For the Qualitative and Semi-Quantitative determination of Rheumatoid Factors in human serum.

Only for in vitro use in clinical laboratory (IVD).

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.

Contents, reagents and material provided
1. RF Latex Reagent: Suspension of polystyrene latex particles, coated with human gammaglobulin (IgG).
2. Positive Control: Stabilized serum control, producing a distinct agglutination with latex reagent. Ready to use.
3. Negative Control: Stabilized serum control, non-reactive with the latex reagent.

Stability
Latex Reagent and Control sera are stable up to the expiry date printed on the labels when stored at 2-8°C. Do Not freeze.

Specimen
Only fresh serum must be used for testing. Should a delay in testing occur, store the sample at 2-8°C. Samples can be stored for up to a week. Plasma should not be used because fibrinogen may cause non-specific agglutination of the latex particles. Do not use lipemic, hemolyzed or contaminated specimen.

Procedure
Bring reagent and samples to room temperature before use.

A. Qualitative analysis (Screening)
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.

Interpretation of results
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.

B. Semi quantitative analysis
1. Using normal saline prepare serial dilutions of the serum sample positive in the qualitative 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 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 serum and RF 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
Agglutination in the highest serum dilution corresponds to the approximate amount of rheumatoid factors in IU/ml. To calculate the RF in IU/ml, use the following formula.

CALCULATIONS

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RF \ (IU/ml) = \frac{S \times D}{X}
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Where \(S\) = Sensitivity of the reagent i.e., 12 IU/ml
\(D\) = Highest dilution of serum showing agglutination

Reagent Performance
Sensitivity:
The latex reagent has a sensitivity of 12 IU/ml for serum sample.

NOTE:
1. 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.
2. Reagent contains 0.1% Sodium Azide as a preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
3. 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.
4. Shake the RF latex reagent well before use to disperse the latex particles uniformly and improve test readability.
5. Only a clean and dry glass slide must be used. Clean the slide with distilled water and wipe dry.
6. Accessories provided with the kit only must be used for optimum results.
7. Markedly lipemic, hemolyzed and contaminated serum samples could produce non-specific results.
8. Use of plasma rather than serum can lead to false positive results.
9. Do not read results beyond two minutes.
10. Rheumatoid factors are not exclusively found in rheumatoid arthritis but sometimes in syphilis, systemic lupus erythematous, hepatitis, hypergammaglobulinemia also.
11. It is recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.
12. RF reagent is sensitive to the presence of IgM RF with heterogeneous specificity.

Literatures