

Complement C3

Quantitative turbidimetric test for the measurement of complement C3 in human serum.

REF: BS.1/CCT1.050.0050

50 test

REF: BS.1/CCT1.100.0100

100 test

CLINICAL SIGNIFICANCE

C3 is the functional link between classical and alternative pathways of activation and it is the most concentrate component of the complement system in human plasma. Hepatic cells synthesize C3, although bacterial endotoxins induce synthesis by monocytes and fibroblasts.

Concentration C3 increases as a consequence of an acute-phase response (trauma, surgery or inflammatory process), biliary obstruction and focal glomerulosclerosis. Decreasing C3 levels are consequence of a genetic deficiency that may increase the risk of infections particularly with encapsulated bacteria, or acquired deficiency that causes vascular disorders and severe infections.

METHOD PRINCIPLE

BioScien The Kit utilizes latex-enhanced immunoturbidimetry to measure the C3 level in human serum or plasma. During the test, C3 in the sample binds with the specific anti C3 antibody to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry, analyzer. The change in absorbance is proportional to the level of C3 in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

REAGENT COMPOSITION

Reagents:	Composition
R1: C3 Buffer	Phosphate buffer, Polyethylene glycol, Sodium azide < 0.1%
R2 - C3 antibody	Anti-C3 antibodies, Tris buffer, sodium azide < 0.1%
Calibrator set	Concentration is stated on each vial label.

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment.

For further information, refer to the C3 reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien C3 reagent is stable until expiration date stated on label when properly stored in an upright position and refrigerated at 2-8°C.

Assay can be performed with use of separate R1-C3 and R2-C3 reagents of 3 parts of R1-C3 with 1 part of R2-C3. Avoid foaming

Deterioration

The **BioScien** C3 reagent can be damaged due to Presence of particles and turbidity.

SPECIMEN COLLECTION AND PRESERVATION

Follow standard laboratory procedures to collect serum samples. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2-4° C for up to 3 days or at -20° C for up to 1 months. Avoid repeated freezing and thawing

SYSTEM PARAMETERS

Wavelength	340 nm
Optical path	1 cm
Assay type	End point Turbidimetric
Temperature	37 °C
Zero Setting	Blank reagent

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes
- Centrifuge
- Variable Micropipettes
- Automatic analyzer

ASSAY PROCEDURE

1. Pipette into a cuvette:

	Calibrator	Sample
R1 C3 Buffer	375 µl	375 µl
Calibrator	5 µl	
Sample		5 µl
Mix well and incubator for 5 mins. at 37° C		
R2 - C3 Antibody	125 µl	125 µl

2. Mix and incubate for 5 minutes at room temperature. Read absorbance of calibrators and samples at 340 nm. Plot a calibration curve and determine the concentration of samples on the curve.

PLOTTING OF MULTIPOINT CURVE

The Turbichem C3 is based on Non-Linear Reactions, hence it is strongly recommended to run Multi-standard mode to plot the Multi-point curve to have better accuracy and precise result.

CALCULATION

Calculate the absorbance difference (A2-A1) of each point of the calibration curve and plot the values obtained against the C3

concentration of each calibrator concentration. C3 concentration in the sample is calculated by interpolation of its (A2- A1) in the calibration curve.

QUALITY CONTROL

Control sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own quality control scheme and corrective actions if controls do not meet the acceptable tolerances. For more information please contact **BioScien** technical support.

PERFORMANCE CHARACTERISTICS

- **Linearity** : 0 to 335.0 mg/dL
- **Precision** : within Run CV < 6 %

INTERFERING SUBSTANCES

Na-citrate (1000 mg/dl), Heparin (50 mg/dl), Triglyceride (2500 mg/dl) and EDTA (5 mg/dl), do not interfere. Bilirubin (60 mg/dl) and hemoglobin (1000 mg/dl) interfere with the test.

LIMITATIONS OF PROCEDURE

1. For 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. 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.

EXPECTED VALUES

80 to 185 mg/dL

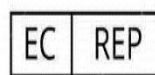
It is recommended for each laboratory to establish its own reference ranges for local population.

REFERENCES

1. Clinical Guide to Laboratory Tests, Edited by NW Tietz W B Saunders Co., Philadelphia, 483, 1983.
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
4. Dati, F. et al., Lab. Med. 13, 87 (1989).
5. Young DS. Effects of drugs on clinical laboratory test, 5th ed.

AACC Press, 1999.

SYMBOLS IN PRODUCT LABELLING		
	For in-vitro diagnostic use	 Number of <n> test in the pack
	Batch Code/Lot number	 Caution
	Catalogue Number	 Do not use if package is damaged
	Temperature Limitation	 Consult Instruction for use
	Expiration Date	
	Manufactured by	



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