

IMMUTREP® VDRL ANTIGEN ^{Ref} OD011

Serodiagnosis of Syphilis by slide or tube flocculation test.

Store at room temperature. DO NOT FREEZE.
For in-vitro diagnostic use only

INTRODUCTION AND INTENDED USE

IMMUTREP VDRL is for use in the non-treponemal flocculation test for the qualitative and semi-quantitative determination of reagin antibodies in serum.
For professional use only.

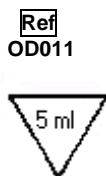
PRINCIPLE OF THE TEST

IMMUTREP VDRL Antigen is a non-treponemal antigen which will detect non-treponemal antibody (reagin) associated with syphilis infection. When the Antigen is added to the VDRL Buffered Saline it forms an emulsion of very fine particles. These particles will flocculate in the presence of reagin, to produce a test result which is 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.

CONTENTS

^{Ref} OD011	
VDRL	Ag
Suspension of 0.03% Cardioliipin, 0.2% Lecithin and 0.9% Cholesterol. Working Strength.	
Soln	Saline
Buffered Saline. Working Strength.	
Instruction Leaflet	



MATERIALS REQUIRED, BUT NOT PROVIDED

Glass ring slides
Rotary/Kahn shaker
Glass tubes 12 x 75mm
Micropipettes capable of dispensing 22, 50 and 1000µl.
Isotonic saline: 0.9% NaCl

PRECAUTIONS

IMMUTREP VDRL 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.

IMMUTREP VDRL 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

Store reagents at room temperature (20°C to 25°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.

The antigen bottle must be tightly closed after removal of an aliquot of the antigen. Take care not to introduce a wet pipette into the antigen as it will precipitate the antigen. If crystals become visible in the antigen solution they can be re-dissolved by gently warming the product to 50 °C.

SPECIMEN COLLECTION AND PREPARATION

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.

Do not use haemolysed, contaminated or lipaemic serum 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.

Serum must be inactivated by heating for 30 minutes at 56 °C. If more than 4 hours elapse between heating and testing the serum should be re-inactivated. CSF may be used for the test but does not require heat inactivation.

DO NOT DILUTE THE TEST SERA 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.

Slide test – Pipette 0.4ml of Buffered Saline into a flat bottomed stoppered bottle. Then add 0.5ml VDRL Antigen to the saline (using a clean pipette) dropwise over a 6 second period whilst rotating the bottle on a flat surface.

Continue rotation for a further 10 seconds and then add 4.1ml of Buffered Saline. The prepared antigen is now ready for use and must be used within 24 hours if the antigen is kept at 2 to 8 °C.

Tube Test – Take one volume of the VDRL Antigen emulsion as prepared for the slide test. Then add 4 volumes of 0.9% Sodium Chloride solution and mix vigorously and allow to stand for at least 5 minutes before use. Do not use after 2 hours.

LIMITATIONS OF USE

The use of samples other than serum or CSF 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 VDRL Antigen when the patient has infections other than syphilis. If a positive VDRL 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

Qualitative Method

1. Dispense 50µl of inactivated serum 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 inactivated 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 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.

Tube Test

1. Dispense 0.5ml of inactivated serum sample in a tube.
2. Add 0.5ml of diluted working antigen to the tube.
3. Shake the tube using a Kahn shaker for 5 minutes.
4. Centrifuge the tube to 2000 rpm for 10 minutes.
5. Shake the tube for one minute and read immediately.

RESULTS AND INTERPRETATION

Known level value samples should be tested with each test run. If levels of 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.

Tube Test

Aggregation in the tube - Reactive
 No aggregation visible - Non Reactive
 Titres of 1/128 have been detected with **IMMUTREP VDRL** 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

Reproducibility of Immurep VDRL is 100% (+/- one double dilution).

	Immurep VDRL		Totals
	+	-	
Untreated Syphilis	20	1	21
Treated Syphilis	26	5	31
Normal Samples	5	448	453
	51	454	505

Overall sensitivity $20/21 + 26/31 = 46/52 = 88.5\%$

Specificity $448/453 = 98.9\%$

REFERENCES

1. Manual of Tests for Syphilis. PHS Publication No.411, U.S. Govt. Printing Office (1969).
2. Harris, A., et. al. J.Ven. Dis. Information 27, 169 (1946).
3. Harris, A., et. al. J.Ven. Dis. Information 29, 72 (1948)

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