



Instructions For Use

Valid as of 03.11.2025

RF Latex

REF 4096

Latex agglutination test for the detection of rheumatoid factor (RF) in human serum



GA Generic Assays GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow OT Dahlewitz
Germany

Phone.: +49 33708 9286 0
Fax: +49 33708 4417 25

info@genericassays.com
www.genericassays.com



1 Intended Purpose

The RF Latex is a qualitative and semi-quantitative immunoassay for the determination of rheumatoid factor (RF) in human serum.

The RF Latex is intended as an aid in the diagnosis of rheumatoid arthritis in conjunction with other clinical and laboratory findings.

The immunoassay is designed for manual professional *in vitro* diagnostic use.

2 Diagnostic Relevance

Rheumatoid factors (RF) are antibodies directed against antigenic sites in the Fc fragment of human and animal IgG. Their frequent occurrence in rheumatoid arthritis makes them useful for diagnosis and monitoring of the disease.

One method used for rheumatoid factor detection is based on the ability of rheumatoid arthritis sera to agglutinate sensitized sheep red cells, as observed by Waaler and Rose. A more sensitive reagent consisting of biologically inert latex beads coated with human gamma globulin was later described by Singer and Plotz. The RF Latex is based on the principle of the latex agglutination assay of Singer and Plotz.

3 Test Principle

The agglutination test is widely used for the determination of specific antigens. Latex particles are coated with antigen-specific antibodies. If specific antigens are present in the patient's sample, they bind to the antibodies resulting in visible agglutination of the latex particles.

4 Test Components

Component	Description
Latex reagent A LATEX 1 x 4.0 mL	Latex particles coated with human IgG (ready-to-use; contains sodium azide)
Negative control N CONTROL - 1 x 1.0 mL	Dilution of human serum (ready-to-use; contains sodium azide)
Positive control P CONTROL + 1 x 1.0 mL	Dilution of human serum (ready-to-use; contains sodium azide)
Agglutination slide 1 item	-
Disposable stirring sticks 50 items	-
Instructions for Use 1 item	-

5 Materials required but not provided

- Common laboratory equipment
- Precision pipettes (5 – 1000 µL) and disposable tips
- Sample tubes for the preparation of dilutions and rack
- High intensity light source
- Phosphate or glycine buffered saline (0.9 %)
- Optional: Horizontal rocking shaker
- Timer

6 Storage and Stability

Upon receipt, all test components must be stored at 2 °C to 8 °C, preferably in the original kit box. If stored properly in their original containers, all components are stable until their expiry date. All components are stable for at least 3 months after opening when stored properly at 2 °C to 8 °C.

7 General Information

This product is for *in vitro* diagnostic use only. The instructions for use must be carefully read before use. They are valid only for the present product with the given composition and must be strictly followed to ensure reliable test results. Deviations can lead to erroneous test results. Components must not be exchanged by test reagents of different lots or of other manufacturers.

Contamination of reagents must be avoided by use of aseptic techniques when removing aliquots from the vials. After use, reagent vials must be tightly closed with their corresponding caps.

Cross-contamination of samples or reagents can lead to inconsistent test results and must be avoided by use of consistent pipetting techniques.

8 Preparation

8.1 Preparation of Reagents

All components must be brought to room temperature (RT: 18 °C to 25 °C) before use for at least 30 min. All liquid components and suspensions must be mixed gently to ensure homogeneity.

8.1.1 Latex Reagent

The latex reagent is ready-to-use. Mix gently before use to ensure homogeneity. The suspension must be uniform without visible clumping. Do not vortex. When stored at 2 °C to 8 °C, a slight sedimentation may occur. Do not freeze and do not use the

latex reagents if it is marked with turbidity as this may indicate reagent deterioration or contamination.

8.1.2 Controls

The controls are ready-to-use and must not be diluted any further. Controls must be used in each test run. Laboratories can also validate their own control samples and use them alternatively.

8.1.3 Agglutination Slide

The agglutination slide must be rinsed thoroughly with water and wiped with lint-free tissue after each use.

8.2 Preparation of Samples

8.2.1 Sample Material

The use of freshly collected serum from blood taken by venipuncture is recommended. The use of icteric, lipemic, hemolytic or bacterially contaminated samples should be avoided. Insoluble substances must be removed from the sample by centrifugation. Samples must not be thermally inactivated.

