Complement C4 FS*

Diagnostic reagent for quantitative in vitro determination of complement component C4 in serum or plasma on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 1812 99 10 966
R1: 2 x 100 tests
R2: 2 x 100 tests

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. 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. 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 trays.

Specimen [1]

Serum, heparin plasma or EDTA plasma

During storage, 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 DiaSys TruCal Protein calibrator set 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
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 90 mg/dL (0.90 g/L) 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**	1 mg/dL (0.01 g/L) C4
No prozone effect up to 180 mg/dL (1.8 g/L) C4	
On-board stability	6 weeks
Calibration stability	6 weeks

Interferences < 10% by
Bilirubin (conjugated and unconjugated) up to 60 mg/dL
Hemoglobin up to 900 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
RF up to1200 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 [5].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	15.8	27.0	43.6
Mean [g/L]	0.158	0.270	0.436
Coefficient of variance [%]	3.04	2.41	1.94
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	15.6	30.8	41.7
Mean [g/L]	0.156	0.308	0.417
Coefficient of variance [%]	3.17	2.57	2.23

Method comparison (n=100)	
Test x	Competitor Complement C4
Test y	DiaSys Complement C4 FS
Slope	1.003
Intercept	0.38 mg/dL (0.0038 g/L)
Coefficient of correlation	0.9997

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

Reference Range [2]

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. 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.
3. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 794-806.
4. 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.
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. 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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BioMajesty

Complement C4 FS

Chemistry code 10 181

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)	2.3
Sample vol (U)	2.3
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	C4
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.	2.3	2.3
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	#	2.3	No dil	0	0	0	9.999	-9.999
1	#	2.3	No dil	0	0	0	9.999	-9.999
2	#	2.3	No dil	0	0	0	9.999	-9.999
3	#	2.3	No dil	0	0	0	9.999	-9.999
4	#	2.3	No dil	0	0	0	9.999	-9.999
5	#	2.3	No dil	0	0	0	9.999	-9.999

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