Cenogenics

RF LATEX DIRECT TEST

INTENDED USE

Rapid latex agglutination test for the qualitative and semi-quantitative determination of Rheumatoid Factor (anti-gamma globulin).

SUMMARY AND EXPLANATION

Rheumatoid arthritis is a chronic systemic disease of unknown etiology. It is frequently characterized by swelling and pain in the joints and by inflammatory and degenerative processes involving cartilage, synovial membrane or muscle tissue. The disease is widespread in the United States and throughout the world, and is found in all age groups. Most typically, its onset is in young adults in their thirties and forties. While no specific cure has yet been found, early therapy is of great value in halting or minimizing irreversible damage to the joints. For this reason prompt diagnosis is of great importance.

A characteristic of rheumatoid arthritis is the presence in the blood and in synovial fluid of a reactive group of proteins called Rheumatoid Factor.[1,3] These are macroglobulins having a molecular weight of 1 million. In the opinion of many investigators, the Rheumatoid Factors are antibodies directed against "altered" human gamma globulins.[4,5,6] The Rheumatoid Factors are found in 70-100% of cases of definite rheumatoid arthritis depending on the test procedure used to detect them. Because of this widespread incidence of RF, its demonstration is a useful laboratory criterion for the diagnosis of suspected rheumatoid arthritis. By comparison the occurrence of RF in arthritis or rheumatic fever is less than 2 and 3% respectively. It should be noted that incidence of RF have been reported in a variety of nonrheumatic diseases such as pulmonary tuberculosis, bacterial endocarditis and syphilis as well as others. A significant incidence of RF in the aged has also been observed.

Since the discovery of RF, there have been many techniques developed to identify and quantitate these factors. The most generally useful techniques have been agglutination procedures employing polystyrene particles coated with a layer of absorbed human gamma globulin.[7] The RF present in a test serum reacts with the coating material causing a visible agglutination of the inert latex particles. It is this reaction which is the basis of the CENOGENICS' RF TEST.

CENOGENICS' RF TEST SET for the detection of Rheumatoid Factors rapidly and accurately identifies the presence of RF, one of the criteria for the diagnosis of rheumatoid arthritis.

In the presence of Rheumatoid Factor positive antiserum, CENOGENICS' latex-globulin RF reagent can be used to demonstrate agglutination both qualitatively and quantitatively.

PRINCIPLES OF THE PROCEDURE

The principle of the test is an immunologic reaction between the Rheumatoid Factor (RF), a macromolecular molecule globulin found in serum and the corresponding IgG coated onto finely dispersed polystyrene latex particles.

CLIA COMPLEXITY: Moderate

REAGENTS

RF LATEX DIRECT REAGENT: polystyrene latex particles coated with human IgG and suspended in a glycine buffer.

POSITIVE CONTROL SERUM: a stabilized human serum containing rheumatoid factors reactive with the latex reagent.

NEGATIVE CONTROL SERUM: a stabilized human serum nonreactive with the latex reagent.

Note: All reagents are preserved with sodium azide (1mg/ml).

SENSITIVITY

8 IU/ml with a tolerance of 6-16 IU/ml calibrated against the WHO International RA standard.

MATERIALS PROVIDED WITH TEST SET

1. RF Latex Direct Reagent
2. Positive Control Serum
3. Negative Control Serum
4. 6- Well Test Slide
5. Disposable Pipettes
6. Product Instructions

MATERIALS REQUIRED BUT NOT PROVIDED

1. Test Tubes (for quantitative method)
2. Serological Pipettes
3. Laboratory Timer
4. Laboratory Rotator (optional)
5. Isotnic Saline (0.85% sodium chloride, for quantitative method)

STORAGE CONDITIONS

Store at 2° - 8°C.

STABILITY

Expiration date is specified on the label. Biological indication of product instability is evidenced by inappropriate reaction of the latex reagent with the corresponding positive and negative controls.

