GENESIS

Instructions For Use

RF Latex (Agglutination Method)

Cat no.	Test
3103 101	100 Test
3103 201	50 Test
3103 301	100 Test + Controls
3103 401	50 Test + Controls

INTENDED USE
RF Latex Reagent (Agglutination Test) is intended for Qualitative and Semi quantitative Determination of rheumatoid factor (RF).

DIAGNOSTIC CHARACTERISTICS
Rheumatoid Factors (RF) are a group of IgM antibodies (although IgG and IgA have been also described) directed against the Fc fragment of the IgG molecules.
RF is mainly present in the serum of patients with rheumatoid arthritis but other diseases may also produce RF: chronic inflammatory processes, infectious diseases such as subacute bacterial endocarditis, malaria, syphilis, leprosy, leishmaniasis, tuberculosis and a variety of autoimmune diseases such as systemic lupus erythematosus

PRINCIPLE OF THE METHOD
The RF-latex is a slide agglutination test for the qualitative and semi quantitative detection of RF in human serum.
Latex particles coated with human gammaglobulin are agglutinated when mixed with samples containing RF.

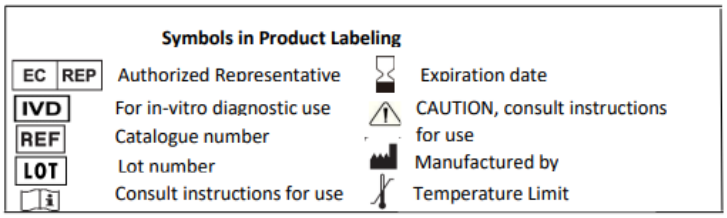
COMPOSITION

Latex Reagent
-Latex particles coated with human gamma globulin - pH 8.2 -Sodium azide 0.95 g/L
(+) Control
-Human serum with an RFconcentration > 30 IU/mL -Sodium azide 0.95 g/L
(-) Control
-Animal serum,Sodium azide 0.95 g/L

STORAGE
Store at 2-8ºC.
Reagent and Controls are stable until the expiry date shown on the vial label when stored tightly closed and if contaminations are prevented during their use.

REAGENT PREPARATION
Reagent and Controls are provided ready to use.

ADDITIONAL EQUIPMENT
Stop watch, Test tubes, A high intensity direct light source, physiological saline.
Note: For latex.
sample dispensing pipette and mixing sticks would be required additionally.



SAMPLES
1.Fresh serum. Stable 7 days at 2-8ºC or 3 months at < –20ºC.
2.Samples with presence of fibrin should be centrifuged before testing.
3.Do not use highly hemolysed or lipemic samples.

PRECAUTIONS AND WARNING
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.

PROCEDURE
Bring reagent and samples to room temperature before testing.
Qualitative Method
1. Pipette one drop (40 µl) of test specimen (serum) on the latex slide using disposable pipette.
2. Add one drop of GENESIS-RF latex reagent to the drop of test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
3. Using a mixing stick, mix the test specimen and latex reagent uniformly over the entire circle.
4. Immediately start a stopwatch. Rock the slide gently back and forth, observing for agglutination macroscopically at two minutes.
Semi Quantitative Method
1. Using physiological saline prepare serial dilutions of the test specimen positive in the qualitative method 1:2, 1:4, 1:8,1:16, 1:32, 1:64 and so on.
2. Pipette one drop (40 µl) of each dilution of the test specimen onto separate reaction circles.
3. Add one drop of GENESIS-RF latex reagent to the drop of test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
4. Using a mixing stick, mix the test specimen and the latex reagent uniformly over the entire circle.
5. Immediately start a stopwatch. Rock the slide gently, back and forth, observing for agglutination macroscopically at two minutes.

INTERPRETATION OF RESULTS

Qualitative Method

Agglutination is a positive test result and indicates presence of detectable levels of RF in the test specimen.

No agglutination is a negative test result and indicates absence of detectable levels of RF in the test specimen.

Semi Quantitative Method

Agglutination in the highest serum dilution corresponds to the approximate amount of RF in lU/mL present in the test specimen.

Concentration of RF can be calculated as follows:

RF (mg/dl) = S x D

Where, S = Sensitivity of the reagent i.e. 8 lU/mL.

D = Highest dilution of serum showing agglutination

REFERENCE VALUES

Up to 8 lU/mL

METROLOGICAL CHARACTERISTICS

	Total	+Ve	- Ve
RF + ve samples	25	25	0
RF - ve samples	75	0	75
Total	100	25	75

* Sensitivity: 100%
* Specificity: 100%.

– INTERFERENCES:

Hemoglobin (up to 10 g/L), bilirubin (up to 20 mg/dL) and lipemia (up to 10 g/L) do not interfere. Rheumatoid factors (>100IU/mL) interfere.Other substances may interfere

BIBLIOGRAPHY

1. Haffejee . Quarterly Journal of Medicine 1992. New series 84; 305: 641-658.

2. Ahmed Samir et al. Pediatric Annals 1992; 21: 835-842.

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