



# INSTRUCTION MANUAL

REF 4096

January 02, 2009

## RF Latex

- 100 determinations -



IVD *In vitro* diagnostic device

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

<b>REF</b>	Catalogue number	<b>LOT</b>	Batch code
	Consult accompanying documents		Manufactured by
	Temperature limitation		Use by
	Consult operating instruction		Biological risk



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### INTENDED USE

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

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 (1,2).

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 (3) and Rose (4). A more sensitive reagent consisting of biologically inert latex beads coated with human gamma globulin was later described by Singer and Plotz (5). The RF Latex is based on the principle of the latex agglutination assay of Singer and Plotz (5). The major advantage of this method is rapid performance (two minute reaction time) and lack of heterophile antibody interference.

1. Taborn J.D, et al.: Rheumatoid Factor: 1 Review, Lab. Med. 10, 392 (1979).
2. Dornerm RW, et al.: Critical Review Rheumatoid Factor. Clin Chem Acta 167, 1 (1987).
3. Waaler E: Acta.Path. Microbial Scan 17, 172 (1942).
4. Rose HM, et al.: Proc Soc Exp Biol Med 68, 1 (1943).
5. Singer JM, et al.: Am J Med 21, 888, (1956).
6. Winchester R: Am. Soc. Micro 665 (1976).
7. Rothermich NO, et al.: JAMA 164, 1999 (1957).
8. Hansen SL, et al.: Am J Clin Pathol 73, 110 (1980).

### PRINCIPLE OF THE TEST

RF Latex is used for the determination of rheumatoid factor (RF) in human serum.

The RF reagent is based on an immunological reaction between human IgG bound to biologically inert latex particles and rheumatoid factors in the test specimen. When serum containing rheumatoid factors is mixed with the latex reagent, visible agglutination occurs.

### TEST COMPONENTS for 100 determinations

<b>A</b>	<b>Latex reagent,</b>	4.0 ml
<b>LATEX</b>	Latex particles coated with human IgG	ready for use dropper bottle
<b>P</b>	<b>Positive control</b>	1.0 ml
<b>CONTROL</b>	RF positive human serum concentration > 20 IU/ml	 ready for use dropper bottle
<b>N</b>	<b>Negative control</b>	1.0 ml
<b>CONTROL</b>	RF negative human serum	 ready for use dropper bottle
	<b>Agglutination slide</b>	1 ready for use
	<b>Disposable stirring sticks</b>	100 ready for use

### Materials required but not provided

- timer
- test Tubes and rack.
- serological pipettes
- high intensity light
- Glycine saline buffer (alternatively PBS)
- rocking shaker (optional)

## Size and storage

RF Latex has been designed for 100 determinations.

The expiry date of each component is reported on its respective label that of the complete kit on the box labels.

Upon receipt, all components of the RF Latex have to be stored at 2 - 8 °C, preferably in the original kit box. The RF Latex Reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal. **Do not freeze!**

Do not use the latex reagents if it is marked with turbidity as this may indicate reagent deterioration or contamination.

After opening all kit components are stable for at least 3 months, provided proper storage.

Agglutination slide should be thoroughly rinsed with water and wiped with lint-free tissue after each use.

## PATIENT SAMPLES

Use fresh serum collected by centrifuging clotted blood.

If the test cannot be carried out on the same day, the serum may be stored between 2 - 8°C for no longer than 72 hours after collection. For longer periods the sample must be frozen.

As in all serological tests, hemolytic or contaminated serum must not be used. **Do not use plasma!**

## ASSAY PROCEDURE

### Qualitative evaluation

1. Allow all reagents and samples to reach room temperature prior to testing. Shake well all reagents before use.
2. Place **1 drop** (appr. 40 µl) of the positive control (P) on field no. 1 of the agglutination slide.
3. Place **1 drop** (appr. 40 µl) of the negative control (N) on field no. 2 of the agglutination slide.
4. Place **40 µl** of each undiluted patient sample to the following fields of the agglutination slide using different serological pipettes.
5. Gently resuspend the RF Latex reagent (A) and add **1 drop** (40 µl) to each test field.
6. Mix well using separate stirring sticks.
7. Gently rock the slide for **2 minutes** by hand or use a rocking shaker (80-100 rpm).
8. Read immediately under direct light.

