VDRL Antigen Test

IVD *For In-Vitro and professional use only*
Store at 2- 8°C

INTENDED USE

Venereal Disease Research Laboratory test (VDRL) Antigen Test is intended to be used to measure the plasma reagin of patient affected by syphilis based on the slide agglutination test for qualitative and semi-quantitative detection.

INTRODUCTION

The Venereal Disease Research Laboratory test (VDRL) is a blood test for syphilis that was developed by the eponymous lab. The VDRL test (which has a high sensitivity) is used to screen for syphilis, while other, more specific tests are utilized to diagnose the condition.
VDRL is a non-treponemal serological screening of syphilis and is also used to assess response to treatment, detect central nervous system involvement, and assist in the diagnosis of congenital syphilis. The basis of the test is that an antibody produced by a patient with syphilis reacts with an extract of ox heart (diphosphatidyl glycerol). It able to detect anti-cardiolipin antibodies (IgG, IgM or IgA), visualized through foaming of the test tube fluid, or "flocculation".

PRINCIPLE OF THE TEST

The VDRL test is a non-treponemal slide agglutination test used to detect plasma reagin qualitatively and semi-quantitatively. The antigen suspension, a lipid complex, is agglutinated when mixed with samples containing reagin of patient affected by syphilis.

REAGENT PREPARATION & STABILITY

- The reagents are ready to use
- All components of the kit are stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use.
- Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
- Do not freeze. The freezing of VDRL antigen may cause a loss of its functionality.

SAMPLES FOR TESTING

- Use fresh serum or plasma. Stable 7 days at 2-8ºC or three months at -20ºC.
- The samples with presence of fibrin should be centrifuged before use.
- Do not use highly hemolized or lipemic samples

MATERIALS

MATERIAL PROVIDED

- 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).
- VDRL Positive Control (Optional).
- VDRL Negative Control (Optional).

MATERIAL NEEDED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 180 r.p.m.
- Glass slides.
- Light microscope (10x objective lens).
- Pippetes 50 µL.
- Saline Solution.
- Stirring Sticks.

PROCEDURE

A. QUALITATIVE METHOD

1. Bring reagents and samples to room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place (50 µL) of the sample, positive control, and negative control on each slide circle.
3. Gently swirl the VDRL suspension before use and add one drop (20 µL) of this reagent into separate circle on the slide test.
4. Mix the drops with different stirring sticks for each sample; spreading them over the entire surface of the circles or place the slide on a mechanical rotator at 160-180 r.p.m. for 4 minutes. False positive results could appear if the test is read later than 4 minutes.

B. SEMI-QUANTITATIVE METHOD

1. Make serial two-fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

READING OF RESULT AND INTERPRETATION

Examine the presence or absence of agglutination immediately after rotation using the light microscope (10x objective lens).

INTERPRETATION

Negative	Finely dispersed particles with no clumping
Weak Positive	Finely dispersed particles with some clumping
Positive	Medium and large clumps, the clumps are usually fairly uniform in size.

In the semi-quantitative method, the titer is defined as the highest dilution showing a positive result

INTERFERENCES

- Haemoglobin (10 g/L)
- Bilirubin (20 mg/dL)
- Lipids (10 g/L)
- Rheumatoid factor (300 IU/mL)

Other substances may interfere.

PROCEDURES LIMITATIONS

- VDRL test is non-specific for syphilis. To confirm the results, all Reactive samples should be retested using treponemic procedures like as TPHA and FTA-Abs.
- A Non-Reactive result by itself does not exclude a diagnosis of syphilis.
- False positive results have been reported in diseases such as infectious mononucleosis, viral pneumonia, toxoplasmosis, pregnancy, and autoimmune diseases.

QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
- Results that differ from the results of negative controls are considered positive.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity:
Accurate titer determination of the Reference Material, under the described assay conditions.

PROZONE EFFECT
No prozone effect was detected up to titers ≥ 1/128.

SENSITIVITY
100 %.

SPECIFICITY
100 %.

PRECAUTION

1. This reagent is for in vitro diagnostic and professional use.
2. Protective equipment should be worn when handling the reagents. Washing the area of contact with water immediately if contact occurs.
3. Do not pipette by mouth. Flash with water if contact occurs.
4. Specimens should be considered infectious and handled appropriately.
5. Do not use the reagents if damaged and discard the contents immediately.
6. Test materials and samples should be discarded in biohazards container.
7. Wash hands and the test table top with water and soap once the testing is done.

REFERENCES

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4. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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