IMMUTREP® USR ANTIGEN Ref OD111/ OD111A

Serodiagnosis of Syphilis by Slide flocculation test.
Store at 2ºC to 8ºC. DO NOT FREEZE.
For in-vitro diagnostic use only.

INTRODUCTION AND INTENDED USE

IMMUTREP USR ANTIGEN is for use in the non-treponemal floccultion test for the qualitative and semi-quantitative determination of reagin antibodies in serum or plasma.
For professional use only.

PRINCIPLE OF THE TEST

IMMUTREP USR is a modified form of IMMUTREP VDRL ANTIGEN which has been stabilised and is ready for use.
When the Antigen is mixed with serum or plasma containing reagin antibodies the Antigen particles will flocculate, the result being visible under the microscope. A lack of flocculation indicates a negative result.

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

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Ag		

Suspension of 0.003% Cardiolipin, 0.02% Lecithin and 0.09% Cholesterol in stabilising buffer. Working Strength.

Control	**+**	**N/A**	**0.5ml**

Positive Control. Serum containing antibodies against Treponema pallidum. Working Strength.

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MATERIALS REQUIRED, BUT NOT PROVIDED

Glass ring slides
Rotator set at 180 r.p.m.
Micropipettes capable of dispensing 22µl and 50µl.
Isotonic saline: 0.9% NaCl

PRECAUTIONS

IMMUTREP USR reagents contain materials of human origin which have been tested 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 USR 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 USR reagents contain 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 2ºC to 8ºC.

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.

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 adversly affect the results.

Serum or plasma may be stored at 2ºC to 8ºC for up to 48 hours prior to testing. If longer storage is required, store at ï20ºC 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 (20ºC to 25ºC) and mixed gently prior to use. Do not induce foaming.

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 USR Antigen when the patient has infections other than Syphilis. If a positive USR Antigen result is found, a specific treponemal test should be performed. OMEGA manufactures and supplies IMMUTREP TPHA for the detection of specific anti-treponemal antibodies.

ASSAY PROCEDURE

Qualitative Method

1. Dispense one drop (50µl) of patients sample on the ring slide.
2. Add 22µl of shaken antigen to the sample. (There is no need to mix the two components.)
3. Rotate the test slide for 4 minutes at 180 r.p.m.
4. Immediately after the 4 minutes, inspect the result microscopically under 100x magnification.

Semi Quantitative Method

1. Using isotonic saline prepare serial dilutions of the patients sample (1/2, 1/4, 1/8, 1/16, 1/32, 1/64 and so on)
2. Transfer one drop of each sample dilution (50µl) to the test circle on the slide.
3. Add 22µl of shaken antigen to the sample. (There is no need to mix these two components).
4. Rotate the slide/card for 4 minutes at 180 r.p.m.
5. Immediately after the 4 minutes. Inspect the result microscopically under 100X magnification.

RESULTS AND INTERPRETATION

Kit controls or known level value samples should be tested with each test run. The kit positive control should give a positive result at a titre of 1/4 +/- one double dilution after 4 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 USR** 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 (20ºC to 25ºC). 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

Reproducability of Immutrep USR is 100% (+/- one double dilution).
Calibrated to major competitors and in house standards.
In an evaluation carried out at a European reference centre 675 samples were tested in parallel with a major competitor.

Comparative overall sensitivity: 100%
Comparative specificity: 100%

REFERENCES

1. Manual of Tests for Syphilis. PHS Publication No.411, U.S. Govt. Printing Office (1969).
2. Portnoy, J. and Garson, W. Pub. Hlth. Rep. 75, 985-988 (1960).
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