8.2.2 Sample Dilution

For qualitative evaluation, samples are used undiluted. For semi-quantitative evaluation, samples are diluted 1:2, 1:4, 1:8, 1:16, 1:32 etc in glycine buffered saline as follows:

1:2 dilution: 100 µL sample plus 100 µL saline,

1:4 dilution: 100 µL 1:2 dilution plus 100 µL saline,

1:8 dilution: 100 µL 1:4 dilution plus 100 µL saline, etc.

8.2.3 Sample Storage

Samples may be kept at 2 °C to 8 °C up to three days. Long-term storage requires -20 °C. Repeated freezing and thawing should be avoided. For multiple use, samples should be aliquoted and kept at -20 °C.

9 Test Performance

9.1 Procedure

The indicated incubation times and temperatures must be adhered to and significant time shifts during pipetting samples and reagents must be avoided.

Step	Description
1. Addition of positive control	Add 40 µL (1 drop) ready-to-use positive control on test field #1 of the agglutination slide
2. Addition of negative control	Add 40 µL (1 drop) ready-to-use negative control on test field #2 of the agglutination slide
3. Addition of sample	Add 40 µL (un-) diluted sample on the following test fields of the agglutination slide
4. Addition of latex reagent	Add 40 µL (1 drop) ready-to-use latex reagent to each test field. Mix latex reagent and sample using individual stirring sticks per field over a large area (use the top and bottom of the stick).
5. Incubation	Gently shake the agglutination plate by hand in a circular motion for 2 min (alternatively: on a shaker at 80 – 100 rpm)
6. Analysis	Read immediately under strong light source

10 Test Evaluation

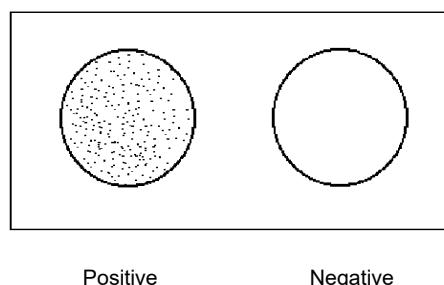
10.1 Metrological Traceability

The immunoassay was calibrated using the reference preparation NIBSC 64/002. Results are given qualitatively or semi-quantitatively as titer steps, a conversion of the titer steps into IU/mL is possible due to the calibration.

10.2 Evaluation

A sample is evaluated negative, if a uniform milky suspension appears without signs of agglutination.

A sample is evaluated positive, if any signs of agglutination is observable in the reaction mixture. A weakly reactive sample produces a very fine granulation or a partial clumping especially in the border area. The reaction should be compared with the negative control for precise evaluation.



Clear agglutination indicates an RF content of more than 8 IU/mL in the non-diluted serum specimen. Sera that are positive in the qualitative test should be re-tested in the semi-quantitative test to verify borderline results.

For semi-quantitative evaluation, record the last dilution showing a positive reaction. The titer of the serum is the reciprocal of the highest dilution, which exhibits a positive reaction. For example, if the last positive reaction is found in the 1:8 dilution, the titer of the sample is 8.

To determine the concentration in IU/mL, multiply the titer with the conversion factor 8:

Dilution	1:2	1:4	1:8	1:16	etc.
IU/mL	16	32	64	128	etc.

10.3 Criteria of Validity

Test runs are only valid if the following criteria of validity are fulfilled:

- The negative control must be evaluated negative.
- The positive control must be evaluated positive.

If these criteria are not met, the test is not valid and must be repeated.

10.4 Troubleshooting

In case of an invalid test run, the expiry dates and storage conditions, incubation times and temperatures, and precise calibration of all instruments used should be verified. If no reason for an invalid test run could be identified, please contact the supplier or manufacturer of the product.

10.5 Reference Ranges

The diagnosis of rheumatoid diseases is based largely on clinical examination, but laboratory tests are useful to support the clinical diagnosis and to evaluate the severity and course of the disease in the individual patient. One of the most useful clinical markers for rheumatoid arthritis is rheumatoid factor in serum.

Rheumatoid factor is a term used to describe a variety of antibodies or immune complexes or both, that occur with rheumatoid arthritis as well as in a variety of other diseases.

Different studies have shown positive serological reactions for rheumatoid factor in as high 90% of patients with rheumatoid arthritis compared with less than 5% in control groups.

As a result of different prevalences in individual regions, each laboratory should verify the reference ranges by own analysis and adapt, if necessary.

