respons®920

Complement C4 FS*

Diagnostic reagent for quantitative in vitro determination of complement component C4 in serum or plasma on DiaSys respons®920

Order Information

Cat. No. 1 1812 99 10 921
4 twin containers for 100 determinations each

Method

Immunoturbidimetric test

Principle

Determination of the C4 concentration by photometric measurement of antigen-antibody-reaction of antibodies to human C4 with C4 present in the sample.

Reagents

Components and Concentrations

R1:	TRIS	pH 7.5	100 mmol/L
	NaCl		320 mmol/L
R2:	TRIS	pH 8.0	100 mmol/L
	NaCl		300 mmol/L
	Anti-human C4 antibody (goat)		< 1%

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8 °C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions

1. Reagent 1: Warning. H319 Causes serious eye irritation. P280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention.
2. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
3. Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
4. 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.
5. In very rare cases, samples of patients with gammopathy might give falsified results [6].
6. 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.
7. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

Specimen [1]

Serum, heparin plasma or EDTA plasma
During storage of serum the C3 and C4 proteins slowly degrade into C3c resp. C4 fragments (fragmentation is inhibited by EDTA). These fragments still contain the reactive epitopes and may even display higher signals than the intact protein. Depending on the conditions of this aging process, fresh serum samples may show up to 30% lower C3 values than samples stored at 2 – 8 °C for 8 days. The fragmentation of C4 is much slower than for C3 and only 15% lower values can be observed under similar storage conditions.
Discard contaminated specimens.

Calibrators and Controls

For calibration the DiaSys TruCal Protein calibrator set or TruCal Protein high calibrator is recommended. The assigned values of the calibrators have been made traceable to the ERM®-DA470k/IFCC Reference Material. For internal quality control a DiaSys TruLab Protein control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Protein Set	5 9200 99 10 039	5 x 1 mL
TruCal Protein high	5 9200 99 10 037	3 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

Measuring range up to 90 mg/dL complement component C4, at least up to 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 the rerun function.	
Limit of detection**	1 mg/dL C4
No prozone effect up to 180 mg/dL C4	
On-board stability	4 weeks
Calibration stability	4 weeks

Interferences < 10% by
Bilirubin up to 60 mg/dL
Hemoglobin up to 1000 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
RF up to 1200 IU/mL
IgA up to 6400 mg/dL
IgM up to 4100 mg/dL
IgG up to 6400 mg/dL
For further information on interfering substances refer to Young DS [2].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	27.4	42.0	67.5
Coefficient of variance [%]	1.57	0.94	1.57
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	12.0	27.9	41.4
Coefficient of variance [%]	2.32	3.42	1.83

Method comparison (n=103)	
Test x	DiaSys C4 FS (Hitachi 917)
Test y	DiaSys C4 FS (respons®920)
Slope	1.059
Intercept	–1.19 mg/dL
Coefficient of correlation	0.997

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

Reference Range [3]

10 - 40 mg/dL (0.1 – 0.4 g/L)

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

Literature

1. Okumura N, Nomura M, Tada T et al. Effects of sample storage on serum C3c assay by nephelometry. Clin Lab Sci 1990; 3(1): 54–57.
2. 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.
3. Dati F, Schumann G, Thomas L, Aguzzi F, Baudner S, Bienvenu J et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996; 34: p. 517-20.
4. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 794–806.
5. Johnson AM, Rohlfs EM, Silverman LM. Proteins. In: Burtis CA, Ashwood ER. editors. Tietz textbook of clinical chemistry. 3rd ed. Philadelphia: W. B. Saunders Company; 1999. p. 502-7.
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

IVD CE
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* fluid stable

respons®920

Complement C4 FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	C4				Auto Rerun	☐	
Report Name	:	Complement C4				Online Calibration	☐	
Unit	:	mg/dL	Decimal Places	:	1	Cuvette Wash	☐	
Wavelength-Primary	:	340	Secondary	:	0	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Cubic spline	Reagent R1	:	C4 R1
M1 Start	:	16	M1 End	:	16	Reagent R2	:	C4 R2
M2 Start	:	33	M2 End	:	33	**Consumables/Calibrators:**		
Sample Replicates	:	1	Standard Replicates	:	3	Blank /Level 0		0
Control Replicates	:	1	Control Interval	:	0	Calibrator 1		**
Reaction Direction	:	Increasing	React. Abs. Limit	:	*	Calibrator 2		**
Prozone Limit %	:	97	Prozone Check	:	Lower	Calibrator 3		**
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000	Calibrator 4		**
Technical Minimum	:	*	Technical Maximum	:	*	Calibrator 5		**
Y = aX + b a=	:	1.0000	b=	:	0.0000	Calibrator 6		**

*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	:	C4		
Sample Type	:	Serum		

Sample Volumes

Normal	:	4.40 µL	Dilution Ratio	:	1 X	
Increase	:	10.00 µL	Dilution Ratio	:	1 X	
Decrease	:	3.00 µL	Dilution Ratio	:	1 X	
Standard Volume	:	4.40 µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	180 µL	R1 Stirrer Speed	:	Medium
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	:	C4		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	10.00	40.00
Panic	:		

Sample Types

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