

COMPLEMENT C4

Cat.No.	Pack name	Packing (Content)
BLT20008	C4	5 x 25 ml Buffer 1 x 10 ml Antiserum 1 x 1 ml Calibrator



Intended Use

Quantitative determination of Complement C4 (C4) in human serum by turbidimetric immunoassay.

Diagnostic Implications

Complement C4 is a constituent of C3 convertase and C5 convertase.

Decreased levels are found in hereditary angioneurotic oedema, immune complex diseases and congenital deficiencies.

Method

Measurement of antigen-antibody reaction by the end-point method.

Reagents Provided

Buffer

Phosphate buffered saline (pH 7.43)

Polyethylene glycol (40 g/l)

Sodium azide (0.95 g/l)

Antiserum

Phosphate buffered saline (pH 7.43)

Polyclonal goat anti-human C4C (variable)

Sodium azide (0.95 g/l)

Calibrator

Defibrinated human plasma, liquid stabilised. Contains 0.09 % sodium azide.

Concentration: See the bottle label

Preparation and Stability of Reagents

Reagent Preparation

Liquid reagents, ready to use.

Stability and Storage

The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

Reagents required but not supplied

0.9 g % sodium chloride

Sample collection

Use fresh serum. If the test can not be carried out on the same day, the serum may be stored at 2 - 8°C for 48 hours. If stored for a longer period, the sample should be frozen.

Automation

Application procedures on clinical chemistry analyzers are available upon request.

Manual Procedure

Sample/Control: dilute 1:10 in saline 9 g/l

Reference curve: generate a reference curve by diluting the standard high level 1:10, 1:20, 1:40, 1:80, 1:160 in saline 9 g/l Use saline 9 g/l as zero point.

Test: Mix 100 µl diluted samples, standards and control(s) with 900 µl buffer. Read optical density (OD1) of samples, standards and control(s) at 340 nm. Add 70 µl of C4 Antiserum. Mix and incubate for 5 minutes at room temperature. Read optical density (OD2) of samples, standards and control(s) at 340 nm.

Calculate ΔOD's, plot a standard curve and read the concentration of controls and samples.

Reference Values

9 - 36 mg/dl (IFCC)

This range is given for orientation only. Each Laboratory should establish its own reference values.

Performances

The performance characteristics for the Complement C4 reagents were measured on a clinical chemistry analyzer.

Measuring Range : 0 - 80 mg/dl

Detection Limit : 2 mg/dl

Hook effect : > 1000 mg/dl

Sensitivity : 0.0022 ABS units / concentration unit

Precision:

[%CV]

	Low	Medium	High
Intra-Run	4.54	2.18	3.97
Inter-Run	4.17	3.08	

Accuracy :

[mg/dl]

Control	Assigned	Measured
Biorad 1	16 (13-19)	16.7
Biorad 2	52 (42-62)	47.4

Specificity : Monospecific

Interferences : No interference for : Haemoglobin (1000 mg/dl), Na-citrate (1000 mg/dl), Heparin (50 mg/dl), Turbidity (5%), Billirubin (20 mg/dl) and Triglyceride (2500 mg/dl).

Limitations : None

Comparison with Nephelometry :

$$y = 0.9341x - 0.1518$$

$$r = 0.9940$$

Precautions and warnings

1. In vitro diagnostic use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
3. Polyethylene glycol is non biohazardous.
4. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.











QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485



References

1. Dati, F. et al., Lab. Med. 13, 87 (1989)
2. Müller-Eberhard, H.H., Ann. Rev. Biochem. 44, 697 (1975)
3. Lachmann, P.J., Hobart, M.J. and Ashton, W.P. (1973) in Handbook of Experimental Immunology, 2nd Ed., 16, Ed. D.M. Weir, Blackwell Scientific Publications

USED SYMBOLS:

	Catalogue No		CE Mark - Device comply with the Directive 98/79/EC
	Batch Code		In Vitro Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufactured by		Storage temperature
	Product Name		Content

