

Rheumatoid Factor (RF)

A Rapid latex slide test

IVD

REF.	Pack size
370 01 005	100 test (latex only)
370 02 025	50 test (latex with positive control)
370 02 045	100 test (latex with positive control)
370 03 025	50 test (Complete Kit)
370 03 045	100 test (Complete Kit)

Intended Use

Rapid latex agglutination test for the qualitative screening and semi-quantitative determination of rheumatoid factor (RF) in human serum.

Introduction

Rheumatoid factors are immunoglobulins which are directed against the Fc portion of IgG. Rheumatoid arthritis is a chronic systemic disease of unknown etiology. Its diagnosis is based on combined clinical and radiographic analysis. The determination of RF is the laboratory test that is most commonly used not only for the diagnosis of rheumatoid arthritis but also assists in the prognosis of the disease and in the monitoring of therapeutic response.

Method

latex qualitative slide test

Principle

RF latex reagent is a suspension of polystyrene particles sensitized with human gamma globulin. When the latex reagent is mixed with a serum containing rheumatoid factor, visible agglutination occurs. The latex reagent has been produced so that agglutination will take place only when the level of RF is greater than 10 IU/ml.

Reagents

Latex Reagent

A suspension of polystyrene latex particles in glycine-saline buffer pH: 8.6 ± 0.1 , coated with human gamma globulin.

Positive Control Serum (bottle with red cap)

Is prepared from a stabilized human serum pool containing RF. Both reagents contain 0.9 g/L Sodium azide as a preservative.

Negative Control Serum (bottle with white cap)

Reagent contain 0.9 g/L Na azide as a preservative.

NOTE: Negative Control Serum, Slides and Stirrers are only included in Complete Kits

Reagents Preparation, Storage and stability

The reagents are stable till the expiration date specified when stored at $2 - 8^{\circ}\text{C}$. Open vials are stable for 6 months at the specified temperature.

Precautions and warnings

All human blood components used to prepare controls have been tested for Hepatitis B surface antigen (HBsAg) and HTLV-III antibodies by FDA approved procedure and found to be non-reactive. No known test method for HBsAg or HTLV-III antibodies offers total assurance that a human-derived product will not transmit hepatitis or HTLV-III virus. The user is therefore cautioned to handle reagents as if being capable of transmitting these diseases.

Specimen collection and preservation

Use only serum specimens, samples can be stored for 24 hrs at $2 - 8^{\circ}\text{C}$. For longer storage, it is recommended to store the samples at -20°C .

Procedure

Qualitative Test (Screening)

1. Bring all reagents and specimens to room temperature.
2. Place one drop (50 μl) of the positive control and 50 μl of the patient serum into separate circles on the glass slide.

3. Shake the RF latex reagent gently and add one drop (45 μl) on each circle next to the sample to be tested and control.

4. Mix well using disposable stirrer spreading the mixture over the whole test area and tilt the slide gently. Agitate for about 2 minutes with rotator or by hand and observe for the presence or absence of agglutination.

Results

Negative result: No agglutination of the latex particles suspension within two minutes.

Positive result: An agglutination of the latex particles suspension will occur within two minutes, indicating a RF level of more than 10 IU/ml.

Semi-Quantitative Test

1. Serum to be titrated is serially diluted (1:2, 1:4, 1:8 etc) in 0.9 g/L saline solution.
2. Place one drop of positive control on slide. Do not attempt to dilute the RF positive control serum for comparative or other purposes as no correlation exists between actual titre of the control and titre of unknown sera.
3. Place 50 μl of each serum dilution individually in successive circles on the slide and proceed as in screening methodology.

Results

The serum RF titre can be defined as the highest dilution showing a positive result. The approximate RF level (IU/ml) present in the sample can be obtained by the following formula:

$$\text{RF Titre (IU/ml)} = \text{Highest dilution with positive reaction} \times \text{Reagent sensitivity (10 IU/ml)}$$

e.g. if the agglutination is present up to a titre 1:8, the approximate serum RF level is $8 \times 10 = 80 \text{ IU/ml}$.

Expected Value

Not clearly specified. However, it has been found that the existence of significantly high titre (more than 30 IU/ml) are present in more than 70 % of patients with rheumatoid arthritis.

Limitations of the procedure

Occasional agglutinations observed after 4 minutes have no diagnostic significance. Highly haemolyzed and lipemic serum as well as plasma interfere with the test.

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Performance characteristics

- 1-Prozone effect: No detected prozone effect up to 1500 IU/ml
 - 2-Analytical Sensitivity: 10 IU/ml.
 - 3-Diagnostic Sensitivity: 100 %
 - 4-Diagnostic Specificity: 99 %
- The diagnostic sensitivity and specificity were obtained by comparing 150 samples with one commercial kit.

Interferences

Lipids (10g/L), hemoglobin (10g/L) and Bilirubin (20mg/dL) do not interfere.

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Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.









S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Ball J. et al. Ann Rheum. Die 1963 ; 22 : 311-314.
2. Halbert, SP. Ann. N.Y. Acad. Sci., 103, 1027:1051; 1963.
3. Klein GL, Applied Microbiology, 21:999, 1971.
4. Klein GC: Manual of Clinical Immunology ASM 264-273:1976.
5. Rantz LD, DiCapri JM, Randall E. Am. J. Med. Sci., 24,1952.

SYMBOLS IN PRODUCT LABELLING

	For in-vitro diagnostic use
	Batch Code/Lot number
	Catalogue Number
	Consult instructions for use
	Temperature Limitation
	Use by/Expiration Date
	CAUTION. Consult instructions for use
	Manufactured by