respons®910

Complement C3c FS*

Order Information

Cat. No.	Kit size
1 1802 99 10 921	Σ 400 (4 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of complement C3c in human serum or heparin plasma on automated DiaSys respons®910.

Summary

The complement system represents a group of at least 20 plasma proteins and several receptor proteins that interact in a regulated proteolytic cascade in order to destroy invading bacteria and prevent deposition of immuncomplexes. The activation results in decreased concentrations of C3 and/or C4 due to consumption of the intact proteins. The complement cascade can be activated by two different pathways. The classical pathway is activated by immunocomplexes or antibodies bound to bacteria or virus. The cascade starts with the binding of the C1q part of C1 to the Fc-part of the antibodies and it activates C3 by proteolysis of C4. The alternative pathway is activated independently of antibodies by microorganisms, Polysaccharides, autolysis of C3 or aggregated immunoglobulins. The alternative pathway does not need C4 protein. Because C3 is common to both pathways, lowered concentrations indicate general complement activation. Lowered C3 values are found in inflammatory and infectious diseases especially in glomerulonephritis and SLE (Systemic Lupus erythematodes). Depending on the activated pathway C4 values may be lowered or stay normal. Lowered C4 concentrations without simultaneously lowered C3 concentrations occur in hereditary or acquired angioneurotic edema. Hereditary deficiency states of both complement factors have been reported. C3 as well as C4 react as acute phase proteins. This increase due to an inflammatory process may mask a moderately increased complement consumption. [1,2]

Method

Immunoturbidimetric test

Determination of C3c concentration by photometric measurement of antigen antibody reaction of antibodies to human C3c with C3c 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 C3c antibody (goat)		< 1%

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. Protect from light.

Warnings and Precautions

1. ⚠ Reagent 1: Warning. H319 Causes serious eye irritation. P280 Wear protective gloves/protective clothing/eye 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 practice.
4. In very rare cases, samples of patients with gammopathy might give falsified results [3].
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

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

During storage of serum, the C3 and C4 proteins slowly degrade into C3c resp. C4 fragments. 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 [4].

Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal Protein calibrator set or TruCal Protein high is recommended for calibration. Calibrator values have been made traceable to the reference material ERM®-DA470k/IFCC. 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 Protein	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

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 500 mg/dL, 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**	0.7 mg/dL
No prozone effect up to 1000 mg/dL.	
Onboard stability	3 weeks
Calibration stability	10 days

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Bilirubin (conjugated)	60 mg/dL	93.6
	60 mg/dL	152
Bilirubin (unconjugated)	65 mg/dL	67.9
	70 mg/dL	128
Hemoglobin	1200 mg/dL	74.1
	1200 mg/dL	104
IgA	6400 mg/dL	94.6
IgM	4100 mg/dL	101
IgG	6400 mg/dL	172
Lipemia (triglycerides)	2000 mg/dL	49.1
	2000 mg/dL	142
For further information on interfering substances refer to Young DS [5,6].		

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Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	58.1	130	208
CV [%]	3.26	3.81	2.22
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	64.8	123	191
CV [%]	3.94	2.50	2.48

Method comparison (n=132)	
Test x	DiaSys Complement C3c FS (Hitachi 917)
Test y	DiaSys Complement C3c FS (respons®910)
Slope	0.985
Intercept	0.505 mg/dL
Coefficient of correlation	0.986

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

Reference Range [7]

90 – 180 mg/dL 0.9 – 1.8 g/L

In case of fresh samples, lower reference ranges are expected.

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

Literature

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 794-806.
2. 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.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
4. 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.
5. 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.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in August 2021. Published by AACC Press and John Wiley and Sons, Inc.
7. 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.

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:	C3c
Shortcut:	
Reagent barcode reference:	704
Host reference:	704

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	0.7000
Concentration technical limits-Upper	500.0000
SERUM	
Normal volume [µL]	2.6
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.6
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	2.6
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.6
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2.6
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.6
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2.6
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.6
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	2.6
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.6
Above normal dilution (factor)	6

Results	
Decimals	1
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>=90.0 <=180.0
URINE	
PLASMA	>=90.0 <=180.0
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	0.0150
Cal. 5	0.0250
Cal. 6	0.0400
Drift limit [%]	5.00

Calculations	
Model	Cubic Spline
Degree	

* Enter calibrator value