Rheumatoid factor FS*

Order Information

Cat. No.	Kit size				
1 7022 99 10 021	R1	5 x 25 mL	+	R2	1 x 25 mL
1 7022 99 10 930	R1	4 x 20 mL	+	R2	2 x 8 mL
1 7022 99 10 935	R1	2 x 20 mL	+	R2	1 x 8 mL
1 7022 99 90 309	R1	4 x 20 mL	+	R2	2 x 8 mL

Intended Use

Diagnostic reagent for quantitative in vitro determination of rheumatoid factors (RF) in human serum or heparin plasma on automated photometric systems.

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.

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.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	340/694 nm (bichromatic)
Temperature	37°C
Measurement	Endpoint
Sample/calibrator	5.0 µL
Reagent 1	80 µL
Reagent 2	16 µL
Addition Reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 17/18 (231 s/244 s)
Absorbance 2	Cycle 41/42 (586 s/600 s)
Calibration	Spline

Calculation

The concentrations of RF in unknown samples are derived from a calibration curve using an appropriate mathematical model such as logit/log. The calibration curve is obtained with 5 calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.

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

Data evaluated on BioMajesty® JCA-BM6010/C

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. When values exceed this range, samples should be diluted 1 + 2 with NaCl solution (9 g/L) and the result multiplied by 3.	
Limit of detection**	2 IU/mL
No prozone effect up to 3000 IU/mL.	

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.

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.
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5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45()): 1240-1243.
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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.

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* Fluid Stable