10.6 Interpretation of Test Results

A positive test result indicates the presence of specific antibodies. A negative result indicates the absence of specific antibodies.

10.7 Limitations of the Method

Reaction time is critical. If reaction time exceeds 2 minutes, drying of the reaction mixture may cause false positive result.

Freezing the RF Latex Reagent will result in spontaneous agglutination.

Intensity of agglutination is not necessarily indicative of relative RF concentration; therefore, screening reactions should not be graded.

Increased levels of RF may be found in some diseases other than rheumatoid arthritis such as infectious mononucleosis, sarcoidosis, lupus erythematosus, Sjogren's syndrome.

Certain patients with rheumatoid arthritis will not have the RF present in their serum (6).

The interpretation of test results must always be considered in combination with the clinical picture of the patient. The diagnosis should not be based on the results of a sole diagnostic method. All clinical and laboratory findings should be evaluated to state a diagnosis. For confirmation, further investigations should be carried out.

11 Performance Characteristics

11.1 Analytical Performance Characteristics

11.1.1 Analytical Sensitivity and Specificity

The analytical sensitivity was assessed to 8 IU/mL.

The limit of detection has been determined according to WHO International RA standard. Concentration of sample used has been confirmed by turbidimetry, defined dilutions have been tested in the Latex assay:

RF (IU/mL)						
Conc.	50	20	16	12	8	4
Result lot 1	3+	3+	3+	2+	+	-
Result lot 2	3+	3+	3+	2+	+/-	-

The analytical specificity was assessed by addition of potentially interfering substances to samples. A significant influence of bilirubin (up to 20 mg/dL), hemoglobin (up to 10 g/L) and triglycerides (up to 10 g/L) on test results was not observed.

11.1.2 Precision

The precision of test results was assessed by the determination of the intra- and interassay variation by the analysis of multiple samples with different antigen activities. No differences in the qualitative evaluation has been detected.

11.2 Diagnostic Performance Characteristics

11.2.1 Diagnostic Sensitivity and Specificity

118 samples have been compared in RF Latex and a latex test from a competitor. The relative sensitivity of GA RF Latex has been detected at 98 %, the relative specificity was found at 97 %.

		RF Latex	
		+	-
Competitor Latex	+	48	1
	-	2	67

Another 123 samples have been compared with turbidimetric assay. The relative sensitivity of GA RF Latex has been determined at 100 %, the relative specificity at 99 %.

		RF Latex	
		+	-
Turbidimetry	+	35	0
	-	1	87

12 Warnings and Precautions

The product is designed exclusively for *in vitro* diagnostic use by qualified, authorized and trained personnel. All test components and human samples should be handled with care as potentially hazardous. Good laboratory practices (GLP) and all relevant regulations should be adhered to.

In case the product is damaged or product information including labelling is wrong or incorrect, please contact the manufacturer or supplier.

As the product contains potentially hazardous materials, the following precautions should be followed: Do not smoke, eat or drink while handling kit material or samples. Avoid direct contact to kit material or samples by wearing protective gloves laboratory coat and safety glasses. Never pipette material by mouth. Wipe up spills promptly and wash the affected surface thoroughly with a decontaminant. Wash hands thoroughly after use.

Some of the reagents contain sodium azide (< 0.1 %) as a preservative and must not be swallowed or allowed to come into contact with skin or mucosa. The possible formation of heavy metal azides in the drainage has to be prevented by sufficient rinsing with water.

The information in the safety data sheet on possible hazards, first aid measures, measures in the event of the unintentional release of large quantities, handling and storage, personal protective equipment, information on disposal as well as information on toxicology must be observed.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the member state in which the user and/or the patient is established.

13 Disposal

For decontamination and disposal the recommendations of the CDC as well as the relevant local and national environmental guidelines and regulations should be adhered to. Samples, potentially contaminated materials and infectious waste must be decontaminated, e.g. by autoclaving for 20 min. at 121 °C.

14 References

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15 Symbols

	Manufacturer
	CE marking of conformity
	Not for near patient testing
	In vitro diagnostic medical device
	Catalogue number
	Unique device identifier
	Batch code

	Temperature limit
	Use-by date
	Consult instructions for use
	Contains sufficient for <n> tests
	Do not re-use
	Caution
	Biological risk
	Keep away from sunlight
	Latex reagent
	Negative control
	Positive control

16 Changes

Changes in current Instructions for Use	
Current Version	007/11.2025
Summary of Changes	Editorial changes in section 10