RF-latex

Slide agglutination

CE

Qualitative determination of Rheumatoid Factors (RF)
IVD Store at 2-8ºC.

REF: KRFL-007B

Summary:

Rheumatoid factors are a group of antibodies directed to determinants in the Fc portion of the immunoglobulin G molecule. Although rheumatoid factors are found in a number of rheumatoid disorders, such as systemic lupus erythematosus (SLE) and Sjögren's syndrome, as well as in nonrheumatic conditions, its central role in clinic lies its utility as an aid in the diagnosis of rheumatoid arthritis (RA).
A study of the "American College of Rheumatology" shows that the 80,4% of RA patients were RF positive.

Principle:

The RF-latex is a slide agglutination test for the qualitative and semiquantitative detection of RF in human serum. Latex particles coated with human gammaglobulin are agglutinated when mixed with samples containing RF.

Composition:

Latex: Latex particles coated with human gamma-globulin, pH 8,2. Preservative
Control + Red cap: Human serum with a RF concentration > 30 IU/mL. Preservative
Control - Blue cap: Animal serum, Preservative

Precautions:

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2).
However handle cautiously as potentially infectious.

Calibration:

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

Storage and stability:

All the kit components are ready to use, and will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.
Mix reagents gently before use.
Reagents deterioration: Presence of particles and turbidity.

Samples:

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.
Samples with presence of fibrin should be centrifuged before testing. Do not use highly haemolized or lipemic samples.

Equipment:

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pipettes 50 µL.

Procedure:

Qualitative method

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the RF-latex reagent rigorously or on a vortex mixer before using and add one drop (50 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

Semi-quantitative method

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:

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

Calculations:

The approximate CRP concentration in the patient sample is calculated as follow:
6 x CRP Titer = mg/L

Quality control:

All clinical laboratories should establish an Internal Quality Control program. Check instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At pre-established intervals following the Q.C. Laboratory recommandations.

Reference values:

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

Performance characteristics:

Prozone effect:

No prozone effect was detected up to 1500 IU/mL.

Sensitivity:

8 (6-16) IU/mL, under the described assay conditions

Diagnostic Sensitivity:

100 %

Diagnostic specificity:

100 %

Interferences:

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

Notes:

- 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.
- 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.

Notes:

Results obtained with a latex method do not compare with those obtained with Waaler Rose test. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.

References:

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4. Adalbert F S et al. The New England Journal of Medicine 1959; 261: 363 – 368.
5. Charles M. Plotz 1956; American Journal of Medicine; 21:893 – 896.
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

Sorachim