Atlas Medical CE

VDRL Antigen Test

IVD *For In-Vitro diagnostic and professional use only*

Store at 2 to 8°C

INTRODUCTION

The Venereal Disease Research Laboratory test (VDRL) is a blood test for syphilis that was developed by the eponymous lab. The VDRL test is used to screen for syphilis (it has high sensitivity), whereas other, more specific tests are used to diagnose the disease.

The VDRL is a nontreponemal serological screening for syphilis that is also used to assess response to therapy, to detect central nervous system involvement, and as an aid 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 therefore detects anti-cardiolipin antibodies (IgG, IgM or IgA), visualized through foaming of the test tube fluid, or "flocculation".

PRINCIPLE OF THE METHOD

The VDRL test is a non-treponemal slide agglutination test for the qualitative and semi-quantitative detection of plasma reagins. The antigen suspension, a lipid complex, is agglutinated when mixed with samples containing regains of patient affected by syphilis.

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.

STORAGE

- All the kit components will remain 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.

PREPARATION

The reagents are ready to use

PRECAUTION

1. This reagent is for in vitro diagnostic and professional use.
2. Protective clothing should be worn when handling the reagents. Also 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.

SAMPLES FOR TESTING

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

PROCEDURE

QUALITATIVE METHOD

1. Allow the reagents and samples to reach 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. Swirl the VDRL suspension gently before using 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.

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

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.
- All result different from the negative control result, will be considered as a positive.

PERFORMANCE CHARACTERISTICS

1. **Analytical Sensitivity:** Accurate titer determination of the Reference Material, under the described assay conditions.
2. **Prozone effect:** No prozone effect was detected up to titers ≥ 1/128.
3. **Diagnostic sensitivity:** 100 %.
4. **Diagnostic specificity:** 100 %.

INTERFERENCES

Bilirubin (20 mg/dL), haemoglobin (10 g/L) and lipids (10 g/L) do not interfere. Rheumatoid factor (300 IU/mL) interferes. Other substances may interfere.

LIMITATIONS OF THE PROCEDURE

- VDRL test is non-specific for syphilis. All Reactive samples should be retested with treponemic methods such as TPHA and FTA-Abs to confirm the results.
- 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.

REFERENCES

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

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry