INSTRUCTIONS FOR USE

Rheumatoid Factor (RF) Latex Test

Catalog No. 52029-50, 52029-100

Intended use

The RF Latex Test (RF TEST) is intended to be used for the qualitative screening and semi-quantitative determination of Rheumatoid Factor (RF) in serum as an aid in the diagnosis of Rheumatoid Arthritis (RA).

Summary and Explanation of the Test

RA is a chronic systemic disease characterized by swelling and pain in the joints and by inflammatory and degenerative processes involving cartilage, synovial membrane or muscle tissue. Early therapy helps in minimizing irreversible damage to the joints and prompt diagnosis is crucial. A characteristic of RA is the presence in the blood and in synovial fluid of a reactive group of proteins collectively known as the RF[1,2]. These are macroglobulins having a molecular weight of about one million. In the opinion of many investigators[3] the RF are antibodies directed against "altered" human gamma globulin[4,5,6]. The RF are found in 70-100% of definite RA cases. The occurrence of RF in osteoarthritis or rheumatic fever is less than 2% and 3% respectively. It should be noted that incidence of RF had been reported in non-rheumatic diseases such as pulmonary tuberculosis, bacterial endocarditis, syphilis, as well as others. The principle of this test is based on the immunologic reaction between RF in serum with the IgG coated onto latex particles resulting in visible agglutination.[7]

Test principle

The test kit employes human IgG immobilized onto latex particles. IgG bound particles are combined with patient serum samples to detect the presence of RF. The test kit contains 50 or 100 qualitative tests worth of latex beads coated with human IgG. The test procedure has a single rection step performed by adding the RF Latex suspension directly to the specimen on the Black test card. This mixture is incubated for two minutes by manual (hand held) rocking technique to facilitate agglutination of latex particles in the presence of RF. Reactions are read visually and reported differently for qualitative and semi-quantitative assays. Qualitative assays are reported as a binary positive or negative result for the agglutination of the RF Latex suspension. Semi-quantitative results are reported as an approximate titer value being the inverse of the lowest dilution providing a positive agglutination result.

Contents of the Kit 52029-50

Component	Spec.	Component Description	Qty
RF Latex	2mL	Latex particle coated with human IgG	1
RF Positive Control[1]	0.5mL	Stabilized Human Sera	1
Latex Negative Control[1]	0.5mL	Stabilized Human Sera	1
Glycine Buffer 20X	2mL	Concentrated Glycine Buffer	1
Black Card	Each	Low absorption coated test card	9
0.05mL blunt cut pipet	Each	0.05mL volumetric dispensing pipet	50

Note: Exchange of components from different lots is not allowed. Store all reagents at 2–8°C; do not freeze.

Contents of the Kit 52029-100

Component	Spec.	Component Description	Qty
RF Latex	4mL	Latex particle coated with human IgG	1
RF Positive Control[1]	1mL	Stabilized Human Sera	1
Latex Negative Control[1]	1mL	Stabilized Human Sera	1
Glycine Buffer 20X	2mL	Concentrated Glycine Buffer	1
Black Card	Each	Low absorption coated test card	17
0.05mL blunt cut pipet	Each	0.05mL volumetric dispensing pipet	100

Note: Exchange of components from different lots is not allowed. Store all reagents at 2–8°C; do not freeze.

WARNING – Human Sera

Each donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for the presence of HbsAg and antibody to HIV Virus. However, as no known test method can offer complete assurance that hepatitis B virus, HIV Virus, or other infectious agents are absent, all human serum products and patient specimens should be handled in accordance with good laboratory practices.

Additional Materials and Equipment (not supplied with the test kit)

- Timer
- Tube - minimum volume 500ul
- Micropipettes and associated tips
- Physiological saline

Precautions

Strict adherence to assay instructions is required. Any variation in pipetting technique, incubation time or temperature, and use of reagents beyond the expiry date can cause differences and can affect the results. This product is for In Vitro Diagnostic Use Only. Each donor unit used in this product has been tested by an FDA approved method and found to be non-reactive for the presence of HbsAg and antibody to HIV Virus. Because no known test method can offer complete assurance that hepatitis B virus, HIV Virus, or other infectious agents are absent, all human blood-based products should be handled in accordance with good laboratory practices. The preservative sodium azide may react with metal plumbing to form explosive metal oxides. In disposal, flush with a large volume of water to prevent metal azide build up.

- The kit/reagents should not be used beyond the expiration date on the kit label.
- To avoid cross contamination, disposable pipette tips should be used.
- All reagents and samples should be prepared before starting the procedures.
- If the kit will be used multiple times, ensure the reagents are sealed fully and store components in original kit box at recommended storage temperature.