## Semi-quantitative evaluation

1. Allow all reagents and samples to reach room temperature prior to testing. Shake well all reagents before use.
2. Set up at least five dilutions per patient sample: 1:2, 1:4, 1:8, 1:16, 1:32, etc. with glycine saline solution
3. Place **1 drop** (appr. 40 µl) of the positive control (P) on field no. 1 of the agglutination slide.
4. Place **1 drop** (appr. 40 µl) of the negative control (N) on field no. 2 of the agglutination slide.
5. Place **40 µl** of each sample dilution (refer 2.) to the following fields of the agglutination slide using different serological pipettes.
6. Gently resuspend the RF Latex reagent (A) and add **1 drop** (40 µl) to each test field.
7. Mix well using separate stirring sticks.
8. Gently rock the slide for **2 minutes** by hand or use a rocking shaker (80-100 rpm).
9. Read immediately under direct light.

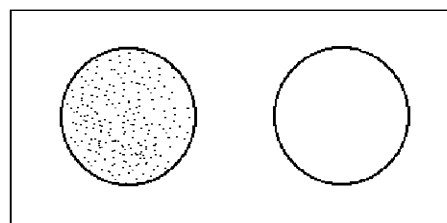
## EVALUATION OF RESULTS

### POSITIV

A positive reaction is indicated by any observable agglutination in the reaction mixture. A weakly reactive serum produces a very fine granulation or a partial clumping. The specimen reaction should be compared to the RF Controls

### NEGATIV

A negative reaction is indicated by a uniform milky suspension with no agglutination as observed with the RF Negative Control.



Positive

Negative

Clear agglutination indicates an RF content of more than 20 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.

### Semi-quantitative test evaluation

The titer of the test is equal to the highest dilution, which shows a visible agglutination. To determine the concentration in IU/ml, multiply the titer with the conversion factor (20):

Dilution	1:2	1:4	1:8	1:16	etc.
IU/ml	40	80	160	320	etc.

### Test validity

RF Positive and Negative Control should be included in each test batch.

Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the RF Negative Control and agglutination with large aggregates is observed with the RF Positive Control.

## Expected values

The diagnosis of rheumatoid 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 (8).

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 (1).

## 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 (6,7).

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

Any clinical diagnosis should not be based on the results of in vitro diagnostic methods alone. Physicians are supposed to consider all clinical and laboratory findings possible to state a diagnosis.

## SAFETY PRECAUTIONS

- **This kit is for in vitro use only.** Follow the working instructions carefully. GA GENERIC ASSAYS GmbH and its authorized distributors shall not be liable for damages indirectly or consequentially brought about by changing or modifying the procedure indicated. The kit should be performed by trained technical staff only.
- The expiration dates stated on the respective labels are to be observed.
- Do not use or mix reagents from different lots. Do not use reagents from other manufacturers.
- All reagents should be kept at 2 - 8 °C before use in the original shipping container.
- Some of the reagents contain small amounts of Sodium azide (0.095%) as preservative. They must not be swallowed or allowed to come into contact with skin or mucosa.
- Positive and negative controls prepared using human sera found negative for hepatitis B surface antigen (HBsAg) and antibodies to HIV (Human Immunodeficiency Virus) and HCV (Hepatitis C Virus) by FDA required test. However, handle controls as if potentially infectious.
- Since the kit contains potentially hazardous materials, the following precautions should be observed:
  - Do not smoke, eat or drink while handling kit material,
  - Always use protective gloves,
  - Never pipette material by mouth,
  - Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.
- In any case GLP should be applied with all general and individual regulations to the use of this kit.

**Remarks:**