

Complement C4 FS*

Order Information

Cat. No.

1 1812 99 10 966

Kit size

200 (R1: 2 x 100, R2: 2 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of complement C4 in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

Summary

The complement system is a complex innate immune surveillance system, playing a key role in defense against microbial pathogens and prevention of immune complex depositions. It consists of more than 30 plasma proteins and several membrane proteins and serves as a "complement" to antibody-mediated immunity. The complement cascade can be activated by the classical pathway, alternative pathway or by the mannan binding lectin pathway. The classical pathway is activated by immune complexes or by antibodies bound to bacteria or virus. The complement 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. Microorganisms, polysaccharides, autolysis of C3 or aggregated immunoglobulins activate the alternative pathway. The activation results in decreased concentrations of C3 and/or C4 due to consumption of the intact proteins. Since C3 is common to both pathways, lowered concentrations indicate a general complement activation. In order to differentiate between the pathways C4 levels are measured, considering that C4 is not involved in the alternative pathway. Lowered C3 values are found in inflammatory and infectious diseases, especially in glomerulonephritis and systemic lupus erythematosus (SLE). Depending on the activated pathway, C4 values may be lowered or stay normal. Decreased C4 concentrations without simultaneously lowered C3 levels occur in hereditary or acquired angioneurotic edema. Moreover, hereditary deficiency states of both complement factors have been reported. As acute phase proteins, the protein synthesis of C3 and C4 increases during an acute inflammatory episode. Therefore, a moderately increased complement consumption, due to an activation of the complement system, might not be detected during an acute inflammatory process [1,2].

Method

Immunoturbidimetric test

Determination of 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 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. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

Warnings and Precautions

1. Components contained in Complement C4 FS are classified according to EC regulation 1272/2008 (CLP) as follows:



⚠ 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 material of biological origin. 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. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
7. Please refer to the safety data sheets (SDS) 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.
8. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

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

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [4]:

2 days	at	20 – 25°C
8 days	at	4 – 8°C
3 months	at	-20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal Protein is recommended for calibration. Calibrator values have been made traceable to the reference material ERM®-DA470k/IFCC. Lot specific uncertainties can be obtained on request. Use DiaSys TruLab Protein Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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
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

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.l	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.l.	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

entered by user