- Positive and negative controls should be included in each run of the assay.
- Modifications to the kit components or procedures may provide false results.

Specimen Collection

The test should be performed on fresh serum specimens only. If testing is delayed, specimens should be refrigerated (or frozen where applicable). Bacterial contamination may cause protein denaturation and false positive agglutination.

Test Procedure

Reagent Preparation

- All reagents must be brought to room temperature and mixed thoroughly prior to use.
- All specimens must be brought to room temperature and mixed thoroughly prior to use.
- Tightly close unused kit reagents and store at 2–8°C in original kit packaging.
- Do not interchange components of different lots. Do not use reagents beyond the expiration date indicated on labels.
- Dilute Glycine Buffer 20X, 1:20 with water

Sample Preparation

- All specimens must be brought to room temperature and mixed thoroughly prior to use.
- The test should be performed on fresh serum specimens only. If testing is delayed, specimens should be refrigerated (or frozen where applicable). Bacterial contamination may cause protein denaturation and false positive agglutination. Avoid repeated freezing and thawing of samples.

Assay Procedure Qualitative

1. Bring all test reagents and serum specimens to room temperature.
2. Gently shake the RF latex vial to suspend the latex particles.
3. Place one drop of test serum (with disposable pipette) onto a circle on the slide. Use new pipette for each test serum. Deliver one drop of RF Latex to each circle that contains specimens or controls. Use paddle end of pipette to spread the mixture on each circle. Do not use the same paddle end to mix each mixture as this will cause cross-contamination.
4. Gently tilt and rotate the black card by hand for two (2) minutes. Observe the internal area of each reaction oval for macroscopic clumping using an indirect oblique light source.

Assay Procedure Semi-Quantitative

1. For each test serum to be titrated, set up at least six tubes and label 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, etc.
2. To each tube add 0.2 ml of Diluted Glycine Buffer.
3. To Tube No. 1 add 0.2 ml of undiluted test serum.
4. Serially make two-fold dilutions by mixing contents of Tube No. 1 with pipette and transferring 0.2 ml to Tube No. 2. Repeat serial transfers for each tube. For the six tubes, the dilutions range from 1:2 to 1:64. If required, additional serum dilutions can be added. Repeat steps 1 to 4 as given in Assay Procedure Qualitative.

Results

Qualitative

Positive Result: Agglutination
Negative Result: Smooth milky suspension

Since negative results may be caused by antigen excess, the test should be repeated using a diluted serum sample in case prozone effect is suspected.

Semi-Quantitative

Borderline positive results should be retested to provide verification for borderline interpretations. The highest dilution of sample showing agglutination is the endpoint. Multiplication of the dilution factor by 8 IU/ml will yield the approximate RF level (table is only a guide to assist in the interpretation). The table below is only a guide to assist In the Interpretation.

Dilution	Concentration (IU/mL)
Neat (No Dilution)	8
1:2	16
1:4	32
1:8	64
1:16	128
1:32	256

Quality Control

Positive and Negative controls should be included in each test series. The Positive control should produce visible agglutination; and Negative control should produce no agglutination.

Limitation of the Test

The results of this test SHOULD NOT be used as a single diagnostic tool to make a clinical diagnosis. Instead, other clinical findings must be evaluated with other observed symptoms to aid in the final diagnosis. This test is to be performed by hand rotation. The use of a mechanical rotator could yield false positive/negative results. Strength of agglutination in screening test is not indicative of actual RF titer. Reaction time longer than 2 minutes may produce apparent false positive reactions due to a drying effect. Lipemic, hemolytic or contaminated sera can cause false positive reactions. Only serum should be used in this test.

Expected Values:

The clinical significance of RF lies in differentiating between RA and rheumatic fever. RF was found in about 80% of RA patient and is almost always absent in rheumatoid fever[8]. About 3.5% of known rheumatoid patients do not react in the screening test. But about 2% of sera from healthy individuals gave a positive RF reaction.

Performance Characteristics

Analytical sensitivity:8 (6-16) IU/ml. The performance of the RF TEST was observed to have a sensitivity of 98% and a specificity of 97%. No prozone effect was observed up to 1500IU/ml.

References

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5. Hannestad, K., Clin. Exp. Immunol., 3, 671, 1968.
6. Epskin, W., Johsen, A. & Ragan, C., Proc. Soc. Exptl. Biol-Med, 91, 235, 1956.
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8. Muller W., The Serology of Rheumatoid Arthritis; Berlin-Goettingen -Heidelberg, 1962, P.97.

Symbol Key


Consult Instructions for Use


Manufacturer


Temperature Limit


Date of Manufacture


Use by Date

Batch Code / Lot Number

Catalogue / Part Number

In Vitro Diagnostic Use


Number of Tests

1.800.960.1080
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