RF - LATEX

METHOD - IMMUNO AGGLUTINATION
PRODUCT CODE –LX03

INSTRUCTIONS FOR USE

ANAMOL
THE ORIGINAL MAKERS

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 in 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.

MATERIALS REQUIRED BUT NOT PROVIDED

Sample Dropper or Micropipette with tips, Stopwatch, Mechanical Rotator of 80-100 r.p.m.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and IFU carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent or shake the reagent vigorously. Contamination of the reagent should be avoided.

STORAGE AND STABILITY

All the kit components are ready to use, and will remain stable until the expiration date printed on the label, if stored at 2-8 ^{0}C and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.

Reagent deterioration: Presence of particles and turbidity.

SPECIMEN COLLECTION & PRESERVATION

Fresh serum is needed. Serum is 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 Positive and Negative controls each into separate circles on the slide.
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 1500 IU/mL.
3. Diagnostic sensitivity: 100%.
4. Diagnostic specificity: 98.8%.

INTERFERENCES

Hemoglobin (500 mg/L), bilirubin (20 mg/dL) do not interfere. Other substances may interfere.

CALIBRATION

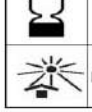
The RF-latex sensitivity is calibrated against the WHO 64/1 Rheumatoid Arthritis serum.

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.

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.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485 : 2016
GMP
CE