BioMajesty®

Rheumatoid factor FS*

Order Information

Cat. No.	Kit size
1 7022 99 10 964	600 (R1: 6 x 100, R2: 6 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of rheumatoid factors (RF) in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

Summary

Rheumatoid factors (RF) are a group of autoantibodies belonging to all immunoglobulin classes directed against the Fc fragment of altered or complexed IgG. Diagnostic tests for RF determination identify mainly RF of the IgM class, which are detectable in several rheumatic diseases, mainly of inflammatory origin. RF occur in approx. 70 – 80% of patients with rheumatoid arthritis (RA), but they are not specific for RA as elevated concentrations are also observed in various non-rheumatic diseases and in approx. 10% of the elderly population without clinical symptoms of RA. The presence or absence of rheumatoid factors represents a valuable tool in the differential diagnosis of rheumatic diseases. Additionally, high RF concentrations in RA are often associated with a more progressive clinical course of the disease. However, a positive RF value has to be confirmed by clinical and other laboratory findings. [1-4]

Method

Immunoturbidimetric test

Determination of the RF concentration by photometric measurement of antigen antibody reaction among heat aggregated IgG and rheumatoid factors present in the sample.

Reagents

Components and Concentrations

R1:	Phosphate buffer	pH 7.4	50 mmol/L
R2:	Heat aggregated human IgG		≤ 0.4 mg/mL

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze reagents and protect them from light.

Warnings and Precautions

1. Reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. In very rare cases, samples of patients with gammopathy might give falsified results [5].
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
4. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Do not use sodium fluoride blood collection tubes.

Stability [6]:

1 day	at	20 – 25°C
3 days	at	4 – 8°C
4 weeks	at	–20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal RF calibrator set is recommended for calibration. TruCal RF calibrator values have been made traceable to the reference material NIBSC Code 64/002. Use DiaSys TruLab Protein Level 1 and Level 2 for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal RF	1 7020 99 10 059	5 x 1 mL
TruLab Protein Level 1	5 9500 99 10 046	3 x 1 mL
TruLab Protein Level 2	5 9510 99 10 046	3 x 1 mL

Performance Characteristics

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range from 10 IU/mL up to 500 IU/mL, depending on the concentration of the highest calibrator. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	2 IU/mL
No prozone effect up to 3000 IU/mL.	
Onboard stability	21 days
Calibration stability	7 days

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	30 mg/dL
Bilirubin (conjugated)	12 mg/dL
Bilirubin (unconjugated)	60 mg/dL
Hemoglobin	300 mg/dL
Lipemia (triglycerides)	1200 mg/dL
For further information on interfering substances refer to Young DS [7,8].	

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [IU/mL]	45.5	89.8	256
CV [%]	0.70	0.78	0.46
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [IU/mL]	14.8	71.7	252
CV [%]	4.20	1.73	1.89

Method comparison (n=88)	
Test x	DiaSys Rheumatoid factor FS (Hitachi 912)
Test y	DiaSys Rheumatoid factor FS (BioMajesty® JCA-BM6010/C)
Slope	0.961
Intercept	3.11 IU/mL
Coefficient of correlation	0.9999

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

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Reference Range

In a healthy population, RF values are usually expected to be < 15 IU/mL (95th percentile).

In a study, a cut-off value of 19 IU/mL was defined for optimum sensitivity (82.4%) and specificity (95.9%) for rheumatoid arthritis [9].

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Winchester RJ. Characterization of IgG complexes in patients with rheumatoid arthritis. Ann N Y Acad Sci 1975; 256: 73-81.
2. Moore TL, Dorner RW. Rheumatoid factors. Clin Biochem 1993; 26: 75-84.
3. Shmerling RH, Delbanco TL. The rheumatoid factor: an analysis of clinical utility. Am J Med 1991; 91: 528-34.
4. Mannik M. Rheumatoid factors in the pathogenesis of rheumatoid arthritis. J Rheumatol Suppl 1992; 32: 46-9.
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45()): 1240-1243.
6. Guder WG, Zawta B et al. The quality of Diagnostic Samples. 1st ed. Darmstadt: Git Verlag, 2001: 42-3
7. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
8. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed on February 2021. Published by AACC Press and John Wiley and Sons, Inc.
9. Ulvestad E, Kanestrom A, Madland TM, Thomassen E, Haga HJ. Clinical utility of diagnostic tests for rheumatoid factor. Scandinavian Journal of Rheumatology 2001; 30: 87-91.

IVD CE

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* Fluid Stable

BioMajesty

Rheumatoid factor FS

Chemistry code 10 702

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	16
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	5.0
Sample vol (U)	5.0
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	RF
Digits	2
M-wave L.	340
S-wave.L	694
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	5.0	5.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting			
Formula	Spline	**Axis Conv**	No conv
Blank	Blank-any value	**Points**	6

	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	5.0	No dil	0	0	0	9.999	-9.999
1	#	5.0	No dil	0	0	0	9.999	-9.999
2	#	5.0	No dil	0	0	0	9.999	-9.999
3	#	5.0	No dil	0	0	0	9.999	-9.999
4	#	5.0	No dil	0	0	0	9.999	-9.999
5	#	5.0	No dil	0	0	0	9.999	-9.999

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