IMMUTREP RPR® [Ref OD051/OD061]
Rapid Plasma Reagin Card test for the Serodiagnosis of Syphilis. Store at 2°C to 8°C. DO NOT FREEZE.
For in-vitro diagnostic use only.

INTRODUCTION AND INTENDED USE

IMMUTREP 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

IMMUTREP RPR® is a modified form of IMMUTREP 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.

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

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

CONTROL + 0.5ml 0.5ml
Positive Control. Serum containing Reagin. Working Strength.

CONTROL – 0.5ml 0.5ml
Negative Control. Serum free of Reagin. Working Strength.

STIRRERS 100 500

DISPOSABLE TEST SLIDES 1x10 5x10
INSTRUCTION LEAFLET 1 1
DISPENSING BOTTLES (PLASTIC) 1 2
DISPENSING NEEDLE 1 2

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.

IMMUTREP 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.

IMMUTREP 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 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 1 year. 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.
**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 IMMUTREP 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.

**EVALUATION DATA**

In 1995 the Syphilis Reference Centre at Bristol Public Health Laboratory in the UK assessed the performance of IMMUTREP RPR.

**IMMUTREP RPR**

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<tr>
<td>Negative Samples</td>
<td>0</td>
<td>655</td>
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<tr>
<td>Positive Samples</td>
<td>20</td>
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All samples tested with IMMUTREP RPR gave the correct result.

**REFERENCES**


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