

**Qualitative determination of Rapid Plasma Reagins in Serum
Only For In vitro Diagnostic Use**

ORDER INFORMATION

REF	CONT
RPR 50	50 TESTS
RPR100	100 TESTS
RPR250	250 TESTS
RPR 500	500TESTS

CLINICAL SIGNIFICANCE

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.

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.

REAGENT COMPOSITION

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

SAMPLE COLLECTION AND PRESERVATION

Fresh serum or plasma. Stable 7 days at 2-8°C or 3 months at -20°C. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

REAGENT PREPARATION

All reagents are ready to use.

REAGENT STORAGE AND STABILITY

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

ASSAY PROCEDURE

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.

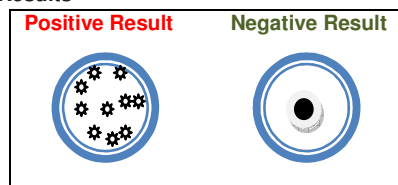
QUALITATIVE TEST RESULTS

Reactive: Characteristic Black clumping of charcoal from slight to intense on a clear background.

Non-Reactive: Black dot of carbon material on center.

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

Results



PROCEDURE: 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.

QUANTITATIVE TEST 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 (circle5) 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

1. Hunter, E.F., W.E. Deacon and P.E. Meyer, 1964. an approved FTA Test for Syphilis, the absorption Procedure (FTA-ABS). PHR 79:410-412.
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).
3. Larsen, S.A., et al, 1981. data on file, Treponemal Research and immunology lab, CDC, Falcone, V.H., G.W. Stout and M.B. Moore, Jr., 1964. PHR 79:491-495.