

VDRL ANTIGEN TEST KIT

Catalogue number
VDRL/010

Product Description
100 Test Kit

INTENDED USE

The Plasmatec VDRL Antigen test kit is for the serodiagnosis of syphilis. It is suitable for both the VDRL tube, (Harris *et al.*, 1948; and Manual of Tests for Syphilis, 1969), and the VDRL slide flocculation techniques, (Harris & Coleman, 1963; Harris *et al.*, 1946; and manual of Tests for Syphilis, 1969).

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only
For professional use only

Health and Safety warnings:

All patient samples and reagents should be treated as potentially infectious and the user must wear protective gloves, eye protection and laboratory coats when performing the test.

Non disposable apparatus must be sterilised after use by an appropriate method.

Disposable apparatus must be treated as biohazardous waste and autoclaved or incinerated.

Spillages of potentially infectious material should be absorbed and disposed of as above. The site of spillage must be sterilised with disinfectant or 70% alcohol.

Do not pipette by mouth.

The test reagent is a modified form of VDRL antigen. The product also contains aqueous buffer salts including formaldehyde- see material safety data sheet

Analytical precautions:

Do not modify the test procedure.

Do not dilute or modify the reagents in any way.

Allow all reagents and samples to reach room temperature (18 to 30°C) before use.

Do not interchange reagents from different kit batches.

COMPOSITION

Kit contents:

?? VDRL Antigen (an ethanolic solution containing 0.9% cholesterol; 0.03% bovine heart cardiolipin and about 0.21% lethicin. The concentration of lethicin is adjusted to give the required sensitivity).

?? Buffered Diluent (Sodium Chloride 10.0g; Formaldehyde 0.5ml; Disodium Hydrogen Phosphate 0.093g; Potassium Dihydrogen Phosphate 0.170g; Distilled water to 1,000ml).

?? Pack insert.

STORAGE AND SHELF LIFE

The VDRL Antigen and Buffer may be stored for up to two years at room temperature. **It is essential that the bottle is firmly closed and stored in the dark.** Under cold conditions cholesterol crystals may be observed in the antibody solutions. The stoppered bottle may then be gently warmed to 50°C until they redissolve.

Do not use reagents after the stated expiry date.

Discard reagents if they become contaminated or do not demonstrate the correct activity with controls.

MATERIALS AND EQUIPMENT REQUIRED BUT NOT PROVIDED.

For slide test.

1. Glass ring slides.
2. Rotatory shaking table (optional).

For tube test

1. Glass tubes 75x12mm.
2. Kahn shaking machine.

SPECIMEN

VDRL test are normally carried out on the serum - which should be clear, and free from bacterial contamination or obvious haemolysis.

Sera must be inactivated by heating at 56°C for 30 minutes before use. If more than 4 hours elapses between heating and testing the sera, they should be reheated at 56°C for 10 minutes.

Tests may be carried out on spinal fluid, which must be free from blood or contamination but does not require heat inactivation.

PROCEDURE

Principle:

Syphilis is a venereal disease caused by the spirochaete micro-organism *T.pallidum*. As the organism cannot be cultured on artificial media the diagnosis of syphilis depends on the correlation of clinical data with the detection of specific antibody by serological tests. Serological screening tests for syphilis using cardiolipin and lecithin as antigens are simple to perform but may give rise to a small proportion of false positive results because the tests use non-treponemal antigens.

The test antigen is a modified form of VDRL Antigen containing microparticulate carbon which aids the macroscopic reading of results. A reactive result is indicated by agglutination which is readily visible without the aid of a microscope. Weak- reactive results can be easily and clearly distinguished from non-reactive patterns which display a macroscopically smooth and even appearance.

Test results are obtained in 8 minutes

Preparation of Reagents

VDRL Antigen Emulsion for Slide Test

1. Pipette 0.4ml of the buffered saline diluent into a flat bottomed, stoppered bottle.
2. Using a dry pipette add 0.5ml of the VDRL Antigen dropwise to the diluent whilst rotating the bottle on a flat surface. Prolong the addition for about 6 seconds and continue rotating the bottle for a further ten seconds.
3. Add 4.1ml of saline diuent to the initial emulsion, stopper the bottle, and shake vigorously for at least 10 seconds.
4. The antigen is now ready for use. The prepared reagent may be used for up to 24 hrs if kept at 4°C.

