respons®920

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®920.

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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
4. 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.
5. 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 15 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**	3.9 IU/mL
No prozone effect up to 3500 IU/mL.	
Onboard stability	3 weeks
Calibration stability	2 weeks

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [IU/mL]
Hemoglobin	500 mg/dL	28.9
	500 mg/dL	88.3
Bilirubin (conjugated)	40 mg/dL	18.0
	40 mg/dL	59.3
Bilirubin (unconjugated)	40 mg/dL	16.7
	40 mg/dL	53.2
Lipemia (triglycerides)	800 mg/dL	30.3
	800 mg/dL	63.2
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]	30.8	68.9	342
CV [%]	3.78	1.97	2.03
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [IU/mL]	33.7	70.6	187
CV [%]	4.20	2.95	1.68

Method comparison (n=96)	
Test x	DiaSys Rheumatoid factor FS (Hitachi 917)
Test y	DiaSys Rheumatoid factor FS (respons®920)
Slope	0.947
Intercept	1.89 IU/mL
Coefficient of correlation	0.998

** 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.
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

respons®920

Rheumatoid factor FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	RF				Auto Rerun	:	☐
Report Name	:	Rheumatoid factor				Online Calibration		☐
Unit	:	IU/mL	Cuvette Wash		☐	Cuvette Wash		☐
Wavelength-Primary	:	340	Secondary	:	700	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	4P Logit-Log	Reagent R1	:	RF R1
M1 Start	:	15	M1 End	:	15	Reagent R2	:	RF R2
M2 Start	:	36	M2 End	:	36			
Sample Replicates	:	1	Standard Replicates	:	3	Consumables/Calibrators:		
Control Replicates	:	1	Control Interval	:	0	Blank/Level 0		0
Reaction Direction	:	Increasing	React. Abs. Limit	:	*	Calibrator Level 1		**
Prozone Limit %	:	97	Prozone Check	:	Lower	Calibrator Level 2		**
Linearity Limit %	:	0	Delta Abs. / Min.	:	0.00	Calibrator Level 3		**
Technical Minimum	:	*	Technical Maximum	:	*	Calibrator Level 4		**
Y = aX + b a=	:	1.00	b=	:	0.00	Calibrator Level 5		**

* Technical limits are automatically defined by the software via the upper and lower calibrator level.
** Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	RF		
Sample Type	:	Serum		

Sample Volumes

Normal	:	11.00 µL	Dilution Ratio	:	1	X
Increase	:	22.00 µL	Dilution Ratio	:	1	X
Decrease	:	2.00 µL	Dilution Ratio	:	1	X
Standard Volume	:	11.00 µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	180 µL	R1 Stirrer Speed	:	High
RGT-2 Volume	:	36 µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	RF		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (IU/mL)	Upper Limit (IU/mL)
Normal	:	0.00	15.0
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other