

RPR Test Kit – 100, 250 & 500 Tests

(Rapid Plasma Reagin Test)



| Cat. No. | Product Description |
|----------|---------------------|
| D-RPR500 | RPR 500 Test Kit |
| D-RPR250 | RPR 250 Test Kit |
| D-RPR100 | RPR 100 Test Kit |

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

| Kit size (no. of tests) | 100 | 250 | 500 |
|-------------------------|-----|-----|------|
| RPR Carbon Antigen | 2ml | 5ml | 10ml |
| Positive Control | 1ml | 1ml | 1ml |
| Negative Control | 1ml | 1ml | 1ml |
| Stirrers | 100 | 250 | 500 |
| Test Slides | 10 | 25 | 50 |
| Dispensing Bottle | 1 | 1 | 1 |
| Dispensing tip | 1 | 1 | 1 |
| Pack insert (IFU) | 1 | 1 | 1 |

RPR Carbon Antigen - Suspension of Carbon approximately 0.2g/L, 0.003% Cardiolipin, 0.02% Lecithin and 0.09% Cholesterol Working Strength.

Positive Control + Positive Control. Serum containing antibodies against Treponema Pallidum. Working Strength.

Negative Control –Negative Control. Serum free of antibodies against Treponema Pallidum. Working Strength.

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 lipaemic 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 3ml plastic (LDPE) bottle and a pipette tip

RPR Test Kit – 100, 250 & 500 Tests

(Rapid Plasma Reagin Test)



For use, remove the white cap from the plastic bottle and fill with reagent from the 10ml vial using the dropper assembly provided with vial, then fit the pipette tip securely in the bottle. Alternatively, the plastic bottle can be filled from the glass reagent vial by fitting the pipette tip and filling by squeezing the plastic bottle and inserting the end of the pipette tip 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 test card at 100 r.p.m. for 8 minutes only on an automatic rotator.
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 8 minutes. 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.

BIBLIOGRAPHY

A Manual of Tests for Syphilis: Larsen et al. 1998 p 193 – 207

Syphilis Serology Principles and Practice : G.D. Wasley and H.H.Y. Wong 1988 p48 -49

KEY TO SYMBOLS:



Manufactured in the UK by: Rapid Labs Ltd
Unit 2 & 2a, Hall Farm Business Centre, Church Road
Little Bentley, Colchester, Essex CO7 8SD, U.K.
Manufactured in the U.K.

Email: info@rapidlabs.co.uk Website www.rapidlabs.co.uk

| | | | |
|-------------|------------------------------------|-----|-----------------------------------|
| IVD | In vitro diagnostic medical device | | Use by date |
| LOT | Batch code or lot number | REF | Catalogue number |
| +2°C - +8°C | Temperature limit | | Consult Instruction for use (IFU) |
| | Manufacturer | | Date of manufacture |