VDRL Antigen for Tube Test

1. To one volume of the antigen emulsion prepared as for the Slide Test, add four volumes of 1% sodium chloride solution.
2. Mix well and stand for at least 5 minutes before use. **Do not use after 2 hours!**

QUALITATIVE TEST METHOD

Slide test

1. Place one drop (0.05ml) of inactivated serum on a ring slide.
2. Shake the antigen emulsion and add one small drop (0.02 ml) to the serum.
3. Mix and spread to fill the ring. Rotate the slides for 4 minutes at two revolutions per second, either by hand or using a mechanical rotator.
4. The tests should be inspected with the naked eye and results confirmed by microscopic examination.

INTERPRETATION OF RESULTS

Negative: Finely dispersed particles with no clumping

Weakly Positive: Finely dispersed particles with some clumping

Positive: Medium and large clumps

The clumps are usually fairly uniform in size. With some sera, however, prozone reaction may be experienced which are characterised by irregular fluffy clumps.

These sera should be tested quantitatively.

QUANTITATIVE METHOD

The Quantitative VDRL slide test is similar to the Qualitative test. Serial doubling dilutions of the sera in isotonic saline are tested and the results expressed as a titre. This titre is the greatest dilution that produces a positive reaction.

Tube Test

1. Place 0.5ml of inactivated test serum in a tube.
2. Add 0.5ml of the diluted working antigen emulsion to each tube.
3. Shake using the Kahn shaker for 5 minutes.
4. Centrifuge at 2,000 rev./min for 10 minutes.
5. Shake for one minute and read immediately. Clumping in a clear or slightly turbid medium indicates a positive result. All other results are negative.

INTERPRETATION OF RESULTS

In common with all lipoidal antigen tests the VDRL test will give a small proportion of false positive results. False positive results may be encountered as a result of viral and bacterial diseases, but titres are usually less than 1:8. Such acute false positives are normally eliminated by retesting after several weeks. Non-Venereal treponemal infections will also give positive results.

Results with VDRL Antigen may differ from those obtained using Reiter's treponemal Antigen.

VDRL	Maltaner	Reiters	Interpretation
+	+	+	Highly probable past or present treponemal infection
-	-	+	Rare false positive; Early syphilis; Late or latent infection
+	+	-	Treated disease; Lipoidal antigen false positive may indicate a non-treponemal disease.

PERFORMANCE CHARACTERISTICS AND LIMITATIONS OF THE METHOD

In common with all reagin tests the test may give a small proportion of false positive results.

Such reactions can be caused by diseases such as infectious mononucleosis, leprosy, lupus erythematosus, vaccinia and virus pneumonia.

Positive test specimens should be subject to further serological studies (i.e. TPHA, FTA, and ABS) since, as with any serological testing procedure, the diagnosis of syphilis should not be made on a single reactive result.

In common with other serological tests Plasmatec VDRL Antigen test cannot distinguish between syphilis and other pathogenic treponemal infections, e.g. Yaws. Clinical evidence should always be considered when making a diagnosis of treponemal infections.

QUALITY CONTROL

Positive and negative control sera should be used to verify the test

VALIDATION

The VDRL test has been fully described and evaluated by the United States Venereal Disease Research Laboratory (see Manual of Tests for Syphilis, 1969).

Plasmatec VDRL Antigen is prepared in accordance with the published description and its sensitivity is carefully adjusted to ensure consistent results. The cardiolipin and lethicin are standardised against the World Health Organisation International Reference standards (W.H.O. Techn. Rep. Ser. No. 463, 1971).

REFERENCES

1. Harris, A. & Coleman, M. B., (Eds). 'Diagnostic Procedures and Reagents', (4th Edition). Amor, Pub, Health Ass, Inc., New York, (1963)
2. Harris, A., et al. *J. Ven. Dis. Information*. **27**, 169, (1946)
3. Harris, A., et al. *J. Ven. Dis. Information*, **29**, 72 (1948)
4. 'Manual of Tests for Syphilis', P.H.S. Publication No. 411, U.S. Govt. Printing Office (1969)

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