

BioMed-RF Latex



REF: RF302050 (50 test)
RF302100 (100test)

INTENDED FOR USE:

Rapid latex agglutination test for the qualitative screening and semi-quantitative determination of rheumatoid arthritis factor, known as "RA" or "RF" (anti-gamma globulins) in serum.

PRINCIPLE:

Due to the presence of rheumatoid factor in the serum, the latex suspension changes its uniform appearance and clear agglutination becomes evident. This change occurs because the rheumatoid factor present in the serum reacts with the IgG coated to the latex particles, starting the formation of a web between them.

SPECIMEN COLLECTION:

Fresh serum.

Sample is stable 7 days at 2-8°C. Store at -20°C for prolonged periods. Bring at room temperature before analysis.

Centrifuge samples if a turbidity appears

REAGENT COMPOSITIONS :

The components of the kit are stable until expiration date on the label.

Keep away from direct light sources.

Latex reagent: 1 x 5 ml (suspension) 100 tests

Composition: suspension of polystyrene latex particles coated with IGG, preservatives.

Store all components at 2-8°C

positive control 1ml

negative control 1ml

PACKAGE: Collection and storage.

Store in refrigerator (+2-8°C).

Stable until the expiration date reported upon the package.

After the unsealing and the taking of the reagent ,it is advised to close up the bottle immediately in order to avoid evaporation, direct light exposure and bacterial contamination.

PRECAUTIONS & WARNING :

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

REAGENT PREPARATION & STABILITY :

Use reagent ready to use.

Stability: up to expiration date on labels at 2-8°C.

Stability since first opening of vials: ≥ 60 days at 2-8°C.

Do not freeze

REQUIRED MATERIALS NOT PROVIDED:

Saline solution, agglutination slide, disposable stirring devices

PROCEDURE:

Allow the reagent to reach room temperature (20 to 30°C).

Gently shake the reagent vial to disperse and suspend the latex particles in the buffer solution. Use the supplied pump dropper to mix well.

Place 0.050 ml of the serum on one section of the disposable slide.

Place a drop of reagent next to the drop of serum.

Mix both drops with a disposable stirrer covering the whole surface of the slide section.

Gently rotate the slide for 2 minutes manually or on a rotatory shaker (100 rpm).

Look for the presence or absence of agglutination after the aforementioned period of time under an artificial light source

INTERPRETATION OF THE RESULTS:

The presence of agglutination indicates a positive result.

The absence of agglutination indicates a negative result.

It is recommended to execute a semi-quantitative procedure on positive samples.

Organize serial dilutions of serum, pipetting in six different areas of test slide 50 µl of saline and 50 µl of sample only in first area.

Always using the same pipette (loading and unloading several times) mix carefully content of first area, transfer ring 50 µl in subsequent area and so on.

Discard 50 µl from last (sixth) area.

Perform the test as described in previous qualitative section. The last evident agglutination will mark the sample approximate title

Dilution	Approximate value of RF (undiluted samples)
(1 : 2)	16 IU/ml
(1 : 4)	32 IU/ml
(1 : 8)	64 IU/ml
(1 : 16)	128 IU/ml
(1 : 32)	256 IU/ml
(1 : 64)	512 IU/ml

EXPECTED VALUE:

Clinical significance of RF determination consists in distinction between rheumatoid arthritis, in which RF is present in at least 80% of cases and rheumatoid disease, in which RF is almost absent. RF is frequent in chronic processes more than acute diseases or at first stage.

Positive results has been occasionally observed in poliartthritis, LES and hepatitis, too

WASTE DISPOSAL:

The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL:

It is suggested to perform an internal quality control. For this purpose a suitable human based control sera has to be used.

REFERENCES:

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Charles M. Plotz 1956; American Journal of Medicine; 21: 893-896.
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PERFORMANCE:

Sensitivity

Test will show positive results from a level of 8 IU/ml.
Existence of prozone at high titer levels is unknown up to 800 UI/ml.

Specificity

A comparison between BioMed and a commercially available product gave a specificity of 98% on 118 different samples.

Interferences






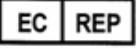



no interference was observed by the presence of




Hemoglobin	≤ 1000 mg/dl
Bilirubin	≤ 20 mg/dl
lipids	≤ 1000 mg/dl

Turbid or lipemic samples could give false positives.

LIMITATIONS :

- Reaction times over 2 minutes could yield an overestimation of sample concentrations.
- As in any diagnostic procedure, if results appear to be incompatible with clinical picture, physician should evaluate data using this test together with other information

	Consult Instructions for Use
	Caution, consult accompanying Documents
	In Vitro Diagnostic Medical Device
	Temperature limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue number
	Batch code
	Use by

 Egy-Chem for lab technology Head Office: 83 Abdel-Hamid Badawy St.Heliopolise, Cairo, Egypt Tel :202- 26236727 / 202- 26236598 Fax :202- 26240986 Website: www.egy-chem.com E-mail: sales@egy-chem.com or sales@egy-chem.net	  MDSS GmbH Schiffgraben 41 30175 Hannover, Germany
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