

IMMUTREP[®] CARBON ANTIGEN **Ref** OD031/ OD041

Serodiagnosis of Syphilis, by slide or automated method.

Store at 2°C to 8°C. DO NOT FREEZE.

For in-vitro diagnostic use only.

INTRODUCTION AND INTENDED USE

IMMUTREP CARBON ANTIGEN 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.

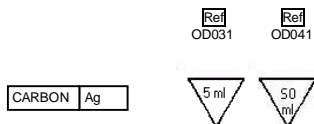
PRINCIPLE OF THE TEST

IMMUTREP CARBON ANTIGEN 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. **IMMUTREP CARBON ANTIGEN** can be used in the manual slide test and on single and multi-channel autoanalyser 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.

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

INSTRUCTION LEAFLET 1 1

MATERIAL REQUIRED BUT NOT PROVIDED

For manual tests:
White backed ringed slides or IMMUTREP RPR Cards with 18mm diameter circles.
Micropipettes capable of dispensing 16ul and 50ul.
Rotator set at 100 r.p.m

For automated tests:
Single or multi-channel auto analyser.
Magnetic Stirrer.
Isotonic saline: 0.9% NaCl

PRECAUTIONS

IMMUTREP CARBON ANTIGEN 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.

IMMUTREP CARBON ANTIGEN 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. Do not ingest.

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.

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 shake well to ensure a homogenous suspension before 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 reassessed. 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 Carbon Antigen when the patient has infections other than Syphilis. If a positive Carbon Antigen 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 50 µl of patient sample onto a glass slide or RPR Test Card. Spread to cover the entire circle.
2. Add 16µl of shaken antigen to the sample. (There is no need to mix these two components).
3. Rotate the slide/card for 8 minutes at 100 r.p.m.
4. Immediately after the 8 minutes, inspect the result visually in good light.

Semi Quantitative Method

1. Using isotonic saline prepare serial dilutions of the patients serum (1/2, 1/4, 1/8, 1/16, 1/32, 1/64 and so on)
2. Transfer 50µl of each serum dilution to the test circle on the slide.
3. Add 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

Known level value samples should be tested with each test run. If 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 CARBON ANTIGEN** with no prozone (Hook) effect.

AUTOMATED TEST

IMMUTREP CARBON ANTIGEN is suitable for most manufacturers equipment but the operator should strictly adhere to the manufacturer's recommendations and instructions when using their equipment.

IMMUTREP CARBON ANTIGEN is supplied in convenient 50 ml volumes for blood banks performing this method of Syphilis screening. Care must be taken to ensure that the antigen is well stirred during use to ensure homogeneity and that any reagent not required for the days testing is stored in the refrigerator.

Every set of tests should include a well characterised control serum to monitor the performance of both the operator and the reagent.

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 CARBON ANTIGEN**.

IMMUTREP CARBON ANTIGEN

	+	-
Negative Samples	0	655
Positive Samples	20	0

All samples tested with **IMMUTREP CARBON ANTIGEN** gave the correct result.

REFERENCES

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3. McGrew, B.E., Duncross, M.J.F., Stout, G.W., Falcone, V.H., Amer. J. Clin. Path. 50,52 (1968)
4. Manual of Tests for Syphilis, PHS Publication No. 411, U.S. Govt. Printing Office (1969)

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