Rapid Plasma Reagin Card test for the Serodiagnosis of Syphilis.

For in-vitro diagnostic use only.

**INTRODUCTION AND INTENDED USE**

RAPID LABS RPR is for use in the non-treponemal flocculation test for the qualitative and semi-quantitative determination of reagin antibodies in serum or plasma.

For professional use only.

**PRINCIPLE OF THE TEST**

RAPID LABS RPR is a modified form of VDRL ANTIGEN which contains carbon particles to improve the visual reading of the result. When binding occurs between cholesterol/ cardiolipin/ lecithin in the reagent and the reagin antibodies in the sample, the results can be seen macroscopically in the form of black clumps.

No visual flocculation indicates a negative result.

The test can be performed on heated, unheated serum or plasma and is therefore very versatile. RAPID LABS RPR can be used in the manual slide test and on single and multi-channel auto analyser instruments that are used in blood banks for mass Syphilis screening of routine blood bank donations.

This test has been calibrated to WHO Reference Serum for Serodiagnostic tests for Treponemal Infections- Ref 3-1980.

**KIT CONTENTS**

<table>
<thead>
<tr>
<th>Ref: 100 Test</th>
<th>Ref: 500 Test</th>
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</thead>
<tbody>
<tr>
<td>RPR Carbon Antigen</td>
<td>RPR Carbon Antigen</td>
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<tr>
<td>Suspension of Carbon approximately 0.2g/L, 0.003% Cardiolipin, 0.02% Lecithin and 0.09% Cholesterol. Working Strength.</td>
<td>10.0ml</td>
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<tr>
<td>Positive Control +</td>
<td>Positive Control +</td>
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<tr>
<td>Positive Control. Serum containing antibodies against Treponema Pallidum. Working Strength.</td>
<td>0.5ml</td>
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<tr>
<td>Negative Control –</td>
<td>Negative Control –</td>
</tr>
<tr>
<td>Negative Control. Serum free of antibodies against Treponema Pallidum. Working Strength.</td>
<td>0.5ml</td>
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**STIRRERS 100**

<table>
<thead>
<tr>
<th>DISPOSABLE TEST SLIDES 1 x 10</th>
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<tbody>
<tr>
<td>INSTRUCTION LEAFLET 1</td>
<td>1</td>
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<tr>
<td>DISPENSING BOTTLES (PLASTIC) 1</td>
<td>2</td>
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<tr>
<td>DISPENSING NEEDLE 1</td>
<td>2</td>
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**MATERIALS REQUIRED, BUT NOT PROVIDED**

- Micropipettes capable of dispensing 50μl and 16μl.
- Test tubes 75 x 12mm
- Rotator set at 100 r.p.m.
- Isotonic saline: 0.9% NaCl

**PRECAUTIONS**

The serum controls are of human origin and have been tested for and confirmed negative for HCV, HIV I and HIV II antibodies, and HBsAg by FDA approved procedures. Because no test can offer complete assurance that products derived from human source will not transmit infectious agents it is recommended that the reagents within this kit be handled with due care and attention during use and disposal. All reagents should, however, be treated as potential biohazards in use and for disposal. Do not ingest.

RAPID LABS RPR Reagents do not contain dangerous substances as defined by current UK Chemicals (Hazardous Information and Packaging for Supply) regulations. All reagents should, however, be treated as potential biohazards in use and disposal. Final disposal must be in accordance with local legislation.

RAPID LABS RPR contains 0.095% sodium azide as a preservative which may be toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.

**STORAGE**

Reagents must be stored at temperatures between 2°C to 8°C.

The kit will perform within specification until the stated expiry date as determined from date of product manufacture and stated on kit and components. Expiry date is the last day of the month on the bottle and the kit label. Do not use reagents after the expiry date.

Exposure of reagents to excessive temperatures should be avoided. Do not expose to direct sunlight.

DO NOT FREEZE ANY OF THE REAGENTS as this will cause irreversible damage.

Do not store the test cards in the refrigerator, store at room temperature and ensure that the test circles are not touched by the fingers. This could leave oily deposits on the test surface which might invalidate the test results.

**SPECIMEN COLLECTION AND PREPARATION**

Serum:

Obtain a sample of venous blood from the patient and allow a clot to form and retract. Centrifuge clotted blood sample and collect clear serum. Fresh serum samples are required.

