# VDRL Antigen Test

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

2°C 8°C Store at 2 to 8°C CE

## INTENDED USE

**VDRL Reagent used for** qualitative and semi-quantitative determination of regains in human serum or plasma.

## 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 specimencontaining regains of patient affected by syphilis.

## KIT COMPONENTS

### Material Provided

- VDRL Antigen (Solution containing 0.3 g/L cardiolipin; 2.1 g/L lethicin and 9 g/L cholesterol in 1.5 mmol/L phosphate buffer. Preservative, pH 7.0. **(Mix gently before use)**.
- VDRL Positive Control (Optional) (Artificial serum with a regain titer ≥ 1/8.
- VDRL Negative Control (Optional) (Animal serum, Preservative.

### 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.

### Packaging Contents

**REF 8.00.20.0.0250: 1x5 ml VDRL Reagent.**

**REF 8.00.20.1.0250: 1x5 ml VDRL Reagent, 1x0.5 ml Positive Control, 1x0.5 ml Negative Control.**

**REF 8.00.20.0.0500: 1x10 ml VDRL Reagent.**

**REF 8.00.20.0.2500: 1x50 ml VDRL Reagent.**

**REF 8.00.20.1. 2500: 1x50 ml VDRL Reagent, 1x3 ml Positive Control, 1x3 ml Negative Control.**

## REAGENT STORAGE AND STABILITY

- 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.

## PRECAUTION

- This reagent is for *in vitro* diagnostic and professional use.
- Protective clothing should be worn when handling the reagents. Also washing the area of contact with water immediately if contact occurs.
- Do not pipette by mouth. Flash with water if contact occurs.
- Specimen should be considered infectious and handled appropriately.
- Do not use the reagents if damaged and discard the contents immediately.
- Test materials and specimen should be discarded in biohazards container.
- Wash hands and the test table top with water and soap once the testing is done.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.

## COLLECTION, HANDLING AND PREPARATION OF THE SPECIMEN

- Serum specimen shall be collected using plain tube (no Anticoagulant).
- Plasma specimen shall be collected using EDTA or sodium Citrate anticoagulant tubes.
- Specimen with presence of fibrin should be centrifuged before use.
- Do not use highly hemolized or lipemic specimens.
- Avoid repeated freezing and thawing of the specimens. Turbid specimen should be clarified by centrifugation prior to use.

## SPECIMEN STORAGE AND STABILITY

- Fresh serum or plasma. Stable 7 days at 2-8ºC or 3 months at -20ºC.
- Frozen specimen should be totally thawed and brought to room temperature before testing.

## REAGENT PREPARATION AND IN USE STABILITY

All reagent is ready to use.

## PROCEDURE

### QUALITATIVE METHOD

1. Allow the reagents and specimen to reach room temperature. **The sensitivity of the test may be reduced at low temperatures**.
2. Place **(50 µL)** of the specimen, and **one drop** of positive and negative controls on each slide circle.
3. Mix the VDRL reagent gently before using and add **one drop (20 µL) of this reagent** into each circle on the slide test.
4. Mix the drops with different stirring sticks for each specimen; 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 specimen in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

## INTERPRETATION OF THE RESULT

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

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|---|---|
| Non-Reactive (Negative) | No Clumping or very slight roughness |
| Weakly Reactive (Weak Positive) | Small clumps |
| Reactive (Positive) | Medium or 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.

**LIMITATIONS OF THE TEST AND INTERFERE FACTORS**

- VDRL test is non-specific for syphilis. All Reactive specimen 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.

**PERFORMANCE CHARACTERISTICS**

- Analytical sensitivity: Accurate titer determination of the Reference Material, calibrated against the international Reference WHO (1st Standard human syphilitic Serum, ref. 05/132).
- **Diagnostic Sensitivity and Specificity:** Atlas VDRL antigen reagent compared with reference microplate agglutination *treponemal* test. The results show the sensitivity and specificity are 100%, Compared with commercial syphilis reagent (RPR). The result show a sensitivity of 96% and specificity of 100%.
- **Prozone effect:** No prozone effect was detected up to titers ≥ 1/128.
- **Interferences:**
  - Bilirubin (20 mg/dL), Hemoglobin (2 g/dL), Intra-lipids (1000 mg/L, Do not interfere
  - Rheumatoid factor (300 IU/mL) interferes.
  - Other substances may interfere[4].

**REFERENCES**


- George P. Schimid. Current Opinion in Infectious Diseases 1994; 7: 34-40.
- Sandra A Larsen et al. Clinical Microbiology Reviews 1995; 8 (1): 1-21.
- Sandra Larsen et al. A manual of Test for Syphilis American Public Health Association 1990: 1-192.
- 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 |