CHRONOLAB

CE
IVD

VDRL stabilized

Slide agglutination

Qualitative determination of plasma reagins

PACKAGING

Ref.: 101-0382	Cont.: 250 tests-5 mL VDRL stabilized antigen; 1 mL control +; 1 mL control -

Store at 2 - 8º C.

CLINICAL SIGNIFICANCE

Reagins are a group of antibodies against some components produced in the damage tissues from patients infected by *Treponema palladium,* the agent which causes the syphilis. This microorganism produces some damage to the liver and heart, releasing some tissue fragments. Immunological patient system reacts producing regains, antibodies against these fragments.
The assay is useful to follow the antibiotic therapy answer.

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 reagins of patient affected by syphilis.

REAGENTS

VDRL antigen stabilized	Solution containing cardiolipin 0.3 g/L, lecithin 2.1 g/L and cholesterol 9 g/L in phosphate buffer 1.5 mmol/L. Preservative, pH 7.0.
Control + Red cap	Artificial serum with a reagin titer ≥ 1/8.
Control - Blue cap	Animal serum. Preservative

PRECAUTIONS

Control +: H319- Causes serious eye irritation.
Follow the precautionary statements given in MSDS and label of the product.

CALIBRATION

The sensitivity is calibrated against the International Reference WHO (1st Standard Human Syphilitic Serum, ref. 05/132).

PREPARATION

The reagents are ready to use.

STORAGE AND STABILITY

All the kit components will remain stable until the expiration date printed on the label, when stored tightly closed at 2 - 8º C and contaminations are prevented during their use. Mix reagents gently before use.
Do not freeze. The freezing of VDRL antigen may cause a lost of its functionality.

ADDITIONAL EQUIPMENT

- Mechanical rotator with adjustable speed at 180 r.p.m.
- Glass slides
- Light microscope (100 x)
- Pippetes 50 µL.

SAMPLES

Fresh serum or plasma. Stable 7 days at 2 - 8º C or three months at -20º C.
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 and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Swirl the VDRL suspension gently before using and add 20 µL of this reagent onto each sample.
4. 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 en 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method

READING AND INTERPRETATION

Examine the presence or absence of agglutination immediately after rotation using the light microscope (100 x).

Interpretation

Agglutination	Reading	Report
Medium or large clumps	R	Reactive
Small clumps	W	Weakly reactive
No clumping or very slight "roughness"	N	Non Reactive

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 (see, Calibration).
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 (2 g/dL) and lipids (1000 mg/dL), do not interfere. Rheumatoid factor (300 IU/mL) interferes. Other substances may interfere[4].

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.

BIBLIOGRAPHY

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