NS Bio-Tec

RA

A rapid latex slide test for detection of Rheumatoid Factor in serum

REF. RA-MA-100 (100 TEST)
RA-MA-100L (100 TEST)
RA-MA-050 (50 TEST)
RA-MA-050L (50 TEST)

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 :

Keep away from direct light sources.
1- Latex reagent Composition: suspension of polystyrene latex particles coated with IGG, preservatives.
Store all components at 2-8°C
2- positive control.
3- negative control.
4- slides.

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.
Do not freeze

REQUIRED MATERIALS NOT PROVIDED:

Saline solution

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.
1- Place 0.050 ml of the serum on one section of the disposable slide.
2- Place a drop of reagent next to the drop of serum.
3- Mix both drops with a disposable stirrer covering the whole surface of the slide section.
4- Gently rotate the slide for 2 minutes manually or on a rotatory shaker (100 rpm).
5- 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 rheumathoid arthritis, in which RF is present in at least 80% of cases and rheumathoid disease, in which RF is almost absent. RF is frequent in chronical processes more than acute diseases or at first stage.
Positive results has been occasionally observed in poliarthritis, 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.

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 NS Biotec 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 .

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	Consult Instruction for Use
	Caution Consult Accompanying Documents
IVD	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative In The European Community
REF	Catalogue Number
LOT	Batch Code
	Use By

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