BioMajesty®

Complement C3c FS*

Order Information

Cat. No.	Kit size
1 1802 99 10 966	200 (R1: 2 x 100, R2: 2 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of complement C3c in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

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 480 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**	0.1 mg/dL
No prozone effect up to 1000 mg/dL.	
Onboard stability	5 weeks
Calibration stability	5 weeks

Interfering substance	**Interferences ≤ 10% up to**
Bilirubin (conjugated and unconjugated)	60 mg/dL
Hemoglobin	800 mg/dL
Lipemia (triglycerides)	2000 mg/dL
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]	92.3	161	228
CV [%]	1.36	1.59	1.84
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	92.7	157	217
CV [%]	2.60	2.73	2.37

Method comparison (n=100)	
Test x	Competitor Complement C3c
Test y	DiaSys Complement C3c FS
Slope	0.993
Intercept	0.241 mg/dL
Coefficient of correlation	0.999

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

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

BioMajesty

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Chemistry code 10 180

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.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	16
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1.2
Sample vol (U)	1.2
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	C3c
Digits	2
M-wave L.	340
S-wave.L	****
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1.2	1.2
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting			
Formula	Spline	**Axis Conv**	No conv
Blank	Blank-any value	**Points**	6

	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	1.2	No dil	0	0	0	9.999	-9.999
1	#	1.2	No dil	0	0	0	9.999	-9.999
2	#	1.2	No dil	0	0	0	9.999	-9.999
3	#	1.2	No dil	0	0	0	9.999	-9.999
4	#	1.2	No dil	0	0	0	9.999	-9.999
5	#	1.2	No dil	0	0	0	9.999	-9.999

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