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

For In Vitro Diagnostic Use Only

The RF Visual Latex assay is intended for the qualitative and Semi-quantitative determination of Rheumatoid Factor in Human Serum.

The product is intended for use by qualified laboratory personnel only.

SUMMARY

Polystyrene Latex particles are coated with Anti Human IgG Fc fraction. If RF positive sample reacts with the latex reagent, agglutination occurs. RF is found to be increased in conditions such as SLE, Sjogren's syndrome and in 80% of patients with Rheumatoid arthritis.

MATERIALS

Materials provided

Latex	Polystyrene Latex particles coated with Anti Human IgG Fc. Sodium Azide: 0.9%
Control + (red cap)	Human Serum based, RF concentration >35IU/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
- 5 slide cards
- 50 plastic stirrers

RL-RA100
- 10 slide cards
- 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

Rapid Labs RF Visual Latex has been calibrated against NIBSC 64/002.

LIMITATIONS

- Use serum. No other sample has been validated with this assay.
- Infection is early or in children from 6 months to 12 months.
- Repeat testing is suggested in intervals of 1 to 2 weeks to rule out positive results. A Clinical judgement should not be arrived at using a single estimation.

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 the slides after 2 minutes under a strong source of light.
- Kit controls or known samples should be tested with each run.
- Visible Agglutination indicates the presence of RF concentration equal to or greater than 8 IU/ml.
- The Semi-Quantitative titre is the highest dilution at which visible agglutination is seen.
- The Approximate concentration of RF in the patient's sample is calculated as follows:

8 x RF Titre = Concentration in IU/ml.

- 8 is the sensitivity of the method.

PERFORMANCE CHARATERISITCS

- No Prozone was seen up to an RF Concentration of 1500 IU/ml
- Analytical Sensitivity of 8 IU/ml
- Diagnostic Sensitivity: 100%
- Diagnostic Specificity: 100%

EXPECTED VALUES

Up to 8 IU/ml

Rheumatoid Factor Latex Kit Assay

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INTERFERING SUBSTANCES

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

BIBLIOGRAPHY

1. Young DS. Effects of drugs on clinical laboratory test, 4th Ed. AACC Press, 1995.
2. Klein GC. Manual of Clinical Immunology, American Society for Microbiology, 1976.
3. Halbert SP. Ann NY Academy Sciences, 1963.

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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