Rheumatoid arthritis is a chronic systemic disease of unknown etiology. It is characterized by swelling and pain in the joints and by inflammatory and degenerative processes involving cartilage, synovial membrane, or muscle tissue. The disease is widespread throughout the world, and is found in all age groups. Most typically its onset is in young adults in their thirties and forties while no specific cure has as yet been found. Early therapy is of great value in halting or minimizing 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 (RA). These are macroglobulins having a molecular weight of about one million. In the opinion of many investigators, the rheumatoid factors are antibodies directed against “altered” human gamma globulin. The rheumatoid factors are found in from 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 rheumatoid fever is less than 2 and 3% respectively. It should be noted that incidences of RF have been reported in a variety of non-rheumatic disease such as pulmonary tuberculosis, bacterial endocarditis, syphilis, as well as others. A significant incidence of RF in the aged has also been observed.

Since the discovery of RF, there have been many techniques developed to identify and quantitate these factors. The most generally useful techniques have been agglutination procedures employing polystyrene latex particles coated with a layer of absorbed human gamma globulin. The RF present in a test serum reacts with the coating material causing a visible agglutination of the inert latex particles. It is this reaction, which is the basis of the RA test. The test set for the detection of the rheumatoid factors rapidly and accurately identifies the presence of RF one of the criteria for the diagnosis of rheumatoid arthritis. The test should be performed on serum.

In the presence of Rheumatoid Factor positive antiserum, RA latex-globulin RF reagent can be used to demonstrate agglutination both qualitatively and quantitatively.

**INTENDED USE**
Rapid latex agglutination test for the qualitative screening and semi-quantitative determination of rheumatoid arthritis factor, known as "RA" or "RF" (anti-gamma globulins) in serum.

**SUMMARY & EXPLANATION**
Rheumatoid arthritis is a chronic systemic disease of unknown etiology. It is frequently characterized by swelling and pain in the joint and by inflammatory and degenerative processes involving cartilage, synovial membrane or muscle tissue. The disease is widespread throughout the world, and is found in all age groups. Most typically its onset is in young adults in their thirties and forties while no specific cure has as yet been found. Early therapy is of great value in halting or minimizing irreversible damage to the joints. For this reason prompt diagnosis is of importance.

**ASSAY PRINCIPLE**
The principle of the test is an immunologic reaction between the rheumatoid factors (RF), a macromolecular globulin found in serum and the corresponding IgG coated onto finely dispersed polystyrene latex particles.

**CONTENTS**
- **Latex Reagent:** a suspension of polystyrene latex particles in glycine-saline buffer pH: 8.6 ± 0.2. The latex particles are coated with human IgG.
- **Positive Control Serum:** Stabilized human serum containing rheumatoid factors reactive with the latex reagent.
- **Negative Control Serum**

All components contain 0.1% sodium azide as preservative.

**WARNING**
For in vitro diagnostics use.

**STORAGE & STABILITY**
All reagents are stable up to the expiration date specified when stored at 2 - 8°C. Do Not Freeze. Avoid extended exposure of reagents to elevated temperatures. Expiration date is specified on the kit label. Biological indication of product instability is evidence by inappropriate reaction of the latex reagent with the corresponding positive control serum.

**SPECIMEN PREPARATION**
- The test should be performed on serum. Specimens can be drawn by venipuncture or convenient fingertip method.
- Plasma should not be used because fibrinogen may cause nonspecific 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 nonspecific reactions.
- Fresh specimens should be used in performing the test, as RF is labile. If testing is delayed, specimens should be refrigerated (or frozen where applicable).

**PROCEEDURE**
- **Materials supplied with RA kit:**
  - RA latex reagent.
  - Positive control serum.
  - Negative control serum.
  - 3-cell glass slide.
  - Dispensing pipettes.
  - **Material required, but not provided:** Pipettes (serological)
  - Lab rotator.
  - Laboratory timer.

**QUALITATIVE TEST (SCREENING)**
1. Bring all reagents and specimens to room temperature.
2. Shake the RA test reagent gently, expel contents of dropper and refill, and then place one drop (50 µl) onto glass slide. Using pipette, add one drop of the patient serum (50 µl) onto the glass slide, and mix both together with the flat end of the dispensing pipettes.
3. Continue to mix for about 1 minute with rotator or by hand and observe for macroscopic clumping using the indirect oblique light source.
4. Positive control and negative control should be run with each series to test sera. The positive control supplied is to be used exactly as outlined in steps 1 through 3 above.
5. The reaction of the test serum is compared to the RA positive control serum.

**QUALITY CONTROL PROCEDURE**
A positive control will produce, usually within 1 minute, coarse agglutinated flocs against a clear background, as demonstrated by the positive control. If the indicated results, using the positive controls not obtained, the RA kit should not be used.

Result
- **Negative result:** No agglutination of the latex particle suspension will occur within two minutes.
- **Positive result:** An agglutination of the latex particle suspension will occur within one minute, showing RA level of more than 8 IU/ml. The results should be read within 1 minute because non-specific reactions may occur after this time period. Sera that are positive in the screening test should be retested in the titration test to provide verification for borderline interpretations.

**SEMI - QUANTITATIVE - TEST**
RA Kit is also suitable for titration purposes.
1. Serum to be titrated is serially diluted (1:2, 1:4, 1:8 etc) in saline, and going out 4 or more tubes.
2. Place one drop of positive control 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. Place one drop of each dilution individually in successive rings and proceed as in screening methodology.

**QUALITY CONTROL PROCEDURE**
Same as described in screening test.

Results
The serum RF concentration can be then calculated approximately by multiplying the dilution factor by the detection limit (10 IU/ml).

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

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EXPEC TF VALUES & SPECIFIC PERFORMANCE CHARACTERISTICS

The clinical significance of RF determination consists in 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, which are less active or are still in early stages.

It is occasionally found in the serum of patients with polyarthritis nodosa, systemic lupus erythematosus, and a variety of chronic inflammatory illness 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