

COMPLEMENT C3

Cat.No.	Pack name	Packing (Content)	
BLT20007	C3	5 x 25 ml Buffer	
		1 x 10 ml Antiserum	
		1 x 1 ml Calibrator	

EN

Intended Use

Quantitative determination of Complement C3 (C3) in human serum by turbidimetric immunoassay.

Diagnostic Implications

Complement C3 is the central point of the classic and alternative Complement pathway.

Complement C3 is a constituent of C5 convertase. On activation split products of Complement C3 has important biological functions. C3b is an opsonin and involved in immune adherence. C3a is an anaphylatoxin and a chemotoxin. Complement C3 behaves also like an acute phase protein, therefore increased levels may be found in acute inflammatory reactions.

Decreased levels are reported in complex disease, recurrent immune infections with pyrogenic bacteria, various glomerulonephritides and in congenital deficiencies.

Method

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

Reagents Provided

<u>Buffer</u>

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 complement C3 (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

<u>Reagent Preparation</u> 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 $2 - 8^{\circ}$ 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 50 μ I diluted samples, standards and control(s) with 900 μ I buffer. Read optical density (OD1) of samples, standards and control(s) at 340 nm. Add 80 μ I of C3 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

75 - 135 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 C3 reagents were measured on a clinical chemistry analyzer.

 Measuring Range
 : 0 - 400 mg/dl

 Detection Limit
 : 20 mg/dl

 Hook effect
 : > 1000 mg/dl

 Sensitivity
 : 0.00076 ABS units / concentration unit

Precision:	
[%CV]	

	Low	Medium	High
Intra-Run	2.82	3.43	3.28
Inter-Run	3.71	2.56	

Accuracy :	Control	Assigned	Measured
[mg/dl]	Biorad 1	78 (62-93)	84.8
	Biorad 2	206 (165-247)	216.1

Specificity : Monospecific

Interferences: No interference : Hemoglobin (1000 mg/dl), Nacitrate (1000 mg/dl), Heparin (50 mg/dl), Bilirubin (20 mg/dl), Triglyceride (2500 mg/dl)

Limitations : None

Comparison with Nephelometry :

y = 0.9978x-2.4553

r = 0.9965

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.



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QUALITY SYSTEM CERTIFIED ISO 9001 ISO 13485

References

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 Lachmann, P.J., Hobart, M.J. and Ashton, W.P. (1973) in
- Lachmann, P.J., Hobart, M.J. and Ashton, W.P. (1973) in Handbook of Experimental Immunology, 2nd Ed., <u>16</u>, Ed. D.M. Weir, Blackwell Scientific Publications

USED SYMBOLS:





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