Rapid test

RF – rheumatoid factor

REF	Σ	REAGENTI	
1001037100T	Content : 100 test Manual : 100 test	R1:1x5ML R2:1x0.5ml R3:1x0.5ml	

1.0 SUMMARY

The sera of most rheumatoid arthritic patients will react with human IgG and the IgG of other animals due to the presence of an immunoglobulin (in most cases of the IgM type) known as rheumatoid factor. During this reaction, which is of the antigen-antibody type, rheumatoid factor acts as an anti-IgG antibody. A positive latex test, indicating the existence of the rheumatoid factor, is practically a decisive test for the diagnosis of rheumatoid arthritis in patients with inflammatory arthritis. Since the rheumatoid factor is probably a set of various immunologically different factors, it is recommended to do in pairs the latex test and the Waaler-Rose test.

2.0 PRINCIPLE

The latex RF reagent is a suspension of polystyrene latex particles of uniform size coated with human gammaglobulin. Latex particles allow visual observation of the antigen-antibody reaction. If the reaction takes place, due to the presence of rheumatoid factor in the serum, the latex suspension changes its uniform appearance and a 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. When you mix the latex RF reagent with the serum, if the serum contains approximately more than 10 IU/ml of rheumatoid factor, a clear agglutination will appear. Results are expressed in International Units per ml (IU/ml) based on the International Reference Preparation of Rheumatoid Arthritis Serum (WHO).

3.0 SAMPLE

Use fresh serum collected by centrifuging clotted blood. If the test can not be carried out on the same day, the serum may be stored at 2-8°C for no longer than 48 hours after collection. For longer periods the sample must be frozen (-20°C). The latex test is not affected by b-lipoproteins nor by cholesterol. However, it is recommended that the patient does not eat anything for a few hours prior to the sample collection. It is not necessary to inactivate the serum. As in all serological tests, hemolytic or contaminated serum must not be used. Do not use plasma.

4.0 REAGENTS AND CONTROLS

R1:Latex. Suspension of polystyrene latex particles coated with human IgG in a buffer.
R2:Positive Control. Stabilized solution of reumatoid factors
R3:Negative Control. Proteic solution non reactive with latex.

5.0 PREPARATION AND STABILITY OF REAGENTS

All reagents are ready to use.Latex must be mixed with very care, until the solution is homogenous by inversion.
Stability : up to expiry indicated on label stored at +2-8°C. Do not freeze.

6.0 PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow. Perform the test according to the general “Good Laboratory Practice” guidelines.

7.0 MATERIAL REQUIRED BUT NOT PROVIDED

Current laboratory instrumentation. Normal saline (0.9% NaCl, only for semiquantitative technique); automatic pipettes; stop watch.

8.0 TEST PERFORMANCE

8.1 Interferences. No interferences are present with :
Hemoglobin ..... ≤ 1000 mg/dl
bilirubin ..... ≤ 20 mg/dl
lipids ..... ≤ 1000 mg/dl
8.2 Sensibility. 8 UI/ml. No prozone is present for RF concentrations until 800 UI/ml.
8.3 Correlation. Valuation performed on 118 samples, gave the following results with a equivalent method as reference:

		MEDIA IVD srl		
		+	-	TOT.
COMPETITORS	+	48	1	49
		98%	2%	
	-	2	67	69
		3%	97%	
	TOT.	50	68	118

9.0 CALIBRATION AND CONTROLS

Controls, when provided with the kit, should always used to distinguish agglutination.

10.0 QUALITATIVE PROCEDURE

Allow the reagent and controls to reach room temperature (20 to 30°C).
Gently shake the reagent vial to disperse and suspend the latex particles in the buffer solution. Vigorous shaking should be avoided.
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 stirrer covering the whole surface of the slide section.
Gently rotate the slide for 3 minutes manually or on a rotatory shaker (100 rpm). Look for the presence or absence of agglutination after the aforementioned period of time.

Reagents	Sample	Positive Control	Negative Control
Sample Control + Control – Latex	50 µl (1 drop) -- -- 50 µl (1 drop)	-- 50 µl (1 drop) -- 50 µl (1 drop)	-- -- 50 µl (1 dropt) 50 µl (1 drop)

• **Interpretation of the results.** The presence of agglutination indicates a content of rheumatoid factor in the serum equal to or greater than 10 IU/ml.
3 + Large clumping with clear background.
2 + Moderate clumping with fluid slightly opaque in background.
1 + Small clumping with opaque fluid In background.
The absence of agglutination Indicates a content of rheumatoid factor in the serum of less than 10 IU/ml (no visible clumping, uniform suspension.)

11.0 SEMIQUANTITATIVE PROCEDURE

Preparation of the serum dilutions (see the following descriptive diagram for the technique):

Reagents	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6
Saline sol. Sample	50 µl 50 µl	50 µl 50 µl from 1	50 µl 50 µl from 2	50 µl 50 µl from 3	50 µl 50 µl from 4	50 µl 50 µl from 5
Reject 50 µl from last area						
Latex	50 µl	50 µl	50 µl	50 µl	50 µl	50 µl
Title	16 UI/ml	32 UI/ml	64 UI/ml	128 UI/ml	256 UI/ml	512 UI/ml

Use the same procedure described in qualitative assay.
The approximate titer will correspond to the highest serum dilution that still presents a clearly visible agglutination.

12.0 LIMITATIONS

Reading of the results should be done after 3 minutes from the beginning of the reaction. A reading obtained after this period of time may be incorrect. Existence of prozone at high titer levels is unknown.

13.0 WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.
S56:dispose of this material and its container at hazardous or special waste collection point. S57:use appropriate container to avoid environmental contamination. S61:avoid release in environment. Refer to special instructions/safety data sheet.

14.0 REFERENCES

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SYMBOLS – DIRECTIVE CE 98/79

Attenzione, consultare le istruzioni per l’uso	N°determinazioni per kit	Fabbricante	
IVD Solo per uso diagnostico *in vitro*	Usare entro	Non riutilizzare	
Conservare a 2-30°C	LOT Numero del lotto	REF Codice #	

MANUFACTURER

MeDia diagnostici srl
Design, production and marketing of in vitro diagnostics devices
Sede Legale : via Costiera 31D/E, 47100 Forlì, FC – ITALY
Tel. 0543 782.786, Fax 0543 782.787 - www.mediagnostics.com

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If You need to be sure !