respons®910

Complement C4 FS*

Diagnostic reagent for quantitative in vitro determination of complement component C4 in serum or plasma on DiaSys respons®910

Order Information

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

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. In very rare cases, samples of patients with gammopathy might give falsified results [6].
5. 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.
6. 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 fragment into C3c resp. C4 components (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 the calibration of automated photometric systems the DiaSys TruCal Protein calibrator set is recommended. The assigned values of the calibrators have been made traceable to the Reference Material ERM-DA470k/IFCC. 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 levels)	5 9200 99 10 039	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

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 rerun function).	
Limit of detection**	3 mg/dL C4
No prozone effect up to 190 mg/dL C4	
On-board stability	2 weeks
Calibration stability	7 days

Interfering substance	Interferences < 10%	C4 [mg/dL]
Hemoglobin	up to 1200 mg/dL	12.7
	up to 1200 mg/dL	34.1
Bilirubin, conjugated	up to 60 mg/dL	13.6
	up to 60 mg/dL	55.7
Bilirubin, unconjugated	up to 60 mg/dL	12.3
	up to 60 mg/dL	55.4
Lipemia (triglycerides)	up to 1500 mg/dL	9.70
	up to 2000 mg/dL	46.1
IgA	up to 6400 mg/dL	23.8
IgM	up to 4100 mg/dL	11.9
IgG	up to 6400 mg/dL	16.5
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]	11.5	34.6	51.6
Coefficient of variance [%]	2.78	2.59	4.12
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	12.6	36.7	40.1
Coefficient of variance [%]	3.38	5.44	4.16

Method comparison (n=128)	
Test x	DiaSys Complement C4 FS (Hitachi 917)
Test y	DiaSys Complement C4 FS (respons®910)
Slope	0.955
Intercept	0.734 mg/dL
Coefficient of correlation	0.993

** according to NCCLS document EP17-A, vol. 24, no. 34

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

DiaSys Diagnostic Systems GmbH
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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:	C4
Shortcut:	
Reagent barcode reference:	705
Host reference:	705

Technic	
Type:	End point
First reagent:[µL]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	36
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	
Polychromatic factor:	
1 st reading time [min:sec]	(04:24)
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
Concentration technical limits-Upper	90
SERUM	
Normal volume [µL]	5
Normal dilution (factor)	1
Below normal volume [µL]	10
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	1
URINE	
Normal volume [µL]	5
Normal dilution (factor)	1
Below normal volume [µL]	10
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	5
Normal dilution (factor)	1
Below normal volume [µL]	10
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	5
Normal dilution (factor)	1
Below normal volume[µL]	10
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	1
Whole blood	
Normal volume [µL]	5
Normal dilution (factor)	1
Below normal volume[µL]	10
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	1

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Gender	All
Age	
SERUM	>=10 <=40
URINE	
PLASMA	>=10 <=40
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	0.1000
Cal. 2	0.0100
Cal. 3	0.0100
Cal. 4	0.0100
Cal. 5	0.0100
Cal. 6	0.0200
Drift limit [%]	5.0

Calculations	
Model	Akima Spline
Degree	Auto

* Enter calibrator value