respons®910

Rheumatoid factor FS*

Order Information

Cat. No.	Kit size
1 7022 99 10 921	Σ 400 (4 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of rheumatoid factors (RF) in human serum or heparin plasma on automated DiaSys respons®910.

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 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**	3 IU/mL
No prozone effect up to 3000 IU/mL.	
Onboard stability	4 weeks
Calibration stability	10 days

Interfering substance	**Interferences ≤ 10% up to**	**Analyte concentration [IU/mL]**
Hemoglobin	600 mg/dL	30.3
	600 mg/dL	53.9
Bilirubin (conjugated)	30 mg/dL	24.5
	20 mg/dL	51.8
Bilirubin (unconjugated)	60 mg/dL	22.5
	20 mg/dL	43.7
Lipemia (triglycerides)	300 mg/dL	29.8
	800 mg/dL	60.4

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]	22.2	32.9	72.7
CV [%]	5.22	4.29	2.69
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [IU/mL]	23.3	28.7	67.3
CV [%]	7.04	5.50	4.11

Method comparison (n=123)	
Test x	DiaSys Rheumatoid factor FS (Hitachi 917)
Test y	DiaSys Rheumatoid factor FS (respons®910)
Slope	1.01
Intercept	–1.02 IU/mL
Coefficient of correlation	0.994

** according to CLSI document EP17-A, Vol. 24, No. 34

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.
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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.

IVD CE

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* Fluid Stable

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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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	RF
Shortcut:	
Reagent barcode reference:	718
Host reference:	718

Technic	
Type:	Fixed time kinetic
First reagent:[µL]	180
Blank reagent	No
Sensitive to light	
Second reagent:[µL]	36
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
1 st reading time [min:sec]	4:48
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	3.0000
Concentration technical limits-Upper	500.0000
SERUM	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
URINE	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
Whole blood	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1

Results	
Decimals	1
Units	IU/mL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	<=15.0
URINE	
PLASMA	<=15.0
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.0100
Cal. 2	0.0100
Cal. 3	0.0100
Cal. 4	0.0100
Cal. 5	0.0100
Cal. 6	0.0100
Drift limit [%]	5.00

Calculations	
Model	Logit (X)
Degree	3

* Enter calibrator value