Rheumatoid Factor Latex Kit Assay

CE

Rapid Labs

REF IVD +2°C +8°C

CATALOGUE NUMBER

RL-RA50 RL-RA50NA
RL-RA100 RL-RA100NA

INTENDED USE

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

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). An study of the "American College of Rheumatology" shows that the 80,4% of RA patients were RF positive.

MATERIALS

Materials provided

Latex	Polystyrene Latex particles coated with human gamma globulin. Sodium Azide: 0.9%
Control + (red cap)	Human Serum based, RF concentration >30IU/ml
Control – (green cap)	Human/Animal serum based, RF negative control Sodium azide <1%

Following materials are available with RL-RA50 & RL-RA100

RL-RA50	RL-RA100
• 5 slide cards	• 10 slide cards
• 50 plastic stirrers	• 100 plastic stirrers

Materials required but not provided

- Mechanical rotor (100 r.p.m
- Micropipette and tips (50µl)
- Isotonic saline

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.
- Reagents must be stored between 2-8^{0}C
- Do not freeze
- Store vials upright
- Reagents are provided ready to use.
- Ensure that the reagents are mixed thoroughly before use
- If reagents have particulate matter and aggregates, discard vial and contact Rapid Labs

SAMPLE COLLECTION AND PREPARATION

- Use fresh serum
- Serum used must not be haemolysed or contaminated or lipemic as it may affect test results.
- Storage and usage after time serum must be stored at 2-8^{0}C.
- Use serum within 7 days
- For longer storage store at -20^{0}C for 3 months.

CALIBRATION AND TRACEABILITY

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

LIMITATIONS

- 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.

DIRECTIONS FOR USE

Qualitative method:

1. Allow reagents to reach room temperature before use. Do not use directly from 2-8^{0}C temperature.
2. On a clean slide, place one drop of negative control, positive control and 50µl of patient sample on separate circles.
3. Mix the RF reagent thoroughly (vortex) and add one drop (50µl) to each of the circles.
4. Mix the reagent and the controls/sample drops with a plastic stirrer, ensuring to spread it throughout a 2cm diameter.
5. Place the slide on a mechanical rotor (100 r.p.m) and mix for 2 minutes. Read results macroscopically, do not interpret results after 2 minutes.

Semi-quantitative method:

1. Prepare serial dilutions of the patient's sample with normal saline (preferable dilution are a double dilution).
2. Follow steps 2 to 5 of the Qualitative method. (negative and positive controls are used neat).

INTERPRETATION OF RESULTS

- 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.
- The approximate RF concentration in the patient sample is calculated as follows:

8 x RF Titer = IU/mL

QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of test procedure, as well as a comparative pattern for a better results interpretation. All result different from the negative control result, will be considered as a positive.

PERFORMANCE CHARATERISTICS

- Analytical sensitivity: 8 (6-16) IU/mL, under the described assay conditions
- 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.

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EXPECTED VALUES

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

INTERFERING SUBSTANCES

No interference from:
Bilirubin up to 20mg/dl
Haemoglobin up to 10g/l
Lipids up to 10g/l

BIBLIOGRAPHY

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3. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528 – 534.
4. Adalbert F S et al. The New England Journal of Medicine 1959; 261: 363 – 368.
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6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995

Index of Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only
REF	Catalogue Number	LOT	Lot Number
+2°C +8°C	Store between 2-8°C		Use by
	Manufacturer		Date of manufacture

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