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RHEUMATOID FACTOR (RF) REAGENT A LATEX SLIDE TEST

REF

Catalog No. S20-702 50 kit
Catalog No. S20-703 100 kit

IVD

For In Vitro Diagnostic Use Only

INTENDED USE

For the qualitative and semi-quantitative measurement of RF in human serum.

INTRODUCTION

Immunospec Rheumatoid factors (RF) are antibodies directed against antigenic sites in the Fc fragment of human and animal IgG. Their frequent occurrence in rheumatoid arthritis makes them useful for diagnosis and monitoring of the disease.[1,2]
One method used for rheumatoid factor detection is based on the ability of rheumatoid arthritis sera to agglutinate sensitized sheep red cells, as observed by Waaler[3] and Rose.[4] A more sensitive reagent consisting of biologically inert latex beads coated with human gamma globulin was later described by Singer and Plotz.[5] The RF kit is based on the principle of latex agglutination assay by Singer and Plotz.[5] The major advantage of this method is rapid performance (3 minute reaction time) and lack of heterophile antibody interference.

PRINCIPLE

The RF reagent is a suspension of polystyrene latex particles sensitized with specially prepared human IgG. The reagent is based on an immunological reaction between human IgG bound to biologically inert latex particles and rheumatoid factors in the test specimen. When serum containing rheumatoid factors is mixed with the latex reagent, visible agglutination occurs. The RF latex reagent sensitivity has been adjusted to detect a minimum of 20 IU/mL of rheumatoid factors according with the WHO International Standard without previous sample dilution.

REAGENTS

1. RF Latex Reagent: A suspension of uniform polystyrene particles coated with IgG (human) in glycine buffer, pH 8.2; reagent sensitivity is standardized with the World Health Organization RF Standard. MIX WELL BEFORE USING.
2. RF Positive Control Serum: A stabilized, prediluted human serum containing at least 8 IU/mL of RF.
3. RF Negative Control Serum: A stabilized, prediluted human serum containing less than 8 IU/mL of RF.
4. Glycine-Saline Buffer (20x): pH 8.2 ± 0.lM glycine and 0.15M NaCl.

NOTE:
1. Dilute buffer following instructions on the label before using.
2. All reagents contain 0.1% (w/v) sodium azide as a preservative.
3. The human sera used in the controls has been tested and found negative for HbsAg and HIV, however, careful handling is always recommended.
4. Store all reagents at 2 - 8°C. DO NOT FREEZE.

WARNINGS AND PRECAUTIONS

1. Reagents containing sodium azide may combine with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
2. For In Vitro diagnostic use. Positive and negative controls prepared using human sera were found negative for hepatitis B surface antigen (HB_SAg) as required by FDA; however, handle controls as if potentially infectious.

REAGENT STORAGE AND STABILITY

1. Reagents are stable until stated expiration date on bottle label when stored refrigerated (2 - 8°C).
2. DO NOT FREEZE.
3. The RF latex reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
4. Do not use the latex reagent or controls if they become contaminated.

SPECIMEN COLLECTION AND STORAGE

1. Use fresh serum collected by centrifuging clotted blood.
2. If the test cannot be carried out on the same day, the serum may be stored between 2 - 8°C for no longer than 72 hours after collection.
3. For longer periods the sample must be frozen.
4. As in all serological tests, hemolytic or contaminated serum must not be used.
5. Do not use plasma.

MATERIALS AND REAGENTS PROVIDED

1.RF Latex Reagent
2.RF Positive Control
3.RF Negative Control
4.Glycine-Saline Buffer
5.Reaction Slide
6.Pipette/Stir Sticks

MATERIALS REQUIRED BUT NOT PROVIDED

1.Timer
2.Test Tubes
3.Serological pipettes

PROCEDURE

Qualitative Test:

1.Bring reagents and specimens to room temperature

before use.
2.Place one drop (50 µl) of the RF Positive Control on field #l of the reaction slide. Place one drop (50 µl) of the RF Negative Control on field #2. The remaining fields are used for test specimens. Using pipettes provided. Place one drop of the undiluted specimens on successive fields. Retain Pipette/Stir Sticks for mixing step.
3.Gently resuspend the RF Latex Reagent and add one drop to each test field. Use pipette/Stir Stick to spread reaction mixture over entire test field.
4.Rotate the slide manually or with a mechanical rotor at 80-100 rpm for 2 minutes and read immediately under direct light.
5. Presence of agglutination of the latex particle is a positive result (see figure 1). Agglutination indicates a RF concentration of equal or more than 20 IU/ml. Sera with positive agglutination should be run again with the Quantitative Test.

