RPR TEST

(VDRL TEST)

Rapid Plasma Reagin Test

BIO LAB DIAGNOSTICS
ISO 9001:2015
ISO 13485:2016
CE

CLINICAL SIGNIFICANCE

In Treponema pallidum infection an antibody complex called *Wassermann antibody* or Reagin appear in the serum after 4-6 weeks. A positive reactivity of RPR antigen indicates presence of syphilitic reagin which is commonly found in treponema pallidum infection. The test may be found negative after 6-12 months after treatment of primary Syphilis and 12-18 months in secondary Syphilis.

PRINCIPLE

RPR (Rapid Plasma Reagin) test is based on a reaction between syphilitic Reagin found in serum of the patient during treponema pallidum infection with a nontreponimal antigen containing cardiolipin tagged with micronized carbon particle (5-10 micron particle size) resulting in a clear flocculation of black carbon particles in case of syphilitic antibody in that serum. The addition of choline chloride inactivate nonspecific reactive antigens thus eliminates heat inactivation.

REAGENTS AND ACCESSORIES

1. **Negative Control**
   Non human sera
   Contains preservatives and stabilizers.
2. **Positive Control**
   Reactive Synthetic Control
   Contains preservatives and stabilizers.
3. **RPR Antigen**

Cardiolipin	0.03 G/L
Lecithin	0.40 G/L
Cholesterol	0.85 G/L
Carbon particle	0.05 G/L
NaCl	10.00 Gs/L
Phosphate buffer	10 mMol/L

Contain stabilizer and preservatives.

4. RPR test cards with circles	QS*
5. Disposable mixing rods	QS*
6. Sample dispensing Device	QS*
7. Antigen dispensing Device	1
8. Rubber teat	1
9. Pack insert	1

*QS= Quantity sufficient to perform number of test marked on each kit

Working Reagent Preparation

All reagents are ready to use.

STORAGE AND STABILITY

When stored at 2-8^{0}C and protected from light, the reagents are stable until the expiry date stated on the label.

CROSS REACTIVITY

Cross reactivity with RPR reagent is found in certain cases of acute viral infection, acute Rheumatoid Arthritis, toxoplasmosis, infectious mononucleosis, lupus erythematosus, autoimmune diseases, leprosy, malaria and patient with heroin addition.

SAMPLE

Fasting Sample is not mandatory. Fresh Serum, Plasma (EDTA or Heparin) or CSF Preferred. Avoid contaminated or hemolysed samples. Centrifuge if necessary to avoid

QUALITATIVE PROCEDURE

Preparation of Accessories

1. Clean RPR Test Card with Distilled Water and dry at air.
2. Assemble Sample dispensing Device to the rubber teat.

Mark 3 circles of RPR Card	Control Negative	Test Sample	Control Positive
1. Add negative control (Reagent No.1)	1 Drop	-	-
2. Add Test sample using disposable sample dropper	-	1 Drop	-
3. Add positive control (Reagent No.2)	-	-	1 Drop
4. Add well mix RPR reagent (Reagent No.3)	1 Drop	1 Drop	1 Drop

5. Mix the antigen and spread out fluid on entire area of the circle using separate disposable stick for each circle. Place the Test Card over a flat surface or a VDRL rotator and gently rotate for 7 minutes. Do not allow to dry out the fluid.

6. Compare test with positive and negative control under a bright light source for clumping of carbon particle. If the test is positive proceed with a quantitative test given as under.

RPR QUANTITATIVE PROCEDURE

RPR reactive (positive) sample should be screened for quantitative titer at a progressive dilution.

PROGRESSIVE DILUTION

Label 5 Circles of RPR Card	1	2	3	4	5
1. Add normal saline (0.9%)	1 drop	1 drop	1 drop	1 drop	1 drop
2. Add sample; mix with same pipette ..... and transfer to circle No.2 ; mix and repeat transferring one drop each to next circle till circle No. 5 and discard last drop.	1 drop	↳ 1 drop	↳ 1 drop	↳ 1 drop	↳ 1 drop → discard
3. Add RPR Antigen (Reagent No.3)	1 drop	1 drop	1 drop	1drop	1 drop
Corresponding dilution	2	4	8	16	32

Mix the antigen and spread out fluid on entire area of the circle using separate disposable stick for each circle. Place the Test Card over a flat surface or a VDRL rotator and gently rotate for 7 minutes. Do not allow to dry out the fluid. Observe the circle under a bright light source for clumps of carbon particles and its corresponding dilution.

RESULTS

Normal patient serum may contain minute quantity of circulating reagin which may show a very week reaction on undiluted serum. In such cases the test can be confirmed by a dilution of 1:1 and screened for reactivity. A positive result should be confirmed by the dilution method given above. Distinct clumps (flocculation) of carbon particle can be reported as reactive (positive). Report the dilution of circle showing visible agglutination as reactive or positive (Example "VDRL reactive up to 1:16 dilution of serum" in case of clumps found up to 4th circle and no clumps found there after).

LIMITATION

This test is primarily a screening procedure. As with all diagnostic methods, the final diagnosis should not be made on the result of a single test as well as laboratory diagnosis must be confirmed with clinical manifestation.

WARNING

All reagents and sample should be handled as potential infective agents as no laboratory methods make conclusive finding for its safety. Therefore, adequate protective laboratory measures should be taken while handling such materials.

BIBLIOGRAPHY

1. Syphilis, a Synopsis, 1968, Veneral Disease Program, NCDC. Public Health services Publication No.1660, Washington D.C., 1968.
2. Manual of tests for syphilis, 1969, PHC Publication No. 411 Atlanta, Center for Disease Control.
3. Tuffanelli, D.L., Wuepper, K.D., Bradford, L.L., and Wood, R.M.:N.Engl. J.Med. 276:258, 1967.
4. Burns, R.E.: J.A.M.A. 234:617, 1975.
5. Drew, F.L., and Sarandria, J.L.: J.Am. Verier. Dis. Assoc. 1:165, 1975.
6. Portnoy, J., Garson, W., and Smith, C. A.: Public Health Rep. 72:761, 1957.
7. Portony, J., Bossak, H.N., Falcone, V.H., and Harris, A.: Public Health Rep. 76:933, 1961.
8. Portony, J.: Am. J. Clin. Pathol. 40:473, 1963.

BIOLAB DIAGNOSTICS (I) PVT. LTD.
J-245, MIDC, Tarapur, Boisar – 401 501, MS. INDIA.
E-mail : biolab@vsnl.com / www.biolabdiagnostics.com
Customer Care : (+ 9122) 28088243

Revised 27.3.2015 KI