




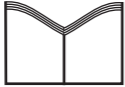
BHAT BIO-TECH INDIA (P) LTD.

RF TEST

RF Latex Slide Test for the detection of Rheumatoid factor in human serum.

For Professional Use IVD



READ THIS PACK INSERT CAREFULLY BEFORE PERFORMING THE TEST

CATALOGUE No. : IR

INTENDED USE :
RF latex slide test is a latex agglutination test for qualitative and semi quantitative in vitro determination of Rheumatoid Factor in human serum.

INTRODUCTION :
Immunologic factors are involved in both the articular and extra-articular manifestation of the disease. Rheumatoid Arthritis (RA) may represent an unusual response to are or perhaps many etiologic agents. An infectious etiologic is possible, although it is not been established.

RA is a chronic, visually progressive inflammatory disorder of the joints. It is however, a highly variable disease that ranges from a mild illness of brief duration to a progressive, destructive polyarthritis associated with a systemic vasculitis.

The incidence of RA is 1% to 2% in most population that have been studied. The disorder occurs worldwide but no definite racial, geographic or climatic variations. Womens are two to three times more likely than men to develop RA. It can begin at any age, but the disease initially occurs more frequently between the ages of 30 and 50 years. Complications due to an increased frequency of local or extra articular infections in RA patients have been demonstrated. Mortality may result from conditions such as septicaemia, pneumonia, lung abscess or pyelonephritis.

Rheumatoid factors are antibodies directed against antigenic sites in the Fc fragment of human and animal IgG. Their frequent occurrence makes them useful for the diagnosis and monitoring of the disease.

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PRINCIPLE :
The RF kit is based on the principle of latex agglutination. Polystyrene latex particles are coated with specially purified human gammaglobulin. When serum containing rheumatoid factors is mixed with the suspension of coated latex particles, visible agglutination occurs. The major advantage of this method is rapid performance and lack of heterophile antibody interference.

STORAGE AND STABILITY :
Storage :
Store the reagents at 2-8°C. Do not use the reagent beyond the expiry date mentioned on it. Before performing the test bring all the reagents to Room temperature. Replace the reagents to 2-8°C soon after performing the test. **DO NOT FREEZE THE REAGENTS.**

Stability :

- The unopened kit is stable for 24 months from the date of manufacturing as indicated on the package.
- The opened kit is stable for 6 months from the date of opening.
- Repeated freeze thaw of reagents from 2-8°C to Room temperature several times will reduce the stability of the kit.

PACK SIZE : Available in packs of 25, 50, & 100 Tests.

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CONTENTS OF THE KIT :

| Materials | 25 Tests | 50 Tests | 100 Tests |
|---|----------|----------|-----------|
| RF Positive Control serum | 0.3 ml | 0.3 ml | 0.3 ml |
| RF Negative Control serum | 0.3 ml | 0.3 ml | 0.3 ml |
| RF Latex Reagent | 0.8 ml | 1.6 ml | 3.2 ml |
| Glass slide | 1 No. | 1 No. | 1 No. |
| Disposable applicator sticks | 25 Nos. | 50 Nos. | 100 Nos. |
| Disposable plastic dropper with rubber teat | 25 Nos. | 50 Nos. | 100 Nos. |
| Product pack insert | 1 | 1 | 1 |

SPECIMEN :
Use fresh serum for testing. The specimen should be Non-hemolysed and free from contamination.

The specimen may be stored at 2-8°C for up to 8 days and at -20°C for up to 4 weeks. (Use EDTA, Heparin or Oxalate as anticoagulant).

SPECIMEN COLLECTION AND HANDLING :
Collect blood in a clean sterilized vial and allow it to clot. Separate the serum by centrifugation at 10000 rpm for 10 minutes at room temperature. It is recommended that fresh samples should be used. If serum is not used for testing immediately it should be stored at 2-8°C or Frozen at -20°C. Bring specimen to room temperature, and specimen should be mixed properly and centrifuged before use. Do not heat or repeatedly freeze thaw the specimens.

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PRECAUTIONS :

- For invitro diagnostic use only.
- Bring all reagents and specimens to Room temperature, prior to testing.
- Avoid using lipemic, haemolysed or contaminated specimen.
- All human serum and plasma samples should be considered potentially infectious. It is recommended that all specimens of human origin should be handled as recommended for any potentially infectious human serum or blood specimen in the center for disease control/National Institute of Health Manual "Biosafety in Microbiological and Biomedical Laboratories", 1984.
- Never pipette by mouth.
- Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.
- Wear disposable gloves while handling specimens and kit reagents. Afterwards wash hands carefully.
- Avoid splashing or forming aerosols.
- Discard all materials and specimens as if capable of transmitting infection. The preferred method of disposal is autoclaving for a minimum of one hour at 121°C. Liquid waste containing acid may be mixed with sodium hypochlorite in volumes such that the final mixture contains 50-500mg/l available chlorine. Allow 30 minutes for decontamination to be completed.

NOTE :

- Liquid waste containing acid must be neutralized with a proportional amount of base prior to the addition of sodium hypochlorite.
- Spills should be wiped thoroughly using either an iodophor disinfectant or sodium hypochlorite solution. Materials used to wipe up spills should be added to biohazardous waste matter for proper disposal.