Plasma:

Obtain a sample of venous blood from the patient and add to plasma collection vial. Centrifuge sample and collect clear plasma. Fresh plasma samples are required.

Do not use haemolysed, contaminated or lipoaemic serum or plasma for testing as this will adversely affect the results.

Serum may be stored at 2°C to 8°C for up to 48 hours prior to testing. If longer storage is required, store at –20°C for up to 6 weeks. Thawed samples must be mixed prior to testing.

Do not repeatedly freeze-thaw the specimens as this will cause false results.

DO NOT DILUTE THE PATIENT SERUM PRIOR TO USE IN THE QUALITATIVE TEST.
REAGENT PREPARATION

All reagents should be brought to room temperature (20°C to 25°C) and mixed gently prior to use. Do not induce foaming.

Shake the Antigen suspension well to ensure a homogeneous suspension before use. The kit contains an antigen dispensing system comprising a plastic bottle and a blunt ended 20 ga. needle.

For use, remove the cap from the plastic bottle and fit the needle hub securely on the nozzle of the bottle. To fill the bottle, squeeze the vial and insert the end of the needle into the well shaken antigen suspension.

Then allow the plastic bottle to expand and this will then allow the antigen up into the bottle. Storage of the antigen in the plastic bottle reduces the shelf life of the product. It is recommended that any remaining antigen in the bottle after a day’s testing should be returned to the original glass vial. The plastic bottle/needle dispenser should then be rinsed through with distilled water and air dried.

LIMITATIONS OF USE

The use of samples other than serum or plasma has not been validated in this test.

There is no reuse protocol for this product.

A low or suspected positive result should be re-assessed. Diagnosis should not be made solely on the findings of one clinical assay. When making an interpretation of the test it is strongly advised to take all clinical data into consideration.

False positive reactions are known to occur with RPR tests when the patient has infections other than Syphilis. If a positive RPR result is found, a specific treponemal test should be performed. Rapid Labs manufacture and supply TPHA test kits for the detection of specific anti-treponemal antibodies.

ASSAY PROCEDURE

Manual Slide Method

1. Dispense one drop (50μl) of patient sample onto a glass slide or RPR Test Card. Spread to cover the entire circle.

2. Spread the sample over the entire area of the test circle using the flat end of the pipette/stirrer.

3. Using the dispensing bottle/needle assembly allow one free-falling drop (16μl) of antigen to drop onto the test specimen. Do not re-stir.

4. Rotate the slide/card for 8 minutes at 100 r.p.m.

5. Immediately after the 8 minutes, inspect the result visually in good light.

Semi Quantitative Method

1. Using isotonic saline prepare serial dilutions (50μl) of the patients serum (1/2, 1/4, 1/8, 1/16, 1/32, 1/64 and so on)

2. Transfer one drop of each serum dilution to the test circle on the slide.

3. Add one drop (16μl) of shaken antigen to the sample. (There is no need to mix these two components).

4. Rotate the slide/card for 8 minutes at 100 r.p.m.

5. Immediately after the 8 minutes, inspect the result visually in good light.

RESULTS AND INTERPRETATION

Kit controls or known level value samples should be tested with each test run. The kit negative control should give a negative result after 8minutes. The kit positive control should give a positive result at a titre of 1/4 +/- one double dilution after 8 minutes. If levels of controls or users known samples do not give expected results, test results must be considered invalid.

Qualitative Method

Medium and large aggregates = Reactive

Finely dispersed aggregates = Weak Reactive

No aggregates visible smooth grey appearance = Non Reactive

Semi-Quantitative Method

The titre is the last dilution that produces a reactive result. Titres of 1/128 have been detected with RAPID LABS RPR with no prozone (Hook) effect.

TROUBLESHOOTING

Use a separate disposable tip for each sample to prevent cross contamination.

Replace caps on all reagents immediately after use. Prior to the start of the assay bring all reagents to room temperature (20°C to 25°C). Gently mix all reagents by gentle inversion or swirling.

For use by operatives with at least a minimum of basic laboratory training.

Do not use damaged or contaminated kit components.

Manufactured in the UK, by:

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CO7 8SD. U.K.
Email: info@rapidlabs.co.uk
Website www.rapidlab.co.uk

KEY TO SYMBOLS

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