FUTURA SYSTEM GROUP s.r.l.
IVD AND MEDICAL DEVICES
Via degli Olmetti, 18 Zona Industriale – 00060- FORMELLO (RM)
TEL. 06/9075726 – 06/90400314 Fax.06/9075724
E - mail: info@futurasystem.it - Web site: www.futurasystem.it

RHEUMATOID FACTOR (RF)

QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION
LATEX AGGLUTINATION

IVD CE

Packaging

REF. N°ND303 (with Controls, Slides and Stirrers) 100 Tests
REF. N°ND333 (Latex only) 100 Tests

Reaction principle

When a serum containing Rheumatoid Factors is mixed with the reagent that contains latex particles coated with IgG an agglutination appears

Reagents composition, Contents and Safety warnings

1. Latex Suspension (1x5 ml)
Latex particles coated with IgG - Sodium Azide 0.095%

2. Positive Control * only in REF. N° ND303 (1x0,5 ml)
Stabilized solution containing enough human RF to give a visible agglutination
Sodium Azide 0.095%

3. Negative Control only in REF. N° ND303 (1x0,5 ml)
Protein solution no reactive with the latex - Sodium Azide 0.095%

4. Reaction Slides only in REF. N° ND303 (8)

5. Plastic Stirrers only in REF. N° ND303 (50)

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).
Further information on the risks to health and / or the environment are given in the data sheet.

Storage and Stability of Reagents

Store the kit at 2 - 8° C

All the components are stable until the stated expiration date if stored closed and refrigerated

Preparation and Stability of working solution

Latex Suspension: liquid and ready to use
Positive and Negative Control: liquid and ready to use

Gently mix the Latex to obtain a homogeneous suspension before use.

Keep reagents at Room Temperature before use

Samples

Fresh serum

Serum may be stored at 2 - 8° C for 7 days, for longer storage should be at - 20° C

Precaution

BIOLOGICAL RISK

* Each unit of source material used in the preparation of Positive Control has been tested by a licensed method and found no reactive for HbsAg and negative for Antibodies to HCV and HIV1/2.
However no known test can offer complete assurance that Products derived from human blood will not transmit Hepatitis,
AIDS or other infectious diseases. This products, like all materials of human origin, should be handled as potentially infectious biological material

Safety Precautions

For in vitro diagnostic use only
Do not pipette by mouth
Exercise the nornal precautions required for handling laboratory reagents

Procedure

Qualitative

Reagents	1ª reactive area Sample	2ª reactive area Positive Control	3ª reactive area Negative Control
Sample	1 drop (~ 50 µl)		
Positive Control		1 drop (~ 50 µl)	
Negative Control			1 drop (~ 50 µl)
Latex	1 drop (~ 50 µl)	1 drop (~ 50 µl)	1 drop (~ 50 µl)

Mix and spread with the stirrers to fill the area. Rotate the slide (also with a mixer at 100 rpm) for 2 minutes and observe for any agglutination which should occur.

Results

Every visibile agglutination within 2 minutes indicates positive result
Absence of agglutination indicates negative result

Positive samples should be titrated **(see semiquantitative procedure)**

Semiquantitative

Pipette in the reactive areas:

Reagents	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6
Saline Solution	50 µl	50 µl	50 µl	50 µl	50 µl	50 µl
Sample	50 µl	50 µl from area 1	50 µl from area 2	50 µl from area 3	50 µl from area 4	50 µl from area 5
discard 50 µl from the last area						
Latex	50 µl	50 µl	50 µl	50 µl	50 µl	50 µl
Titre (IU/ml)	16	32	64	128	256	512

Result interpretation

Positive results can be obtained in about 70 - 80 % of patients affected with rheumatic arthritis.
Positive results can be obtained in almost all patients affected with variants of the rheumatic arthritis as the Felty's syndrome or Sjogren.
Positive results can be obtained in the 5% of healthy people only; percentage that increases up to 30% in people over sixty.

Each laboratory should establish its Normal Reference Range

Performance Characteristics

A. DETECTION LIMIT:
8 IU/ml

B. PROZONE EFFECT:
No prozone effect was detected up to 800 IU/ml of RF concentration

C. ACCURACY
Comparison between this method and another commercial one on 118 samples gave the following results:

		FUTURA SYSTEM +	FUTURA SYSTEM -	TOTAL
ANOTHER METHOD	+	48	1	49
	-	2	67	69
	TOTAL	50	68	118

D. INTERFERENCES
1. Haemoglobin till to ≤1000 mg/dl does not interfere
2. Bilirubin till to 2 minutes ≤ 20 mg/dl does not interfere
3. Lipids till to ≤1000 mg/dl do not interfere

Notes

1. Do not read beyond 2 minutes, false agglutinations may occur
2. The final diagnosis should not be made using a single test but should be based on more than one result and confirmed by clinical data
3. Markedly lipaemic or turbid sera should give false positive results

Quality control

To distinguish a possible agglutination of suspension one's own it is necessary to be run wich each serie of tests the controls, Positive and Negative, supplied with the kit

Bibliography

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