RPR (RAPID PLASMA REAGINS)

METHOD - IMMUNO AGGLUTINATION
PRODUCT CODE - AB08 *INSTRUCTIONS FOR USE*

ANAMOL
THE ORIGINAL MAKERS

INTENDED USE: Test for determination of RPR (Rapid Plasma Reagins) in human serum by Slide Test method.

INTRODUCTION

Reagins are a group of antibodies against some components of the damage tissues from patients infected by *Treponema pallidum,* 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 reagins, antibodies against these fragments.

METHOD PRINCIPLE

The RPR Syphilis screening test is a macroscopic non-treponemal flocculation card test for detection and to quantify reagin, an antibody like substrate present in serum or plasma and spinal fluid from syphilitic persons.

REAGENTS

Reagent I - Carbon Antigen Suspension.
Reagent II - Positive Control Serum.
Reagent III - Negative Control Serum.

ACCESSORIES

20G Dispensing Needle, Disposable Test cards, Stirring rods And Sample droppers

SEPCIMEN COLLECTION & STORAGE

Fresh serum or plasma. Stable for 7 days at 2-8 ^{0}C or 3 months at -20 ^{0}C. The samples with presence of fibrin should be centrifuged before testing. Do not use highly haemolysed or lipaemic samples.

REAGENT PREPARATION. STORAGE AND STABILITY

All reagents and controls are ready for use and stable up to the expiry date when stored at 2-8 °C.

PROCEDURE

A. QUALITATIVE TEST:

1. Bring all reagents and samples to room temperature.
2. Using the disposable sample dropper, dispense one drop of serum or plasma onto a separate circle on the test card. Use a fresh disposable sample dropper for each sample. Repeat step 2 using the positive and negative control sera.
3. Using the disposable stirring rod spread the sample over the entire area of the test circle.
4. Mix the carbon antigen well and Place one drop of "free fall" Antigen suspension onto each test specimen using 20G dispensing needle.
5. Place the card on a rotator and rotate for 8 minutes at 100 rpm. Immediately after 8 minutes rotation, read the results macroscopically in good light.

INTERPRETATION OF RESULTS

Reactive: The presence of large aggregates in the centre or the periphery of the test circle.
Weakly Reactive: The presence of small or fine aggregates.
Non-Reactive: Smooth grey appearance with no aggregates visible.

NOTE: All reactive specimens should be retested with the quantitative test procedure to obtain the titre.

B. QUANTITATIVE TEST: FOR EACH SPECIMEN TO BE TESTED

1. Place 50µl of 0.9% saline with a pipette into test circles, numbered 2 to 5. Do not spread saline.
2. Place 50µl of specimen onto test circle 1.
3. Place 50µl of specimen onto the test circle 2. Prepare serial twofold dilutions by drawing the mixture up and down the pipette 5-6 times (avoid any bubble formation). Transfer 50µl from circle 2 to 3, to 4, to 5. Dispose 50µl from circle 5 after mixing.
4. Using a new stirring rod for each specimen, start at highest dilution of serum (circle 5) and spread over entire area of test circle. Proceed to circles 4, 3, 2 and 1.
5. Follow steps 4 to 5 in the Procedure of qualitative test.

INTERPRETATION OF RESULTS

Circle No.	1	2	3	4	5
Dilution	Undiluted	1/2	1/4	1/8	1/16
Reactive 1/2	R*	R	N**	N	N
Reactive 1/8	R	R	R	R	R
Reactive 1/16	R	R	R	R	R

*R = Reactive **N = Non-Reactive
If the last dilution (circle 5) 1:32 is reactive, proceed to test further dilutions of 1:64, 1:128, 1:256 as above.

WARNING

The diagnosis of syphilis should not be made on a single reactive result. Reactive RPR test specimen should be subjected to further confirmation test (TPI<FTA<TPHA).

QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of procedure, as well as a comparative pattern for a better result interpretation.

BIBLIOGRAPHY

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2. Manual of tests for Syphilis (1969). PHS Publication No. 411. McGrew, B.E., Stout, G.W. and Falcone, V.H. Amer, j. Med. Techs. 34:634 (1968).
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SYMBOLS: Read Instruction for use | IVD In Vitro Diagnostic Use Only | Manufactured by | Expiry Date | Storage Temperature

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