

IMMUTREP® RPR 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.

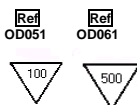
PRINCIPLE OF THE TEST

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.

CONTENTS



RPR Ag

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 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 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.

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. OMEGA manufacture and supply IMMUTREP TPHA 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 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 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

	+	-
Negative Samples	0	655
Positive Samples	20	0

All samples tested with IMMUTREP RPR gave the correct result.

REFERENCES

1. McGrew, B.E, et al., Amer. J. Med Tech., 34, 634 (1968).
2. McGrew, B.E, et al., Amer. J. Clin Path, 50, 52 (1968).
3. Portnoy, J. and Garson, W. Pub. Hlth. Rep. 75, 985-988 (1960).
4. Portnoy, J., Brewer, J.H. and Harris, A.D., U.S. Pub. Hlth. Rep. 77, 654 (1962).
5. Manual of tests for Syphilis, PHS Publications, No. 411, U.S. Govt. Printing Office (1969).

8002A Issue 5 Revised May 2015.

© Omega Diagnostics Ltd 2015.



OMEGA DIAGNOSTICS LTD.
Omega House, Hillfoots Business Village
Alva FK12 5DQ, Scotland, United Kingdom
odl@omegadiagnostics.co.uk
www.omegadiagnostics.com

AN ISO 9001 AND ISO 13485 CERTIFIED COMPANY