RF - LATEX

METHOD - IMMUNO AGGLUTINATION
PACK SIZE -25 Test, 50 Test, 100 Test
PRODUCT CODE –LX03

INSTRUCTIONS FOR USE

INTENDED USE: Test for qualitative determination of Rheumatoid Factors (RF) by Immuno Agglutination method.

CLINICAL SIGNIFICANCE

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 Sjogren'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% RA patients were RF positive.

PRINCIPLE

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

REAGENTS

Latex Reagent	- Latex particles coated with human gammaglobulin, pH 8.2. Sodium azide 0.95 g/L.
Positive Control	- Human serum with an RF conc. >30 IU/mL. Sodium azide 0.95 g/L.
Negative Control	- Protein based with Sodium Azide 1 gm/L.

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 at 2-8 ^{0}C and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionally of the test.

Reagents deterioration: Presence of particles and turbidity.

SAMPLES

Fresh serum. Stable for 8 days at 2-8^0 C or 3 months at -20 ^{0}C. Samples with presence of fibrin should be centrifuged. Do not use highly haemolysed or lipemic samples.

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 40 µl of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Swirl the RF-latex reagent gently before using and add one drop (40 µl) next to the sample to be tested.
4. Mix the drop 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 dilution 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 on RF concentration equal or greater than 8 IU/mL. The titre, in the 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:

8 x RF Titre = IU/mL.

REFERENCE VALUES

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

PERFROMANCE CHARACTERISTICS

1. Analytical sensitivity: 8 (6-16) IU/mL, under the described assay conditions.
2. Prozone effect: Not detected up to 800 IU/mL.
3. Diagnostic sensitivity: 100%.
4. Diagnostic specificity: 98.8%.

INTERFERENCES

Hemoglobin (10 g/L), bilirubin (20 mg/dL) and lipemia (10 g/L) do not interfere. Other substances may interfere.

LIMITATIONS OF PROCEDURE

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 result.

CALIBRATION

The RF-latex sensitivity is calibrated against the WHO 64/1 Rheumatoid Arthritis serum.

BIBLIOGRAPHY

1. Robert W Domer *et.al.* Clinica Chemica Acta 1987; 167: 1-21.
2. Frederick W. *et.al.* Arthritis and Rheumatism 1991; 34: 951-960.
3. Robert H Shmerling *et.al.* The American journal of Medicine 1991; 91: 528-534.
4. Charles M. American Journal of Medicine1956; 21: 893-896.

SYMBOLS:

Read Instruction for use | In Vitro Diagnostic Use Only | Manufactured by | Expiry Date | Storage Temperature

ANAMOL LABORATORIES PVT. LTD.
61, Genesis Industrial Township, Kolgaon,
Palghar – 401 404. India.
Customer Care & WhatsApp: +91-9823388695.

admin@anamollabs.com
exports@anamollabs.com
www.anamollabs.com

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ISO 13485 : 2003
GMP
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