PATHOZYME DIAGNOSTICS

RAPICHEK RF LATEX

(SLIDE AGGLUTINATION)

CAT No.: RFL

Latex slide test for the qualitative and semi-quantitative determination of Rheumatoid Factor in Serum.

DIAGNOSTIC SIGNIFICANCE:

The human body sometimes produces auto antibodies against the host antigen. The role which this aberrant immunity plays in certain rheumatic disease is unknown but their presence serves as credible marker of the disease. The immunoglobulins of the class IgG, IgM, IgA or IgE, auto antibodies are diagnostically important for Rheumatoid arthritis, which are termed as Rheumatoid Factors (RF) In almost 80% of the patient suffering from Rheumatoid arthritis the RF Test gives positive results where as in case of rheumatic fever RF will yield negative results.

PRINCIPLE:

Polystyrene Latex particles are coated with purified human globulin (IgG). 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.

SPECIMEN COLLECTION:

Fresh serum, in case of a delay in testing, store at 2-8^{0}C. Plasma should not be used as fibrinogen may cause nonspecific agglutination of the latex particles. Haemolysed / lipaemic serum should not be used.

KIT PRESENTATION:

PACK SIZE	25 Test	50 Test	100 Test
Latex Reagent	1 Vial	1 Vial	1 Vial
Positive Control	1 Vial	1 Vial	1 Vial
Negative Control	1 Vial	1 Vial	1 Vial
Glass Slide	1 No	1 No	1 No
Mixing Sticks	25 Nos	50 Nos	100 Nos
Sample Dropper	25 Nos	50 Nos	100 Nos
Latex Dropper	1 No	1 No	1 No

REAGENT STORAGE & STABILITY:

All reagents included in the kit are stable at 2-8^{0}C until the expiry date stated on the label.

PRECAUTION:

1. Bring all the reagents and samples to RT before use.
2. Do not freeze the Latex reagent.
3. Do not use haemolysed or turbid specimen. The use of plasma instead of serum could lead to erroneous results. Drying of the mixture at the periphery of the circle could lead to erroneous results.
4. The Latex reagent should be shaken well prior to use, to ensure a homogeneous suspension of latex.
5. The source material used in the manufacturing of Positive control is tested for HBsAg & HIV antibodies and found to be negative. However, for better safety the control should be handled with proper care.
6. While dispensing Latex reagent, hold the glass dropper vertically to ensure uniform drop size.
7. Positive Control is ready to use & should not be diluted while using in test procedure.
8. Contaminated sera and a longer reaction time beyond 2 minutes may lead to false positive results.
9. As with all diagnostic tests, the final diagnosis should be based on correlation of test results with other clinical symptoms & findings.

PROCEDURE:

(A) Qualitative Method:

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place one drop of the sample and one drop of each positive and negative controls into separate circles on the slide test.
3. Swirl the RF-latex reagent gently before using and add one drop next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Rock the slide gently to and fro for 2 minutes and examine for macroscopic agglutination under direct light source.

Interpretation Of Results:

Agglutination within 1-2 minutes is positive test and indicates presence of RF in the test specimen, no agglutination upto 2 minutes is a negative test and indicates absence of RF in the test specimen.

(B) Semi-quantitative Method:

1. Dilute the specimen serially 1:2, 1:4, 1:8. 1:16 using normal saline.
2. Proceed for each dilution as in the qualitative method.

Interpretation Of Results:

The highest dilution shows positive reaction within 2 minutes indicates the RF titre. The approximate RF concentration can be obtained by multiplying titre by sensitivity of the test.

RF in IU/ml = D X S

D - Highest dilution showing positive reaction

S = Sensitivity of the test is 8 IU/ml.

SENSITIVITY:

The reagent has a sensitivity of 8 IU/ml

LIMITATION:

The Latex agglutination test for Rheumatoid factor has occasionally been found positive with same sera of patients with hepatities, sarcoidosis, cirrhosis of liver, syphilis, systemic lupus erythematosus (SLE), hypergammaglobulinemia, scleroderma, siogren's syndrome, as well as acute bactarial and viral infections.

It is almost always absent in case of Rheumatic fever. The latex agglutination test does not provide definite diagnosis of Rheumatoid arthritis and therefor it should be used only in connection with complete clinical evaluation.

REFERENCE:

1. Scott D et al : Systemic rheumatoid vasculitis: A clinical and laboratory study of 50 cases. Medicine 1981:60-288.
2. Zvaifler NJ : Rheumatoid synovitis : An extravascular immune complex disease. Arthritis Rheum 1974; 17:297.
3. Moore T. Weiss T : Immunologic studies in juvenile arthritis. Bull Rheum Dis 1982; 32 : 25

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Expiry Date | IVD In-Vitro Diagnostics Use | Storage | Mfg. Date | LOT Batch Number | REF Catalogue Number | See Package Insert

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