VDRL Antigen MR CE

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REF	2540005 VDRL Antigen MR	250 Tests
For *in vitro* diagnostic use only		

VDRL Antigen MR

Determination of plasma reagins

SLIDE TEST

PRINCIPLE

The assay is a modified VDRL Test. The VDRL Antigen MR is a non-treponemal preparation specially developed for the rapid detection and semi-quantitation by flocculation on a slide of plasma reagins, a group of antibodies directed against tissue components produced by almost every patient infected with *T. pallidum*.
The assay is performed by testing the antigen –an association of lipid complexes and choline chloride- against not inactivated samples. The presence or absence of a visible agglutination indicates the presence or absence of circulating antibodies in the samples tested[1,2].

REAGENT COMPOSITION

R — **VDRL Antigen MR**. Stabilized suspension containing 0.03 g/L cardiolipin, 0.22 g/L lecithin, 0.9 g/L cholesterol, 100 g/L choline chloride, 0.0125 mol/L EDTA in 0.01 mol/L phosphate buffer. Contain 0.95 g/L sodium azide.

Optional

CONTROL + — **RPR-VDRL Positive control.** Immune human serum. Contains 0.95 g/L sodium azide. Ref. 2925105

CONTROL - — **RPR-VDRL-TPHA Negative control.** Animal serum, non reactive with plasmatic regains. Contains 0.95 g/L sodium azide. Ref. 2925805

Precautions: Components of different human origin have been tested and found to be negative for the presence of antibodies anti-HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.
The reagents in this kit contain sodium azide. Do not allow to contact with skin or mucous membranes.
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PACKAGING CONTENTS

REF 2540005, kit 250 tests
1 x 4.25 mL VDRL Antigen MR, 1 dispensing needle.

STORAGE AND STABILITY

Store at 2-8ºC in the dark.

Antigen VDRL and Controls are stable until the expiry date stated on the label when stored tightly closed and contaminations are prevented.

REAGENT PREPARATION

Gently shake the VDRL MR reagent to obtain a thorough mixing; attach the dispensing needle to the dispensing vial (Note 4).

SAMPLES

Serum or plasma, not inactivated or spinal fluid, collected by standard procedure. Hemolyzed and lipemic samples should not be used. Samples containing fibrin should be centrifuged before the assay.
Sample stability: 1 week at 2-8ºC or 1 month at -20ºC.

MATERIAL REQUIRED

- Glass slides with circles of 14 mm diameter.
- Automatic pipettes.
- Saline solution 9 g/L
- Mechanical rotator, adjustable at 180 r.p.m.
- Laboratory alarm clock.
- Microscope (100x).

PROCEDURE

I. Qualitative Test in serum or plasma

1. Bring the reagents and samples to room temperature (Note 1)
2. By means of an automatic pipette place 50 µL of each sample into a separate circle on the glass slide. Use a separate tip for each sample. Place 1 drop of each Positive and Negative Control into two additional circles.
3. Gently shake the dispensing vial and holding the vial in vertical position, slightly press to remove air bubbles from the needle and the drop obtained is correct.
4. Place the needle in a *vertical position perpendicular* to the slide (Note 2). Press gently the dispensing vial and deliver 1 drop (20 µL) of antigen to each circle next to the sample to be tested.
5. Mix the contents of each circle with a disposable stirrer and spread over the entire area enclosed by the ring. Use separate applicators for each mixture.
6. Place the slide on a mechanical rotator and rotate at 180 r.p.m. for **4 minutes**.
7. Observe visually for flocculation and results confirmed by microscopic examination (100x).

Reading

Nonreactive reaction: Absence of visual aggregates (flocculation). Homogeneous suspension.

Reactive reaction: Presence of aggregates (flocculation), that may vary between a weak (W) but clearly defined, and a well-marked and strong (R) flocculation.

II. Qualitative Test in spinal fluid

1. Dilute 1/2 the VDRL MR in ClNa 9 g/L and transfer the diluted solution to the dispensing vial (Note 3).
2. Proceed in a similar way as the steps 2 to 5.
3. Place the slide on a mechanical rotator and rotate at 180 r.p.m. for **4 minutes**.
4. Observe visually for flocculation and results confirmed by microscopic examination (100x).

