RapidTex RF Latex Test

INTENDED USE
The RapidTex RF Latex Test is intended for the qualitative screening and semi-quantitative determination of Rheumatoid Factor (RF) in serum as an aid in the diagnosis of Rheumatoid Arthritis.

SUMMARY
Rheumatoid Arthritis is a chronic systemic disease generally characterised by swelling and pain in the joints and by inflammatory and degenerative processes involving cartilage, synovial membrane or muscle tissue. The onset of this disease is in adults in their thirties and forties. While no specific cure has been found, early therapy helps in halting or minimising irreversible damage to the joints. For this reason, prompt diagnosis is of importance.

A characteristic of rheumatoid arthritis is the presence in the blood and in synovial fluid of a reactive group of proteins collectively known as the Rheumatoid Factors. These are macroglobulins having a molecular weight of about one million. In the opinion of many investigators the RF are antibodies directed against "altered" human gamma globulin. The RF is 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 cases of rheumatoid arthritis. By comparison the occurrence of RF in osteoarthritis or rheumatic fever is less than 2 and 3% respectively. A significant incidence of RF in the aged has also been observed.

PRINCIPLE
The principle of this test is based on the immunologic reaction between the RF in serum with the corresponding IgG coated onto latex particles resulting in visible agglutination.

STORAGE & STABILITY
When not in uses, store reagent and controls at 2º to 8ºC. DO NOT FREEZE. Prior to use, allow reagents and controls to warm up to room temperature. Expiration date is specified on the kit label and on each vial. Biological indication of product instability is evidenced by inappropriate reaction of the latex reagent with the corresponding positive and negative controls.

PRECAUTIONS
1. For in-vitro diagnostic use only.
2. Even though the control sera supplied in the RF TEST kit have been tested by an FDA approved method for the presence of Hepatitis B Surface Antigen (HBsAg) and anti-HIV antibodies and found to be non-reactive, all human serum products and patient specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
3. 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.

REAGENTS AND MATERIALS SUPPLIED
1. RF Latex Reagent : A suspension of polystyrene latex particles coated with human IgG in buffer and 0.1% sodium azide,..
2. RF Positive Control : Human Serum containing more than 20 IU/ml RF and 0.1% sodium azide.
3. RF Negative Control : Human Serum containing 0.1% sodium azide as preservative.
4. Glycine-Saline Buffer (20X) Concentrate : Dilute 1 part with 19 parts distilled water before use.
5. Disposable dropper/stirrer

MATERIAL REQUIRED BUT NOT SUPPLIED
1. Test tubes, 12 x 75 mm.
2. Timer.
3. Serological pipettes.

SPECIMEN COLLECTION
The test should be performed on serum. Plasma should not be used because fibrinogen may cause non-specific agglutination of the latex particles. Heavy bacterial contamination may cause false positive agglutination. Markedly lipemic sera should not be tested because of the possibility of non-specific reactions. Fresh specimens should be used for testing, as RF is labile. If testing is delayed, specimens should be refrigerated (or frozen where applicable).

TEST PROCEDURE
Method 1 (Screening)
1. Bring all reagents and serum samples to room temperature (18º to 25ºC).
2. Shake the RF latex reagent gently, expel contents of dropper and refill, then place one drop (approx.0.05 ml) onto a circle on the glass slide.
3. Using disposable dropper/stirrer provided, add one drop of the UNDILUTED patient serum onto the same circle on the glass slide, and mix both together with the paddle end of pipette/dropper.
4. Rotate the glass slide for 3 minutes and observe for macroscopic clumping using the indirect oblique light source.
5. Positive and negative controls should be run with each series of test sera. The controls supplied are to be used exactly as outlined in steps 1 through 3 above except they are used without further dilution and, because they are supplied with a dropper-tip, no pipet is needed to dispense.
6. The reaction of the test serum is compared to the RF positive and negative control sera.

Note: Read results immediately after 3 minutes mixing.

Method II (Semi-Quantitative)
The RapidTex RF Latex Test is also suitable for titration purposes.
1. Serum to be titrated is serially diluted (1/20, 1/40, and etc.) in diluted glycine-saline buffer, and going out 5 or more tubes.
2. Place one drop of negative and positive controls on slide. (Do not attempt to dilute the RF positive control serum for comparative or other purposes as no correlation exists between actual titer of the control and titer of unknown sera.)
3. Repeat steps 1 to 5 as in the Method I except that these new samples will be used.

**INTERPRETATION OF RESULTS**

**Positive:**
An agglutination of the latex particle when tested with a patient specimen within 3 minutes is a positive result. A weakly reactive serum produces a very fine granulation or a partial clumping. The results should be read within 3 minutes because non-specific reactions may occur after the time period.

Sera that are positive in the screening test should be re-tested in the titration test to provide verification for borderline interpretations. The greatest dilution of test sample showing agglutination is considered the endpoint. Multiplication of the dilution factor by 20 IU/ml will yield the approximate level of RF present.

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<tr>
<th>DILUTIONS</th>
<th>CONCENTRATION (IU/ml)</th>
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<tbody>
<tr>
<td>1:1</td>
<td>20</td>
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<tr>
<td>1:2</td>
<td>40</td>
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<tr>
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**Negative**
No agglutination of the latex particle within 3 minutes is a negative result.

**QUALITY CONTROL**
A positive control will produce within 3 minutes, agglutination against a clear background, as demonstrated by the positive control.

A negative control will produce no agglutination. It should be used as a basis for comparison. The relative degree of smoothness of the RF 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 RapidTex RF kit should not be used.

**LIMITATIONS OF THE PROCEDURE**
1. Strength of agglutination in screening test is not indicative of an actual titer of the RF.
2. Reaction time longer than 4 minutes may produce apparent false positive reactions due to a drying effect.
3. Strongly lipemic or contaminated sera can cause false positive reactions.

**PERFORMANCE CHARACTERISTICS**
The clinical significance of RF determination consists of differentiating 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. The RF test is more frequently positive in active processes of greater duration than in diseases that are less active or are still in early stages.

It is occasionally found in the serum of patients with polyarteritis 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 a positive RF reaction.

**REFERENCES**