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

WAALER ROSE

QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS WITH PASSIVE HAEMAGGLUTINATION METHOD

IVD CE

Packaging

REF. N° SH009 **100 Tests**

Reaction principle

The method is based on the principle of haemaggutination.
Stabilised ram red cells, coated with rabbit IgG, in the presence of Rheumatoid Factors in serum, agglutinate.

Reagent composition, Contents and Safety warnings

Suspension 1x5 ml
Stabilised ram red cells coated with rabbit IgG ,Sodium Azide 0.095 %

Positive Control * 1x0.5 ml
Stabilised solution of human Rheumatoid Factors sufficient to produce a distinct agglutination; Sodium Azide 0.095 %

Negative Control 1x0.5 ml
Proteic solution non - reactive with the Suspension,Sodium Azide 0.095 %

Slide 6 with six cells each

Plastic stirrers 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. (Do not frozen)

The reagents are stable until the stated expiration date if stored tightly closed and refrigerated.

Preparation and Stability of Working solution

Suspension: **liquid and ready to use**
Positive control: **liquid and ready to use**
Negative control: **liquid and ready to use**

Keep all reagents at Room Temperature and gently shake to obtain homogeneous suspension prior to use.

Sample

Fresh serum
If not tested immediately, sample may be stored for 7 days at 2 - 8° C; If longer storage is required, the sample may be frozen at - 20°C

Precautions

BIOLOGICAL RISK

*** Each unit of source material used in the preparation of Positive Control has been tested by an approved method and found non- reactive for HbsAg and negative for antibodies to HCV and HIV 1/2.**
However, no known test method can offer complete assurance that products derived from human blood will not trasmit hepatitis, AIDS or other infectious diseases.
This product, like all materials of human origin, should be handled as potentially infectious biological material

Safety precaution

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

Qualitative Procedure

REAGENTS	1ª CELL SAMPLE	2ª CELL POSITIVE CONTROL	3ª CELL NEGATIVECONTROL
SAMPLE	1 drop (~ 50 µl)		
POSITIVE CONTROL		1 drop (~ 50 µl)	
NEGATIVE CONTROL			1 drop (~ 50 µl)
SUSPENSION	1 drop (~ 50 µl)	1 drop (~ 50 µl)	1 drop (~ 50 µl)

Mix with separate sticks and spread the fluid over the entire area of the particular cell.
Shake the slide manually or with mechanical rotator (100 rpm) for 2 minutes.
Incline of the slide about 30°, wait 1 minute and than observe for any visible agglutination

Results

The presence of agglutination indicates positive test
The lack of agglutination indicates negative test

All the positive results should be re - tested using the semiquantitative procedure

Semiquantitative Procedure

Prepare on the slide 6 dilutions of sample

REAGENTS	CELL1	CELL 2	CELL 3	CELL 4	CELL 5	CELL 6
SALINE SOLUTION	50 µl	50 µl	50 µl	50 µl	50 µl	50 µl
SAMPLE	50 µl	50 µl from Cell 1	50 µl from Cell 2	50 µl from Cell 3	50 µl from Cell 4	50 µl from Cell 5
Discard 50 µl from Cell 6						
SUSPENSION	50 µl	50 µl	50 µl	50 µl	50 µl	50 µl
TITRE (IU/ml)	16	32	64	128	256	512

Reference Values

Positive results can be obtained in about 70 - 80% of patients affected with rheumatic arthritis as the Felty's or Sjogren's syndrome.
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, with agglutination method, 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. SENSITIVITY
A titre above 8 IU/ml indicates positive result

B. PROZONE EFFECT
No prozone effect was detect up to 624 IU/ml

C. SPECIFICITY
Comparation between this method and another commercial one, utilizing 84 samples, showed a specificity of 93.6%

OTHER METHOD	FUTURA SYSTEM GROUP		
	+	-	TOT
+	37	0	37
	100%	0%	
-	3	44	47
	6.4%	93.6%	
TOT	40	44	84

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

Notes

1. Delay in reading (over 3 minutes) could give invalid results
2. A final diagnosis should not be made on the basis of a single test result but should be correlated with other tests and clinical findings
3. Turbid or lipemic sera could give false positive results

Quality Control

Negative and positive control sera should be run with each series. Their results should be compared with those of unknown specimens to distinguish possible agglutination of the reagent its own

Bibliography

1. Singer J. M. et al.: Am J. Med. 21, 888 - 892 (1956)
2. Waaler M. et al.: Arthritis Rheum. 4, 47 - 57 (1961)
3. Jones W. L. et al.: Amer. J. Clin. Path 60, 603 - 608 (1973)