PRECAUTIONS

1. For invitro diagnostic use.
2. Do not use beyond the expiration date.
3. Handle all specimens of human origin as if capable of transmitting disease.
4. The reagents in this kit contain sodium azide. Sodium azide may react with lead and copper plumbing to form highly explosive metal ozides. Upon disposal, flush with large volume of water to prevent ozide build up.

REAGENT PREPARATION

No reagent preparation is required. Reagents are ready to use.

SPECIMENS

This test should be performed on fresh serum. The samples may be stored refrigerated (2° - 8°C) for a maximum of 7 days. If longer storage is required, store at -20°C. Heavy bacterial contamination may cause positive agglutination. Markedly lipemic sera should not be tested because of the possibility of nonspecific reactions.

TEST PROCEDURE (METHOD I, QUALITATIVE)

1. Bring all reagents and specimens to room temperature.
2. Shake the latex reagent gently, expel the contents of the dropper and refill.
3. Deliver on drop (50 µl) of patient sample to a circle on the test slide. Use a new pipet for each sample.
4. Using the dropper provided, place a drop of the latex reagent next to each specimen on the test slide.
5. Mix each specimen and latex with a disposable stirrer and spread over the entire surface of each circle.
6. Rotate the slide (80 - 100 r.p.m.) for 2 minutes.
7. Examine under a bright light source for the presence of agglutination.

RESULTS

POSITIVE: Agglutination (clumping of the latex particles) indicates a positive result. A weakly reactive serum produces a very fine granulation or partial clumping.

NEGATIVE: The absence of agglutination indicates a negative result.

QUALITY CONTROL

Positive and negative controls should be tested with each series of test sera. The controls supplied by CENOGENICS are to be used exactly as outlined in steps 1 thru 4 above without further dilution.

A positive control will produce coarse agglutinated flocs. A negative control will produce no agglutination. It should be used as a basis for comparison. The relative degree of smoothness of the reagent itself should be considered and incorporated in reading the results.

If the indicated results, using the positive and negative controls are not obtained, the RF Latex Kit should not be used.

TEST POSITIVE (METHOD II, SEMIQUANTITATIVE)

1. Using isotonic saline (0.85% sodium chloride), prepare a serial dilution of the serum starting at 1:2 thru 1:64.
2. Test each dilution as described in the Qualitative Procedure.

RESULTS

The titer is reported as the reciprocal of the highest dilution which gives a visible agglutination.

LIMITATIONS OF THE PROCEDURE

The detection limit of the CENOGENICS' RF Latex Direct Test is 8 IU/ml. In a comparison study between the CENOGENICS' RF Latex Direct Test and a commercially available product, the agreement was 98.8%.

EXPECTED VALUES AND PERFORMANCE CHARACTERISTICS

The clinical significance of RF determination consist in differentiation between rheumatoid arthritis, in which the rheumatoid factor has been demonstrated in the serum of approximately 80% of the cases examined and rheumatic fever in which the rheumatoid factor is almost always absent.[8] The RF is more frequently positive in active processes of greater duration than in diseases which are less active or are still in early stages.

It is occasionally found in the serum of patients with polyarthritis nodosa, systemic lupus erythematosus and a variety of chronic inflammatory illnesses such as tuberculosis, leprosy, syphilis and bacterial endocarditis. Sera tested

from these related diseases showed positive reactions in approximately 6% of tested cases.

Approximately 3.5% of known rheumatoid patients do not react in the screening test, on the other hand, 2% of sera from apparently healthy individuals gave RF reaction.

INTERFERING SUBSTANCES

The following substances, at the concentrations listed below, were added to serum specimens and found to have no effect in the assay results:

Bilirubin	0.5 to 20 mg/dl
Hemoglobin	0.63 to 10g/l
Lipids	0.63 to 10g/l

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Printed in U.S.A.
PG - 0340 - 01