RF LATEX

(Direct Latex Agglutination Test)

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Ref. IS-RF.074, 25 Test
IS-RF.74U, 50 Test
IS-RF.74V, 100 Test

INTENDED USE

Rapid latex agglutination slide test for the qualitative and semiquantitative *in-vitro* determination of Rheumatoid factors (RFs) in undiluted serum for the detection of Rheumatoid Arthritis.

INTRODUCTION

Many of the major rheumatological disorders are autoimmune diseases; Rheumatoid Arthritis is one of them. An antigenic stimulus (antigen unknown) leads to the appearance of an abnormal IgG that results in the production of rheumatoid factors and eventual development of rheumatoid disease. These factors are present in serum and synovial fluid of the subject. The 'RFs' are also known as anti-immunoglobulins.

DIAGNOSTIC SIGNIFICANCE

RFs are almost always absent in rheumatic fever; hence the test is useful in differentiating between rheumatic fever and rheumatoid arthritis.

Latex, positive test shows presence of rheumatoid factors in significant quantities, eventhough Latex negative results do not rule out rheumatoid arthritis. The semiquantitative test will give concentration of these factors and requires an experts interpretation using other clinical findings.

Rheumatoid factors are present in serum from patients of rheumatoid arthritis, SLE, Reiter's syndrome, gout, psoriatic arthritis etc. Positive results may occur, sometimes in various pathological diseases including hepatitis, cirrhosis, lymphomas etc.

PRINCIPLE

Polystyrene Latex particles are coated with purified human globulin (lgG). When a serum with rheumatoid factors is mixed with latex, a distinctly visible, agglutination reaction occurs. In a serum with no such RF factors there will be no agglutination and latex suspension will be smooth and uniform.

PRESENTATION

All the reagents to be stored at 2-8^{0}C	No. of vials/pack 25 Test / 50 Tests / 100 Test
• Latex Reagent	1
• Positive control serum	1
• Test Slides • Mixing Sticks • Plastic Droppers • Glass Droppers	Provided as per pack size

PRECAUTION

1. Drying of the test mixture at the periphery of the circle may lead to erroneous interpretation of results.
2. Read and interpret results exactly at 2 minutes.

REAGENT STORAGE AND STABILITY

The ready to use Latex reagent is stable up to the expiry date printed on the label when stored at 2-8^0 C. DO NOT FREEZE.

SPECIMEN COLLECTION

Fresh serum should be used. Serum sample is stable at - 20^{0}C for 4 weeks. Plasma should not be used as fibrinogen may cause nonspecific agglutination of the latex particles. Do not use lipemic hemolysed or contaminated serum.

TEST PROCEDURE

(A) QUALITATIVE TEST

1. Allow reagent and sample to come at room temperature before use.
2. Mix latex reagent well before use.
3. Identify the circles on the slide.
4. Place approx 25 µl of each sample into the center of the circle marked for the sample on the slide.
5. Mix latex reagent well. Hold the dropper vertical and add equal amount of the latex suspension to each sample or controls. Spread over the circle using separate mixing sticks for each sample.
6. Rock the slide back and forth gently for two minutes or place the slide on an automated rotator at 100 rpm.

PROCEDURE AT A GLANCE
25 µl of sample or control
+
25 µl of RF Latex Reagent

Mix
Rock the slide; observe for agglutination up to 2 minutes

TEST RESULTS

Latex agglutination indicated that the RF (Rheumatoid factor) level is higher than 8 IU/ml.
Sera showing positive results in screening test may subject to semi quantitative test.

(B) SEMI-QUANTITATIVE TEST

Prepare serial dilution 1:2, 1:4, 1:8, 1:16, 1:32 of the positive serum sample using physiological saline (0.9 %). Test the diluted sample using qualitative procedure and check for agglutination.

TEST RESULTS

The approximate RF level in the sample can be calculated as follows.

RF (IU/ml) = D x S
D = Highest dilution showing positive reaction
S = Sensitivity of reagent (8 IU/ml).

SENSITIVITY

The reagent has a sensitivity of 8 IU/ml.

QUALITY CONTROL

The use of positive and negative controls are recommended along with serum sample.

NOTE

As with all diagnostic methods, the final diagnosis should not be made using the result of a single test but should be correlated with other clinical findings.

REFERENCES

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