RPR CARBON
Carbon agglutination method

INTENDED USE
Qualitative determination of plasma reagins.

PRINCIPLE
RPR CARBON is a non-treponemal slide agglutination test for the qualitative and semi-quantitative detection of plasma reagins in human serum.

SAMPLE
Fresh Serum. Stable 7 days at 2-8°C or 3 months at -20°C.
Samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

KIT COMPONENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>Volume</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent (A) RPR Liquid</td>
<td>3.0/5.0 ml</td>
<td>Carbon particles coated with a lipid complex, cardiolipin, lecithin and cholesterol in phosphate buffer 20 mmol/l. Preservative. pH 7.0</td>
</tr>
<tr>
<td>Control (+) RPR Liquid</td>
<td>0.5/1.0 ml</td>
<td>Artificial serum with reagin titer 1/4</td>
</tr>
<tr>
<td>Control (-) RPR Liquid</td>
<td>0.5/1.0 ml</td>
<td>Animal serum. Preservative</td>
</tr>
<tr>
<td>Dispensing vial and needle</td>
<td>1 pz</td>
<td></td>
</tr>
<tr>
<td>Stirrers</td>
<td>3 o 5 pz</td>
<td></td>
</tr>
<tr>
<td>Reaction slide</td>
<td>19 pz</td>
<td></td>
</tr>
</tbody>
</table>

The Reagents are stable until the expiration date printed on the label, when stored tightly closed at 2-8°C. Once opened, the reagents are stable one month at 2-8°C if contamination is avoided. Do not freeze.

Keep bottles closed when not in use.

PRECAUTIONS AND WARNINGS
Reagent may contain some non-reactive and preservat ive components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Use the normal precautions required in the laboratory.
Dispose of waste according to local laws.

REAGENT PREPARATION
Swirl the reagent gently to disperse the carbon particles before use.
Open the RPR-Carbon vial, take with the appropriate dispensing vial the required volume of reagents. Once the test is completed, return the reagent to the original vial and rinse the dispensing vial with distilled water.

PROCEDURE
Qualitative method:
Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
Place 50 µl of the sample and one drop of each Positive and Negative Controls into separate circles on the slide test.
Add one drop (20 µl) of reagent RPR-Carbon by placing the dropper in a vertical position and perpendicular to the slide and mix with a stirrer uniformly distributing the liquid over the entire surface of the circle. Use different stirrers for each sample.
Place the slide on a mechanical rotator at 80/100 rpm and observe within 8 minutes the possible agglutination. In positive samples, agglutinated carbon tends to deposit on external edge of selected spot.
False positive results could appear if the test is read later than 8 minutes.
Semi-quantitative method:
Make serial two fold dilutions of the sample in saline solution.
Proceed for each dilution as in the qualitative method.

READING AND INTERPRETATION
Examine the presence or absence of visible agglutination immediately after removing the slide test from the rotator.
The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

QUALITY CONTROL
Positive and Negative Controls are recommended to monitor the performance of the reagent and to have a better results interpretation.

PERFORMANCE
Prozone effect: No prozone effect up to titers ≥ 1/128
Diagnostic sensitivity: 100 %
Diagnostic specificity: 100 %
Interferences: Bilirubin does not interfere up to 20 mg/dl. Lipids and hemoglobin do not interfere 10 g/l. Rheumatoid factors ( 300 U/ml) interfere.

METHOD LIMITATIONS
RPR-Carbon test is non-specific for syphilis. All Reactive samples should be retested with treponemal methods such as TPHA to confirm the results.
A Non Reactive result by itself does not exclude a diagnosis of syphilis. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.
False positive results have been reported in diseases such as infectious mononucleosis, viral pneumonia, toxoplasmosis, pregnancy and autoimmune diseases.

REFERENCES