RHEUMATOID FACTOR (RF) LATEX KIT

IVD *For In-Vitro and professional use only*
Store at 2- 8°C

INTENDED USE
The RF latex test kit is intended to be used to measure RF in human serum qualitatively and semi-quantitatively.

INTRODUCTION
Rheumatoid factors (RF) are antibodies specific to antigenic determinants on the Fc fragments of human or animal IgG. The term rheumatoid factor evolved from the observations of Waaler and Rose, who found that rheumatoid arthritis sera have the ability to agglutinated sensitized sheep erythrocytes with specific rabbit antibodies. Later, as described by Singer and Plotz, a more sensitive reagent consisting of biologically inert latex beads coated with human gamma globulin had been introduced.
The RF kit is based on the principle of the latex agglutination assay of Singer and Plotz. The major advantage of this method is rapid performance (2 minute reaction time) and lack of heterophile antibody interference.
In the presence of Rheumatoid Factor positive antiserum, latex-globulin RF reagent can be used to demonstrate agglutination both qualitatively and quantitatively.

PRINCIPLE
The RF reagent is based on an immunological reaction between human IgG bound to biologically inert latex particles and rheumatoid factors in the test specimen. A visible agglutination will appears when serum containing rheumatoid factors is mixed with the latex reagent.

STORAGE AND STABILITY
- Reagents are stable when stored refrigerated at 2-8^{0}C until the specified expiry date (see Vial and Box Labels). **DO NOT FREEZE**. Slight sedimentation should be considered normal when stored refrigerated.
- The vials must always be in an upright position. If changes of position occurred, gently mix to dissolve aggregates that may present.
- These reagent should be uniform without visible clumping once shaken.
- Avoid using the latex reagents and controls if contamination occurred.
- Presence of particles and turbidity will result in reagents deterioration.

SPECIMEN COLLECTION AND STORAGE
- Use fresh serum collected by centrifuging clotted blood.
- If testing is delayed, specimen can be stored for 7 days at 2-8^{0}C or up to 3 months at -20^{0}C.
- Make sure the samples with presence of fibrin is centrifuged before testing. Avoid using highly hemolysed or lipemic samples.
- Do not use plasma.

MATERIALS
MATERIALS PROVIDED
1. RF Latex Reagent: Latex particles coated with human gamma-globulin, pH, 8.2. Preservative.
2. RF Positive Control Serum (Red cap): Human serum with a RF concentration > 30 IU/ml. Preservative.
3. RF Negative Control Serum (Blue cap): Animal serum. Preservative.
4. Glass Reaction Slide.
5. Stirring sticks.

NOTE: This package insert is also used for individually packed reagent.

MATERIALS NEEDED BUT NOT PROVIDED
- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pipettes 50 µL.
- Glycine Buffer (20x): add one part to nineteen parts of distilled water before use.

PROCEDURES
A.QUALITATIVE TEST
1. Bring the reagents and samples to reach to room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place (40 µL) of the sample and one drop of each Positive and Negative control into separate circles on the slide test.
3. Mix the RF latex reagent vigorously or using vortex mixer and add one drop (40 µL) next to the samples to be tested.
4. Use stirrer to mix the drops and spreading them over the entire surface of the circle. Do not use the same stirrer for each sample.
5. Place the slide on a mechanical rotator at 80-100 rpm for 2 minutes. Avoid reading the test after more than two minutes since it may cause false positive result.

B.SEMI-QUANTITATIVE TEST
The semi-quantitative test can be performed in the same way as the qualitative test using dilutions of the serum.
1. Make serial two fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

READING AND INTERPRETATION
Observe macroscopically the presence of any visible agglutination immediately after removing the slide from the rotator. Visible agglutination of latex particles indicates that RF concentration equal or greater than 8 IU/mL (Note 1). The titer, in semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS
The approximate RF concentration in the patient sample is calculated as follows:
Sensitivity (Indicated on the label of the latex vial) x RF Titer = IU/mL

INTERFERENCES
NONE INTERFERING SUBSTANCES:
- Hemoglobin (10 g/L)
- Bilirubin (20 mg/dl)
- Lipids (10 g/L)

Other substances may interfere.

NOTES
Do not compare the results from a latex method with those obtained with Waaler Rose test. Methods showing differences in the results do not reflect differences in the ability to detect rheumatoid factors.

PROCEDURE LIMITATION
1. Reaction time is critical. False positive result may occur if reaction time exceeded 2 minutes due to reaction mixture may dried up.
2. Spontaneous agglutination may occur if the RF Latex Reagent is stored in freezing condition.
3. Intensity of agglutination is not necessarily indicative of relative RF concentration; therefore, screening reactions should not be graded.
4. Increased levels of RF may be found in some diseases other than rheumatoid arthritis such as infectious mononucleosis, sarcodosis, lupus erythrematosus, Sjogren's syndrome.
5. The incidence of false positive results is about 3-5%.Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive results.
6. In certain cases, patients with rheumatoid arthritis may show negative results of RF.
7. Diagnosis of diseases should include Waaler and Rose test along with the clinical examination and must not only based on the results of latex method.

QUALITY CONTROL
It is recommended to use the positive and negative controls to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation. The results are considered as a positive if all the result are different from the negative control result.

REFERENCE VALUES
Up to the reagent sensitivity (Indicated on the label of the latex vial). Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS
Analytical sensitivity
Refer to vial label.

PROZONE EFFECT
No prozone effect was detected up to 1500 IU/ml.

DIAGNOSTIC SENSITIVITY
100%.

DIAGNOSTIC SPECIFICITY
100%.

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

PRECAUTIONS

- For In Vitro diagnostic use.
- All reagents contain 0.1 % (w/v) sodium azide as a preservative.
- The reagents contain sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. When drained, flush with a large volume of water to prevent azide build up.
- Make sure to wear protective clothing when handling the reagents, such as disposable gloves and a laboratory coat.
- Once testing is done, wash hands and the test table top with water.
- Materials used to produce the kit were prepared using human serum found to be negative for hepatitis B surface antigen (HBsAg), HCV and antibody HIV (1/2) by FDA required test. Care must be taken in the use and disposal of each vial and its contents as it is potentially infectious.
- Use provided dropper and hold perpendicularly when dispensing as the drop size of the latex reagent (40µl) will determine the accuracy of the test.
- For each use, make sure to rinse the slide test thoroughly with water and wiped with lint-free tissue.
- Use provided controls to check reactivity of the reagent.

REFERENCES

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5. Robert W Dorner et al. Clinica Chimica Acta 1987; 167: 1 – 21.
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REF Catalogue Number	Temperature limit	Manufacturer fax number	Fragile, handle with care
IVD *In Vitro* diagnostic medical device	Caution	Manufacturer telephone number	Use-by date
Contains sufficient for <n> tests and Relative size	Consult instructions for use (IFU)	Keep away from sunlight	Date of Manufacture
LOT Batch code	Manufacturer	Do not use if package is damaged	Keep dry