RF

Latex Slide Agglutination Method

INTENDED USE

For the Qualitative and Semi-Quantitative determination of Rheumatoid Factors in Human Serum.

DIAGNOSTIC IMPLICATIONS

RF is a Chronic Systemic Disease of unknown etiology. It is frequently characterized by Swelling, Pain in the joints, Inflammatory and regenerative processes involving Cartilage, Synovial membrane or Muscle tissue. Rheumatoid factors (RF) are group of proteins present in the Blood and in Synovial fluid of individual having Rheumatoid Arthritis. It is believed that RF are Auto Antibodies produced by human body against RF self or against Human Gamma Globulin. The presence of these Auto Antibodies serve as credible marker of the disease. The clinical significance of RF determination consists of differentiation between Rheumatoid Arthritis in which RF have been demonstrated in the serum of approximately 80% of the cases examined and Rheumatic Fever, in which RF are almost always absent.

PRINCIPLE

The Latex particles are coated with Human Immunoglobulin G (IgG). The specimen containing RF on mixing with Latex Reagent agglutinates showing the Positive test result. If RF are absent there will be no agglutination which is the Negative test result.

STORAGE & STABILITY

All the reagents are to be stored at 2-8°C and are stable till the expiry date mentioned on the labels.
When opened contamination must be avoided.

SPECIMEN

Fresh Serum is the preferred Specimen.
Plasma or Hemolysed / Lipaemic Serum should not be used.

PRECAUTIONS

1. Shake the Latex Reagent Vial properly to get the homogenous Latex Particles before testing.
2. Do not freeze the Latex Reagent.
3. Cap the vial properly after use to avoid drying of the Latex Reagent.
4. Drying of the Samples and Latex Reagent mixture at the periphery of the circle could lead to erroneous results.

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PROCEDURE

A. QUALITATIVE TEST

1) Bring the Latex Reagent, Controls and Specimens to room temperature before use. Shake the Latex Reagent gently to ensure Homogenous Suspension.
2) Place one drop (Approximately 50µL) each of Specimen, Positive Control & Negative Control into the separate circle of glass slide using a separate disposable sample dropper provided in the kit.
3) Add one drop of (Approximately 50µL) Latex Reagent in each of these circles.
4) Mix the contents of each circle separately by the disposable mixing sticks provided and spread it in the entire circle.
5) Rock the slide gently for 2 minutes and look for agglutination.
6) Results should be read at a normal reading distance in good light.
7). **Do not read results after 2 minutes.**

DO NOT USE A MAGNIFYING LENS.

Agglutination with Positive Control and no agglutination with Negative Control validate the test results. Agglutination within 2 minutes is a positive test and indicates presence of CRP in the test specimen.
No agglutination up to 2 minutes is a negative test and indicates absence of CRP in the test specimen.

DO NOT OBSERVE RESULTS AFTER 2 MINUTES.

Interpretation of Results

resultination with Positive Control and no agglutination with Negative Control validates test
Distinct agglutination indicates RF content of more than 12 IU/mL. Sera with Positive results should be retested in the Semi-Quantitative test. Agglutination within 2 minutes is a positive test and indicates presence of RF in the test specimen. No agglutination up to two minutes is a negative test, and indicates absence of RF in the test specimen.

B. SEMI QUANTITATIVE TEST

1) Dilute the specimen serially 1:2, 1:4, 1:8, 1:32, 1:64 using Normal Saline.
2) Place one drop each of diluted serum sample using sample droppers in each circle of glass slide & proceed further as in Qualitative Test (A).

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PRODUCT FEATURES

- Detects RF (Rheumatoid Factors) as low as 8 IU/mL. (Cut off Sensitivity 12 IU/mL).
- Uniform and Homogenous Latex Particles ensure clear Agglutination.
- Qualitative and Semi quantitative procedures included in the same kit.
- Positive and Negative Controls are provided for the proper validation of the kit.
- Positive and Negative controls provided in the kit are free from HIV & HBsAg.
- Sample dilution is not required unlike conventional procedures.
- Incorporates Six Sigma methodologies throughout the manufacturing processes wherein the product under goes various stringent process checks like Defining, Measuring, Analyzing, Improving and Controlling. (DMAIC)
- Avid Agglutination ensures proper discrimination between positive and negative results.
- Cut off sensitivity 8 IU/mL is determined in correlation with Quantitative Turbidometry.
- Latex Reagent Sensitivity 8 IU/mL is calibrated against WHO calibrators.
- Optimum Human Gamma Globulin concentration coated on to the Latex particles overcomes immunological interferences like Prozone Effect and Hook Effect.

INTERPRETATION OF RESULTS

The highest dilution which shows clear cut agglutination within two 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 clear cut agglutination.
S = Sensitivity of the test - 8 IU/mL.

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NOTES

- Positive & Negative Controls are ready to use & should not be diluted while using in test procedure.
- As with all diagnostic tests, the final diagnosis should be based on a correlation of test results with other clinical symptoms & findings.
- In addition to Rheumatoid Arthritis, positive result may also be found in Syphilis, Systemic Lupus Erythematosus, Hapatitis, Hypergammaglobulinemia.
- The source material used in the manufacture of Positive and Negative Controls is tested for HBsAg & HIV antibodies, and is found to be Negative. However, for better safety, these controls should be handled as if they are potentially dangerous.
- **Do not read results after 2 Minutes.**

REFERENCES

1) Sanger, J.M., (1956); Am.J.Med. 21, 888

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