RHEUMATOID FACTORS (RF)

PRODUCT CODE: LXRF0025/LXRF0050
LXRF0100/LXRF0150

CE QUALITY MANAGEMENT SYSTEM ISO 13485 CERTIFIED COMPANY

LXRF0025	LXRF0050	LXRF0100	LXRF0150
25 TESTS	50 TESTS	100 TESTS	150 TESTS
STORE AT 2-8°C			
INSTRUCTIONS FOR USE			
FOR IN-VITRO DIAGNOSTIC USE ONLY			

IVD For In Vitro Diagnostics Use Only
LOT Lot Number
REF Catalogue Number
Storage Temperature
Expiry Date (Year / Month)
Warning, Read Enclosed Documents
Instructions For Use
Manufactured By

RHEUMATOID FACTORS (RF)

LATEX

Principle:
The RF-Latex test is a rapid slide agglutination test for the direct detection and semiquantitation of Rheumatoid Factors in serum. The antigen, which is a particulate latex suspension coated with human gamma-globulin, agglutinates in the presence of rheumatoid factors in the patient serum.

Presentation:

Contents	25 Tests	50 Tests	100 Tests	150 Tests
RF Latex	1 x 1.0ml	1 x 2.0ml	1 x 4.0ml	2x3.0 ml
Positive Control	1 x0.5ml	1 x 0.5ml	1 x 1.0ml	1 x 1.5ml
Negative Control	1 x 0.5ml	1 x 0.5ml	1 x 1.0ml	1 x 1.5ml
Test Cards Reusable	1	1	2	3
Pipette / Stirrers	25	50	100	150

Composition:

RF Latex	Suspension of Latex Particles coated with human gamma-globulin to detect 8iu/ml on testing against the International Reference Preparation of Rheumatoid Arthritis Serum (WHO).
Positive Control	Human Serum Sodium Azide 0.95g/L.
Negative Control	Human Serum Sodium Azide 0.95g/L.

Although all our components which have been derived from human origin have been tested and found to be negative for the presence of anti-HIV, anti-HCV as well as HbsAg, it is recommended that they be handled cautiously and treated potentially infectious.

Storage:
Store components at 2-8°C. Cards and Pipettes may be kept at Room Temperature.

Samples:
- Serum stable for 48 hours at 2-8°C.
- Samples should be free from contamination, haemolysis and Lipaemia.

Additional Equipment:
Mechanical Rotator set at 100 r.p.m.

Test Procedure:
1. Bring the reagents and samples to room temperature.
2. Place 50µl of the sample and 1 drop of the control into separate circles on the card.
3. Resuspend the latex gently.
4. Add one drop of the latex reagent to each circle next to the sample which is to be tested.
5. Mix with the disposabe pipette / stirrer and spread over the entire area enclosed by the ring. Use a new stirrer for each sample.
6. Rotate the cards at 100 r.p.m. for 2 minutes.

Quantitative Test
1. Using a semi-automatic pipette, add 50µl of 9g/L saline to
2. circles 2, 3, 4 and 5. Do not spread the saline.
3. Add 50µl of patient sample to circles 1 & 2.
4. Mix the saline and sample in circle 2 by drawing the mixture up and down being careful to avoid the formation of any bubbles.
5. Transfer 50µl from circle 2 to the saline in circle 3.
6. Perform serial dilutions in the same manner until the last circle, discarding 50µl at the end.
7. Using the pipette / stirrer, spread the diluted samples over the entire area of each circle starting at circle 5 and working backwards to the neat sample in circle 1.
8. Proceed as a qualitative test from step 3.

Quality Control:
Each run of tests should be validated with a positive and negative control.

Reading and Interpretation:
- Examine macroscopically for the presence or absence of clumps or agglutination within 1 minute of removing the card from the rotator.
- The presence of visible agglutination indicates a content of rheumatoid factor ≥8 iu/ml.
- Positive sera may be titred. To titrate make serial two-fold dilutions in 9g/L saline as indicated in the Quantitative Test procedure. The serum titre is defined as the highest dilution showing positive agglutination. The approximate RF level (iu/ml) present in the sample may be obtained multiplying the titer by the limit of sensitivity (8iu/ml). For example:-

Dilution	RF ju/(In Neat Specimen)
Neat	8
1:2	16
1:4	32
1:8	64
1:16	128
1:32	256

If the endpoint dilution is 1:32, the corresponding RF serum concentration would be 32 x 8 or 256iu/ml.

Limitations of the Procedure:
- Diagnosis must not be based solely on the result of this test but should be complemented with others (ie RF-Waaler test) along with the clinical examination.
- The incidence of positive results with serum from apparently healthy individuals is 3 – 5%.
- Positive reactions do occur in conditions other than rheumatoid arthritis such as mononucleosis, hepatitis, syphilis and also in elderly patients.

Notes:
1. The sensitivity of the test may be reduced at low temperatures. The best results are obtained over 10°C.
2. Delay in reading the results may result in over-estimation of the RF level.
3. The results obtained with the latex test do not compare with those obtained by the Waaler Rose test. Differences in results do not reflect a difference between techniques in the ability to detect rheumatoid factors.

Reference:

1. Singer JM et al. American Journal Clinical Pathology 1956; 21: 888 – 982
2. Jones WL et al. American Journal Clinical Pathology 1973; 60: 603 – 610
3. Waaler M et al. Arthritis Rheum 1961; 4: 47 – 54
4. Plotz CM et al. American Journal Medicine 1956; 21: 893 – 896
5. Ball J et al. Ann Rheum Dis 1963; 22: 311 – 314
6. Kunkel HG. J Chron Dis 1959; 10: 418 – 427
7. Anderson SG et al. Bull Hlth Org 1970; 42: 311 – 317

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