

ESTROM RF Latex

(Agglutination Method)

This diagnostic reagent kit is used for In Vitro qualitative & semi-quantitative determination of Rheumatoid factor in patient serum.

PRINCIPLE:

The Latex reagent mixed with serum sample containing RF shows agglutination indicating positive test result. The Latex reagent antigen consists of polystyrene latex particles coated with specially purified human gammaglobulin. Agglutination reaction depends on concentration of Rheumatoid factor in serum that may be equal or greater than sensitivity mentioned as detectable by slide test method.

CLINICAL SIGNIFICANCE :

Rheumatoid factor measurement helps in differentiating rheumatoid arthritis from other chronic inflammatory arthritis & is important in the progress & therapeutic management of the disease. The immunoglobulins of the class IgG, IgM, IgA or IgE, auto antibodies are diagnostically important for Rheumatoid arthritis & are termed as Rheumatoid factor. RF also associated with some bacterial & viral infections (eg. hepatitis, infections mononucleosis), some chronic infections (eg. tuberculosis, parasitic diseases, subacute bacterial endocarditis and cancer.

SPECIMEN COLLECTION AND STORAGE:

- Fresh, clear serum is preferred.
- Avoid use of plasma, hemolysed & lipaemic serum, as fibrinogen in plasma may give nonspecific agglutination.
- Serum sample should be stored at 2-8°C after collection.

PRECAUTION:

- Bring all the reagents at room temperature before use.
- Positive & Negative controls are ready to use to ensure greater proficiency of result interpretation
- Drying of reagents & improper mixing will lead to erroneous results.
- Latex reagent should be completely released from the dropper before capping to avoid drying and formation of flakes upon storage at 2-8°C.
- Do not freeze latex reagent or expose to extreme temperature.

KIT CONTENTS:

A) REAGENTS

- Reagent 1 - Latex Reagent
- Reagent 2 - Positive Control
- Reagent 3 - Negative Control

B) ACCESSORIES

- Glass slide, Rubber teats
- Disposable Applicator Sticks
- Disposable plastic droppers

REAGENT STORAGE AND STABILITY

All reagents are stable at 2-8°C till the expiry date mentioned on the label.

PROCEDURE:

A) QUALITATIVE TEST:

- Place one drop of test specimen, positive control & negative control in the separate test circle of glass slide.
- Add one drop of Latex reagent to the above drop & mix well with disposable applicator stick.
- Rock the slide gently for two minutes & observe for agglutination.

Do not use magnifying lens to see

RESULT INTERPRETATION:

- The Presence of agglutination in two minutes indicates concentration of RF in the sample equal or more than 8IU/ml.
- No agglutination confirms negative result & indicates absence of RF in the test serum.

B) SEMI QUANTATIVE TEST:

- Dilute the test serum sample serially in the ratio of 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 using normal saline.
- Place one drop of diluted samples in the separate test circle of glass slide.
- Add one drop of Latex reagent in each of these circle. Mix well with disposable applicator stick.
- Rock the slide gently for two minutes & look for agglutination.

RESULT INTERPRETATION:

- Agglutination in the highest dilution corresponds to the RF concentration. Concentration of
- Rheumatoid Factor can be determined as follows.
- RF in IU/ml = D x S
- D = Highest dilution showing clear cut agglutination
- S = Sensitivity of test is 8 IU/ml











LIMITATIONS

- Positive test results may also found in syphilis, systemic lupus erythematosus, hypergammaglobulinemia, hepatitis, so final diagnosis should be followed after correlation of test results with other clinical symptoms & findings.
- Controls should be handled with proper care though the source material used in the manufacture of positive & negative controls is tested for HBsAg & HIV antibodies and is found to be negative.

BIBLIOGRAPHY:

- Rheins, M.S. et.al (1957), Proc. Soc. Exp. Biol. Med. 97, 180
- Sanger, J.M., (1956); Am. J. Med. 21. 1988

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	Attention, see instructions for use		Consult Instructions For Use
	For in vitro diagnostic use only		Catalog #
	Store between 2-8°C		Lot Number
	Do not use if package is damaged		Date of Manufacturing
	Manufacturer		Use by