Reading

Same as in Qualitative Test in serum

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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III. Quantitative Test (serum)

1. For each specimen to be tested place with an automatic pipette 50 µL of ClNa 9 g/L solution into each of 5 circles on the reaction glass slide.
2. To circle one, add 50 µL of specimen to the ClNa 9 g/L solution and, using the same tip, mix the solution with the sample by repeated aspiration and expulsion of the fluid and transfer 50 µL of the mixture to the ClNa 9 g/L solution in the second circle.
3. Continue with the 2-fold serial dilutions in a similar manner up to the fifth circle, and discard 50 µL from this circle. Final sample dilutions will be: 1:2, 1:4, 1:8, 1:16, and 1:32.
4. Test each dilution as described in steps 2-7 for the Qualitative Test (serum).

Reading

Same as in Qualitative Test (serum). The titer of the specimen is reported as the highest dilution that shows reactivity. The next higher dilution should be negative. If the highest dilution tested is reactive repeat the test starting with a preliminary 1:16 dilution. Use a 1:50 dilution of the negative control sera in ClNa 9 g/L solution to replace the diluent in the new 2-fold dilution series.

QUALITY CONTROL

Positive and negative controls should be run daily following the steps outlined in the Qualitative Test, in order to check the optimal reactivity of the antigen.
Positive control should produce clear flocculation. If the expected result is not obtained, do not use the kit.
Negative Control should not produce ant flocculation.
If the expected result is not obtained, do not use the kit.
Each laboratory should stablish its own Quality Control Scheme and correction actions if controls do not meet the acceptable tolerances.

CLINICAL SIGNIFICANCE[3]

Syphilis is caused by infection with the bacterium *Treponema pallidum* which can be transmitted congenitally or by sexual contact. The VDRL MR test permits a rapid screening of large numbers of persons so that reactors can be given treatment.
VDRL MR test has a high diagnostic value on a tentative diagnosis made on the basis of case history and clinical findings. VDRL MR test only provides a prelaminar analytical result. But, all positive samples should be confirmed performing treponemal tests such as TPHA or FTA-ABS.

PERFORMANCE CHARACTERISTICS

- Analytical sensitivity is equivalent to that observed when using a VDRL Reagent against "Human Reactive Serum" from Center for Diseases Control (CDC), Atlanta, GA, USA.
- Diagnostic specificity: 98%.
- Diagnostic sensitivity: 78% (primary syphilis) and 100% (secondary syphilis).
- Hemolyzed serum and lipemic serum interfere with the assay. Other substances may interfere[4].
- Results obtained with this reagent did not show significant differences when compared with reference reagents. Details of the comparison experiments are available on request.

LIMITATIONS OF PROCEDURE

- Biological false negative reactions can occur in early primary infections and in late latent stages of disease, or as consequence of prozone effect. A negative result in a patient suspected to suffer syphilis, should re-tested with a quantitative method in order to discard the prozone effect.
- With cardiolipinis tests, biological false positive reactions have been reported in diseases such infectious mononucleosis, lupus erythromatosis, hepatitis, brucellosis, malaria, leprosy, measles, viral pneumonia, and other infections. Pregnancy, narcotic addiction and autoimmune diseases also may give false positive reactions.

NOTES

1. The Test sensitivity may be reduced at low temperatures. The optimal results are obtained between 20 at 25ºC.
2. It is extremely important to maintain the dispensing needle vertically at 90º to the reaction card. If this is not adhered to, it is possible to dispense an insufficient amount of antigen due to splattering resulting from air in the needle.
3. The diluted VDRL MR must be used within 2 hours from the reagent preparation.
4. At the end of each day's testing, the needle should be removed, rinsed with distilled water and air dried. Place the needle back in the plastic sleeve.

SOURCES OF ERROR

- The circles of the test slides should never be touched with the fingers since the oil on the fingers may prevent an even spreading of the sample.
- Do not perform the test near heating systems or air conditioners to avoid false positive reactions, high temperature may cause test components to dry on the glass slide giving a flocculation aspect that can be interpreted as false positive results.
- Rotator malfunction and outdated or contaminated Reagents may lead to false negative results.

REFERENCES

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