reagin or RPR Card test is a non-treponemal method for the serological detection of syphilis. The antigen – a particulate carbon suspension coated with lipid complexes – agglutinates in the presence of serum reagins. Reagins are antibodies present in the sera of syphilitic patients. Visible agglutination in the form of black clumps which can be viewed macroscopically, indicate the presence of such antibodies in the sample tested.

#### Presentation:

Contents	25 Tests	50 Tests	100 Tests	500 Tests
RPR Carbon Antigen	1 x 0.5ml	1 x 1.0ml	1 x 2.0ml	2 x 5.0ml
Positive Control	1 x 0.5ml	1 x 0.5ml	1 x 0.5ml	1 x 1.0ml
Negative Control	1 x 0.5ml	1 x 0.5ml	1 x 0.5ml	1 x 1.0ml
Disp. Needle 16µl	1	1	1	1
Dispensing Bottle	1	1	1	1
Disposable Test Cards	3	5	10	50
Pipette / Stirrers	25	50	100	500

#### Composition:

RPR Carbon Antigen	Stabilised Carbon Suspension Coated with a lipid complex. Sodium Azide 0.95g/L.
Positive Control	Human Serum Sodium Azide 0.95g/L.
Negative Control	Animal Serum Sodium Azide 0.95g/L.

Although all our components which have been derived from human origin have been tested and found to be negative for the presence of anti-HIV, anti-HCV as well as HbsAg, it is recommended that they be handled cautiously and treated potentially infectious.

#### Storage:

Store components at 2-8°C. Cards and Pipettes may be kept at Room Temperature.

#### Samples:

- Serum or Plasma stable for 48 hours at 2-8°C,
- Samples should be free from contamination and haemolysis.

- Lipemia will not affect the test results unless it is severe enough to obscure the state of the antigen particles.

#### Reagent Preparation:

Resuspend the Carbon Antigen gently to ensure thorough mixing. Transfer the required volume of Carbon Antigen to the dispensing bottle. Label the dispensing bottle with the antigen lot number, expiry and transfer dates. Once the antigen has been transferred to the dispensing bottle, it is stable for 3 months or until expiry date, whichever comes first.

#### Additional Equipment:

Mechanical Rotator set at 100 r.p.m, circumscribing a circle 2.0 cm in diameter.

#### Test Procedure: Qualitative Test

- Bring the reagents and samples to room temperature.
- Place 50µl of the sample and 1 drop of the control into separate circles on the card.
- Resuspend the antigen gently.
- Add one drop of free falling antigen to each test circle.
- Mix with the disposable pipette / stirrer and spread over the entire area enclosed by the ring. Use a new stirrer for each sample.
- Rotate the cards at 100 r.p.m. for 8 minutes.

#### Semi-Quantitative Test:

- Using a semi-automatic pipette, add 50µl of saline to circles 2, 3, 4 and 5. Do not spread the saline.
- Add 50µl of patient sample to circles 1 & 2.
- Mix the saline and sample in circle 2 by drawing the mixture up and down being careful to avoid the formation of any bubbles.
- Transfer 50µl from circle 2 to the saline in circle 3.
- Perform serial dilutions in the same manner until the last circle, discarding 50µl at the end.
- Using the pipette / stirrer, spread the diluted samples over the entire area of each circle starting at circle 5 and working backwards to the neat sample in circle 1.
- Proceed as a qualitative test from step 3.

#### RPR Qualitative Test in Microtitre Plates:

- Using a flat bottomed microfiltration plate, add 50µl of patient sample.
- Add one drop of carbon antigen.
- Rotate on a Mechanical Rotator for 20 minutes at 50 r.p.m.
- Read macroscopically, either over a light box or under a high intensity incandescent lamp above a white surface.

#### Quality Control:

Each run of tests should be validated with a positive and negative

control.

#### Reading And Interpretation:

Examine macroscopically for the presence or absence of clumps within a minute of removing the card from the rotator. Readings are scored and reported according to the following criteria:-

Observed Agglutinations	Reading	Report
Medium and Large Clumps	R	Reactive
Small Clumps	W	Weakly Reactive
No Clumping or very slight 'roughness'	N	Non-Reactive

Reactive sera may be titred. To titre make serial two-fold dilutions in 9g/L saline as described in the Quantitative Procedure earlier on. The serum titre is defined as the highest dilution showing a positive result.

#### Performance Characteristics:

- Cardiolipin-like tests are non-specific for syphilis. All reactive test samples should undergo a further specific serological test i.e. FTA-Abs, TPHA, to confirm the results.
- Conversely, a Non-Reactive result by itself does not rule out the diagnosis of syphilis.
- Biological false positive reactions have been reported in diseases such as infectious mononucleosis, viral pneumonia and toxoplasmosis, pregnancy and autoimmune diseases.
- This test is useful in determining the effectiveness of antibiotic therapy.

**Sensitivity:** This test has a sensitivity of over 99%.

#### Notes:

- At the end of each days testing, the needle should be removed from the dispensing bottle, rinsed with distilled water and air dried.
- The sensitivity of the test may be reduced at low temperatures. The best results are obtained between 23 and 29°C.
- It is important to position the dispensing needle vertical to the reaction card, in order to deliver the exact quantity of the antigen.
- High temperatures may cause test components to dry on card and as a result false positive results may occur. Place the card under a humidifying cover if necessary.

#### Reference:

- Portnoy J et al. Public Health Report 1962: 77: 654-658
- McGrew BE et al. Am. J. of Clin. Pathology 1968: 50: 52-55
- Portnoy J. Public Health Laboratory 1965: 23: 43-47
- McGrew BE et al. Am. J. of Clin. Pathology 1968:34: 634-639