

IVD
Store at 2 - 8°C.
Ref 22172 VDRL kit
1500 t
6 x 0,5 ml VDRL Antigen
30 ml Buffer
pos and neg control 1 ml



VDRL

VDRL

Slide agglutination

Syphilis Serodiagnostic. Test by flocculation on slide

PRINCIPLE OF THE METHOD

VDRL Antigen is a non treponemal preparation specially developed for the rapid detection and semi-quantification by coagulation on a slide of plasma reagins, a group of antibodies detected against tissue components produced by almost every patient infected with *Treponema pallidum*.

The assay is performed by testing the antigen, an association of lecithin, cardiolipin and cholesterol, against unknown samples. The presence or absence of a visible flocculation or agglutination indicates the presence or absence of circulating antibodies in the samples tested.

The test permits a rapid screening of a large number of samples so that reactors can be give immediate treatment. In the particular case of blood banks the test allows the quick identification of all serological reactive blood samples

REAGENTS

VDRL Antigen: Alcoholic solution containing –cardiolipin 0.3 g/L, lecithin 2.1 g/L and cholesterol 9 g/L.-

VDRL Buffer: Phosphate buffer 1.5 mmol/L. Preservative, pH 6.0.

Control +: Artificial serum with a reagin titer $\geq 1/8$.

Control -: Animal serum. Preservative.

PRECAUTIONS

Control +: Corrosive (C): R35: Causes severe burns. S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S37/39: Wear suitable gloves and eye/face protection.

CALIBRATION

The reagent sensitivity is calibrated against the "Human Reactive Serum" from CDC (Center for Disease Control).

ADDITIONAL EQUIPMENT

- stop watch
- clear glass slides
- mechanical rotator adjustable to 180 rpm.
- light microscope 100X

PREPARATION

Antigen suspension:

1. Bring the VDRL antigen and Buffer to room temperature (23-29°C).
2. Place 0.4 mL of VDRL buffer into a 25 mL glass flat bottomed bottle.
3. Using a glass pipette, add 0.5 mL of VDRL antigen, drop by drop onto the VDRL diluent while continuously and vigorously rotating the bottle on a flat surface.
4. After addition keep on shaking the bottle during 10 more seconds.
5. Add 4.1 mL of VDRL buffer, allowing to flow down the side of the bottle.
6. Put the cap on the bottle and shake it vertically approximately 30 times in 10 seconds
7. Let the suspension stand for 5 minutes. The antigenic suspension is ready to be used. Shake gently before use.

More or less antigenic suspension can be prepared, but always keeping just the same proportions

STORAGE AND STABILITY

All kit reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8°C and contaminations are prevented during their use.

Prepared VDRL antigen suspension remains stable for 24 hours at 15 - 25°C. Do not freeze.

If turbidity or precipitation has occurred the reagent should be discarded.

SAMPLES

Fresh serum, plasma or cerebrospinal fluid. Stable 7 days at 2 - 8°C or three months at -20°C.

The samples with presence of fibrin should be centrifuged before use. Do not use highly hemolyzed or lipemic samples.

PROCEDURE

Qualitative method

1. Bring the test reagents and samples to room temperature
2. Place 50 μ L of the sample and one drop of each Positive and Negative controls into separate circles on the slide test
3. Shake gently the antigen suspension before using and add 20 μ L of this reagent onto each sample.
4. Place the slide on a mechanical rotator at 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 AND INTERPRETATION

Examine the presence or absence of agglutination immediately after rotation using the light microscope.

POSITIVE REACTION : Marked and intense visible aggregates are seen. Serum sample is reactive.

SLIGHT POSITIVE REACTION : Slight but definite small aggregates are seen. Serum sample weakly reactive.

NEGATIVE REACTION : The mixture remains in a smooth suspension with no visible aggregates. Serum is 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.

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 % (primary syphilis) and 100% (secondary syphilis).
4. **Diagnostic specificity**: 100 %.

INTERFERENCES

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

NOTES AND LIMITATIONS

The sensitivity of the test may be reduced at low temperature. The best results are achieved between 23° and 29°C.

With cardiolipin type antigens biological false positive reactions have been reported in diseases such as infectious mononucleosis, viral pneumonia, pregnancy, toxoplasmosis and autoimmune diseases

VDRL test is non-specific for syphilis. This test should be seen as a screening test and results should be confirmed with a treponema test. A negative result by itself does not exclude a diagnosis of syphilis.

Langdorp, 09.2012