Quantitative Test:
1.Bring reagents and specimens to room temperature before use.
2.Using the Glycine-Saline Buffer, dilute the specimens 1:2, 1:4, 1:8, 1:16, 1:32 or as needed.

3.Place one drop (50 µl) each of negative and positive controls on two slide rings. Place on drop (50 µl) of each dilution on successive fields of the reaction slide.
4.Gently resuspend the RF Latex Reagent and add one drop to the reaction slide.
5.Gently resuspend the RF Latex Reagent and add one drop to each test field. Use Pipette/Stir Stick to spread reaction mixture over entire field.
6.Rotate the slide for 2 minutes and read immediately under direct light.

QUALITY CONTROL

1.RF Positive and Negative Control should be included in each test batch.
2.Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the RF Negative Control and agglutination with large aggregates is observed with the RF Positive Control. (Figure 1)

INTERPRETATION

Qualitative Test:
Negative Result: A negative reaction is indicated by a uniform milky suspension with no agglutination observed with the RF Negative Control.
Positive Result: A positive reaction is indicated by any observable agglutination in the reaction mixture. The specimen reaction should be compared to the RF Negative and Positive Controls (Fig. 1).

Semi-quantitative Test:
The titer of the serum is the reciprocal of the highest dilution, which exhibits a positive reaction.
An estimate of the RF concentration in the specimen can be expressed in IU/ml by using the following equation:

IU/ml of specimen= IU/ml control × specimen titer

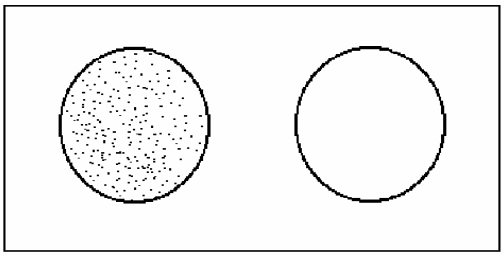

Figure 1.

LIMITATIONS

1.Results should be read two (2) minutes after the mixing or the reagent on the slide.
2.Existence of prozone at high titers has not been encountered.
3.Increased levels of RF may be round in some diseases other than rheumatoid arthritis such as infectious mononucleosis, sarcodosis, lupus erythematosus, Sjogren's syndrome.[6,7]
4.Certain patients with rheumatoid arthritis will not have the RF present in their serum.[6]

EXPECTED VALUES

1. The diagnosis of rheumatoid arthritis is based largely on clinical examination, but laboratory tests are useful to support the clinical diagnosis and to evaluate the severity and course or the disease in
the individual patient. One of the most useful clinical markers for rheumatoid arthritis is rheumatoid factor in serum. Rheumatoid factor is a term used to describe a variety of antibodies or immune complexes or both, that occur with rheumatoid arthritis as well as in a variety of other diseases.[8]

2. Different studies have shown positive serological reactions for rheumatoid factor in as high as 90% of patients with rheumatoid arthritis compared with less than 5% in control groups.[1]

PERFORMANCE

1. Sensitivity: 20 IU/ml or above.
2. Comparison:
   A. Qualitative Results: The RF Latex Reagent was evaluated on a total of 75 samples from the hospital patients. The qualitative test was evaluated by comparison with a commercially available latex agglutination test. This study demonstrated a 96% agreement between these tests. The discrepancy results were obtained in samples with titers near the limit of sensitivity of the reagents.
   B. Semi-quantitative Results: A panel of 10 known RF positive serum samples was quantitated on three consecutive days. The results of the study indicated that RF Latex Reagent has 100% precision.

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