

RHEUMATOID FACTORS (RF)Latex

RHEUMATOID FACTOR(SLIDE LATEX AGGLUTINATION TEST)

Intended Use

The reagents are for *in-vitro* diagnostic use only.

Principle

The RF Reagent is a suspension of polystyrene latex particles sensitized with specially prepared human IgG in order to avoid unspecific agglutination. The RF latex reagent sensitivity has been adjusted to detect a minimum of 8 IU/mL of rheumatoid factors according with the WHO international Standard without previous sample dilution.

Reagent provided

1. Reagent 1- Latex RF in suspension (contains Sodium Azide 0.1%).
2. Reagent 2-Positive Control containing at least 8 IU/mL of RF.*
Human Serum(Contains Sodium Azide 0.1%).
3. Reagent 3- Negative Control containing less than 8IU/mL of RF.*
Human Serum. (Contains Sodium Azide 0.1%).

*The human sera used in the controls has been tested and found negative for HBsAg and HIV.

However a careful handling is always recommended.

Reagent storage and stability

Shake the Reagent 1 (RF Latex) before use. After that it must be uniform and without visible clumping. The test sensitivity depends on the drop volume (40 µl).Do not use droppers other than those provided in the kit and place the dropper perpendicular to the slide surface.

The Reagents, if stored at 2-8°C are stable till the expiry date stated on the label. DO NOT FREEZE.

Specimen collection and preservation

Blood should be collected in a clean dry container. Avoid the use of plastic or siliconized container which may prolong clotting time. Haematic, lipaemic or contaminated sera must be discarded.

Procedure

- Before using the kit, allow the components to reach room temperature.
- Gently shake the reagent to disperse the latex particles.

A. Qualitative Test

1. Check the reagent against the positive and negative controls (as follows).
2. Place a drop (40 µl) of UNDILUTED serum into a circle of the slide.
3. Add a drop (40 µl) of the Reagent 1 (RF Latex) next to the drop of serum.
4. Mix both drops spreading them over the full surface of the circle.
5. Rotate the slide, manually or with a mechanical rotor at 80-100 rpm for two minutes. Read the presence or absence of visible agglutination in this period of time. **Unspecific agglutination could appear if the test is read later than two minutes.**

Reading

- Presence of agglutination indicates a content of RF in the sample equal or greater than 8 IU/ml.
- The lack of agglutination indicates an RF level lower than 8 IU/ml in the sample.

B. Semi-Quantitative Test

The test will be performed in the same way as qualitative test but using dilution of the serum sample in saline (NaCl 9g/l) PBS or glycine buffer.

Dilutions	1:2	1:4	1:8	1:16
Sample Serum	100 µl	-	-	-
Saline	100 µl	100 µl	100 µl	100 µl
	→	100 µl →	100 µl →	100 µl
Volume of above diluted sample	40 µl	40 µl	40 µl	40 µl

Concentration will be the reciprocal of positive reading dilution

8 x n(Ratio of Dilution)	8 x2	8 x4	8 x8	8 x16
IU/ml	16	32	64	128

Normal Range

Adults: < 8 IU /ml

The Rheumatoid Factors are immunoglobulin's (most of the IgM) with antibody activity. These factors are present in most of patients suffering from Rheumatoid Arthritis. There are different rheumatoid factors and does not exist any test capable to detect all of them, due to the fact that some of them acts against human IgG. We recommended the use of WR test specific for detection of rheumatoid factors acting against animal IgG. (Ref: 1200502).

References

- 1Plotz and Singer, Am.J.Med.22, (1979).
2. Adams, L.E., Hess, E.J.Amer.Technol.48 (1978).
- 3.Normausell, D.Immunochemistry 9, (1972).
- 4.Dito, W.Am.Soc.Clin.Pat. 69, (1976).

Symbols

IVD	In Vitro Diagnostics.	 Caution.	 Keep away from sun light.	 Date of Manufacture.
LOT	Batch No.	 Read Instructions.	 Fragile.	 Product Expiry Date.
CONT	Content.	 Storage Temperature.	 Keep Dry.	 Manufactured By.
REF	Catalogue No.			



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