Intended Use:

RF is *in vitro* Medical Device Reagents/Kits for the detection and screening of Rheumatoid Factors (RF) in human specimen. It is intended for in vitro diagnostics use by trained healthcare professionals in IVD laboratory only and not near patients.

Clinical Significance

Measurement of rheumatoid factor is used for differentiating rheumatoid arthritis from other chronic inflammatory arthritis and is important in the progress and therapeutic management of the disease. Rheumatoid factor has been associated with some bacterial and viral infections (ex. Hepatitis, infectious, Mononucleosis) some chronic infections (ex. Tuberculosis, parasitic disease. Subacute Bacterial Endocarditis) and cancer.

Principle

The Latex reagent coated with the Human gammaglobulin (IgG). The test specimen (serum) is mixed with RF latex reagent and allowed to react. If RF is present within detectable levels then a visible agglutination is observed. If RF is absent below detectable levels then no agglutination is observed.

Reagent Composition

R1 RF LATEX	Latex particles coated with human gamma-globulin, pH 8.2, preservative
R2RF Positive Control	Synthetic Positive control with , preservative
R3 Negative Control	Synthetic Negative control with , preservative

Reagent Preparation

Reagents are ready to use.

Stability and Storage

1. Store the reagent at 2-8^{0}C. **DO NOT FREEZE.**
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial labels.

Material provided with the kit

Reagents

RF latex reagent, Positive Control, Negative Control

Accessories:

Glass slide, Plastic Droppers, Mixing sticks.

Additional Material Required

Stop watch, High intensity direct light source, Saline, Pipettes, Test tubes.

Notes

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. All the reagents derived from human source have been tested for HBsAg and Anti HIV antibodies and are found to be non-reactive. However handle the material as if infectious.
3. Reagent contains 0.1% Sodium Azide as a preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive and negative controls supplied with the kit.
5. The Latex reagent should be shaken well prior to use, to ensure homogeneous suspension of latex
6. Only a clean and dry glass slide must be used. Clean the slide with distilled water and wipe dry.
7. Accessories provided with the kit only must be used for optimum results.

Calibration

The RF-latex sensitivity is calibrated against the RF International Standard from NIBSC 64/002.

Sample and Stability

Only fresh serum must be used for testing. Should a delay in testing occur, store the sample at 2-8^{0}C.Samples can be stored for up to a week. Do not use hemolyzed serum.
Fresh serum, Stable7days at2-8ºC or 3months at-20ºC. Samples with presence of fibrin should be centrifuged before testing. Donot use highly hemolyzed or lipemic samples.

Procedure

Bring reagent and samples to room temperature before testing.

Qualitative Method

1. Pipette one drop of serum onto the glass slide using the disposable plastic droppers provided with kit.
2. Add one drop of RF latex reagent to the drop of test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
3. Using a mixing stick, mix the serum and RF latex reagent uniformly over the entire circle.
4. Immediately start a stopwatch. Rock the slide gently, back and forth observing for agglutination macroscopically at **two minutes**.

Semi Quantitative Method

1. Using normal saline prepare serial dilutions of the serum sample positive in the quantitative method 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 and so on.
2. Pipette each dilution of the serum sample onto separate reaction circles.
3. Add one drop of the RF latex reagent to each drop of the diluted Serum sample on the slide. Do not let the dropper tip touch the liquid on the slide.
4. Using a mixing stick, mix the sample and the Latex reagent uniformly over the entire circle.
5. Immediately start a stopwatch. Rock the slide gently, back and forth, observing for agglutination macroscopically at **two minutes**.

Interpretation of Results

Qualitative Method

Agglutination is a positive test result and indicates the presence of rheumatoid factors in the test specimen.

No agglutination is a negative test result and indicates the absence of rheumatoid factors in the test specimen.

Semi Quantitative Method

Agglutination in the highest serum dilution corresponds to the approximate amount of rheumatoid factors in IU/ml.

Calculation

Concentration of RF can be calculated as follows:

RF (IU/ml) = S X D

Where
S = Sensitivity of the reagent i.e., 8 IU/ml
D = Highest dilution of serum showing Agglutination

Reference Values

Up to 8 IU/mL. Each laboratory should establish its own reference range.

Performance Characteristics

1. Analytical sensitivity: 8 (6-16) IU/mL, under the described assay conditions
2. Prozone effect: No prozone effect was detected up to 1500IU/mL.
3. Diagnostic sensitivity:100%.
4. Diagnostic specificity:100%.

The diagnostic sensitivity and specificity have been obtained using 139 samples compared with the same method of a competitor.

Interference

Bilirubin (20 mg/dL), hemoglobin (10 g/L), and lipids (10 g/L), do not interfere. Other substances may interfere[6].

Limitation of Procedure

- The incidence of false positive results is about 3-5 %. Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positiveresults.
- Diagnosis should not be solely based on the results of latex method but also should be complemented with a Waaler Rose test along with the clinical examination.

Remarks

1. Markedly lipemic, hemolyzed and contaminated serum samples could produce non-specific results.
2. Use of plasma rather than serum can lead to false positive results.
3. Do not read results beyond two minutes.
4. Rheumatoid factors are not exclusively found in rheumatoid arthritis but sometimes in syphilis, systemic lupus erythematosus, hepatitis, hyper gammaglobulinemia also.
5. It is recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.
6. RF reagent is sensitive to the presence of lgM RF with heterogeneous specificity.

Reference

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For In vitro Diagnostic Use Only