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NOTE :

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- Spills should be wiped thoroughly using either an iodophor disinfectant or sodium hypochlorite solution. Materials used to wipe up spills should be added to biohazardous waste matter for proper disposal.
- Deterioration is indicated by a significant decrease by weak agglutination.
- Do not use reagents after the expiration date printed on the label.
- When removing reagents from the bottles, use aseptic technique to avoid contamination.
- Mix the reagent bottle gently before use.
- Do not use contaminated serum sample for testing.
- Ensure used glass slide is disinfected, washed thoroughly and rinsed free of detergents.

TEST PROCEDURE :
A. Qualitative Analysis :
Allow all reagents as well as the sample to attain room temperature.

- Using disposable plastic dropper place one drop of specimen in circled area of the slide provided in the kit.
- Add one drop of Latex Gammaglobulin reagent to the above drop and mix well with disposable applicator sticks.
- Rock the slide gently to and fro for two minutes and examine for agglutination. Do not examine beyond two minutes.

For Positive and Negative controls follow the same procedure as mentioned above by taking control serum from respective vials.

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B. Semi quantitative Analysis :

- Dilute the serum serially 1:2, 1:4, 1:8, 1:16, 1:32 using normal saline.
- Place one drop of diluted sample using plastic dropper in each circle of the glass slide.
- Add one drop of Latex Gammaglobulin reagent in each of these circles, mix well with applicator sticks.
- Rock the slide gently to and fro for two minutes and examine for agglutination.

INTERPRETATION OF RESULTS :
Read the result under strong source of light.

A. Qualitative Analysis :
Negative : Uniform milky suspension with no agglutination.
Positive : Any observable agglutination in the reaction mixture.

B. Semi Quantitative Analysis :
Concentration of Rheumatoid Factor can be estimated in IU/ml as follows.
RF in IU/ml = Sensitivity in IU/ml x Titre
Where Sensitivity = 20 IU/ml
Titre = Reciprocal of the highest dilution of serum which exhibits a positive reaction.

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TROUBLESHOOTING :

| FALSE POSITIVE | |
|---|---|
| Cause 1. Contaminated serum or reagents | Remedy Make sure that there is no contamination of serum or reagent. Use clean slide for testing. Do not read the result after 4 minutes. |
| 2. Drying in slide test | Do not read the result after 4 minutes |
| 3. Improper mixing of Latex Reagent | Mix the Latex reagent thoroughly before use. |
| FALSE NEGATIVE | |
| Cause 1. Contamination of serum or reagents | Remedy Make sure that there is no contamination of Serum or reagent Use clean slide for testing. |
| 2. Improper Mixing of Latex Reagent | Mix the Latex reagent thoroughly before use. |
| WEAKLY / DELAYED REACTION | |
| Cause 1. Prolonged storage of Serum sample | Remedy Store the Serum sample at 2-8°C upto 8 days and at 20°C for upto 4 weeks. |
| 2. Expired reagent | Check the expiry date on the reagent. |
| 3. Improper storage conditions of the kit | The kit has to be stored at 2-8°C. |
| 4. Improper Mixing of Latex Reagent | Mix the Latex reagent thoroughly before use. |

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PERFORMANCE CHARACTERISTICS :
Accuracy : Bhat Bio-Scan® RF kit meets the requirements when tested against DCI approved kits.

SPECIFICITY :

| No. of Negative samples tested | No. of Negative by Bhat Bio-Scan® RF Test | Specificity (%) |
|--------------------------------|---|-----------------|
| 40 | 40 | 100 |

SENSITIVITY :

| No. of Positive samples tested | No. of Positive by Bhat Bio-Scan® RF Test | Sensitivity (%) |
|--------------------------------|---|-----------------|
| 35 | 35 | 100 |

LIMITATIONS OF THE TEST :

- It is recommended that with every set of tests, positive and negative controls should be included. The result of positive and negative controls should be read before reading the test results. The satisfactory result of positive and negative control indicates that the reagents are working well.
- Factors other than reagents, which might affect the performance of the test, include cleanliness of glassware, meticulous follow up of the procedure.
- Do not use lipaemic, haemolysed, or contaminated specimens.
- Mix Latex antigen gently before use.

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- While dispensing reagents/specimen, hold pipette/dropper vertically straight.
- Improper mixing of specimen/control with Latex antigen may lead to erroneous results.
- Make sure that the cap of each reagent vial is properly and promptly applied to the same vial. Interchanging of the vial caps and or droppers will lead to contamination of reagents, which might lead to false results.
- The slide should be tilted back and forth gently to avoid disturbance to the reaction pattern.
- Contaminated blood specimen or reagents may interfere with test results. Peripheral drying in slide test should not be misinterpreted as agglutination.
- Interpret results exactly at 2 minutes.
- The reagents contain sodium azide as preservative. Do not swallow. Avoid contact with skin and mucous membrane.


















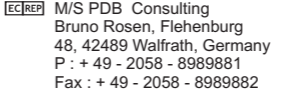
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(Empty space for additional information or instructions)

EN 980:2008 (E) MEDICAL DEVICES SYMBOL

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|---|--|--|---|
|  Temperature Limitation |  Date of Manufacture |  In vitro Diagnostic Device |  Batch Code |
|  Company name & address |  Refer Operating Instructions |  Use by |  Company Name |
|  Authorized Representative in European Community |  Do Not Reuse |  Sufficient for |  KEEP AWAY FROM SUNLIGHT |
|  KEEP DRY |  NON-STERILE |  CONTROL - |  CONTROL + |
|  | |  | |

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