

CENOGENICS CORPORATION

RPR CARBON ANTIGEN INSTRUCTIONS

INTENDED USE

CENOGENICS' RPR test is a non treponemal slide test for the detection of syphilis in serum or plasma.

SUMMARY AND EXPLANATION

Several serological tests are presently used for detecting antibody in serum and spinal fluid to the etiological agent for syphilis, treponema pallidum. Most of these tests fall into 2 categories, non treponemal and treponemal. Nontreponemal tests include precipitation, flocculation and complement fixation methods which utilize antigens derived from animal tissue extracts (e.g. cardiolipin, lecithin, cholesterol) in alcoholic solution. Treponemal tests include agglutination, fluorescent antibody, treponema immobilization and complement fixation methods which utilize antigens extracted from virulent strains of treponema pallidum.

PRINCIPLES OF THE PROCEDURE

The RPR antigen consists of cardiolipin-lecithin coated cholesterol particles to which has been added fine carbon particles. The serum or plasma of syphilitic patients contains an antibody-like substance called reagin. The principle of the RPR test is a flocculation reaction between the RPR antigen and the reagin. The reaction can be seen macroscopically on the test slide as clumping of the carbon particles.

STORAGE

Store reagents refrigerated at 2° - 8°C.

WARNINGS

1. For invitro diagnostic use.
2. Do not use reagents beyond the stated expiration date.
3. Handle all specimens of human origin as if capable of transmitting disease.

SPECIMENS COLLECTION

Use fresh serum or plasma. If test can not be performed immediately, store specimens refrigerated at 2° - 8°C. For extended storage, specimens should be frozen. Hemolytic, lipemic or contaminated samples should not be tested.

ANTIGEN PREPARATION

The RPR Antigen is dispensed using the dispensing needle and vial provided. To fill the vial, place the needle on the vial tip. Shake the antigen bottle to disperse the particles. Insert the dispensing needle into the RPR antigen, squeeze the bottle and release. The dispensing needle and vial will serve as a suction device. Label the vial with lot number and date. Once the antigen is placed into the dispensing vial, it is stable for 3 months.

QUALITATIVE TEST PROCEDURE

1. Bring reagent and test specimens to room temperature.
2. Using a disposable pipet, deliver one drop (50µl) of each specimen to a circle on the RPR slide.
Hold the pipet in a vertical position and allow the specimen drop to fall freely. With the closed,

flat end of the pipet, spread the specimen over the entire surface of the circle. Use a separate pipet for each specimen.

3. Gently shake the antigen vial. Through the dispensing needle, deliver one drop of antigen (20 μ l) to each specimen. Hold the vial and needle in a vertical position and allow the drop to fall freely. It is not necessary to stir. Mixing will occur during the rotation.
4. Mix on an automated rotator for 8 minutes at 100 rpm.
5. Examine the slide under a bright light for the presence of flocculation (clumping).

INTERPRETATION OF RESULTS

REACTIVE: The presence of flocculation (clumping) indicates a reactive test result

NONREACTIVE: A smooth suspension, showing no flocculation, indicates a nonreactive test result.

SEMIQUANTITATIVE TEST PROCEDURE

1. Dilute the specimen with normal saline (0.09% NaCl) at 1:2, 1:4, etc.
2. Test each dilution of the specimen as described in the **QUALITATIVE TEST PROCEDURE**.
3. The titer is reported as the highest dilution showing a reactive test result.

QUALITY CONTROL

It is recommended that sera of established reactivity patterns be tested daily. The controls should be tested simultaneously and following the same procedure as the patient samples.

EXPECTED VALUES

Serum or plasma specimens that contain antibody to the etiological agent, *Treponema pallidum*, will react to some degree with the RPR antigen.

INTERFERING SUBSTANCES

The following substances were studied at the concentrations stated and found to cause no interference with the test performance:

Bilirubin	0.5 to 20 mg / dl
Hemoglobin	0.63 to 10g / l
Lipids	0.63 to 10g / l
Rheumatoid factor	37 to 300 IU / ml

LIMITATIONS OF THE PROCEDURE

A prozone phenomenon occurs occasionally. This type of reaction is demonstrated when a serum produces a weakly reactive or "rough" nonreactive reaction in the qualitative procedure but a maximum reaction when diluted. It is, therefore, recommended that all sera producing weakly reactive or "rough" nonreactive results in the qualitative test be retested using the semi-quantitative procedure.

Biological false positive may occur in diseases such as respiratory infections, hyperproteinemia, varicella, infectious hepatitis, malaria, leprosy, tuberculosis, lymphopathia venerea, leishmaniasis, lupus erythematosus and scarlet fever. A positive reaction may also occur in pinta, yaw, rate bite spirochetosis, relapsing fever and other spirochetal infections. Narcotic addiction and autoimmune diseases may also produce a positive RPR test.

PERFORMANCE CHARACTERISTICS

The RPR antigen is tested for established pattern against a reference antigen suspension to meet product specifications. However, there are many factors which can affect the performance: equipment, reagents, measurements, time period, and temperature. No changes should be made from the recommended procedure.

REFERENCES

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