PATHOZYME DIAGNOSTICS

COMPLEMENT C3

(TURBIDIMETRY METHOD)

CAT No.:C3T

Reagent kit for quantitative estimation of Complement C3 in Serum or Plasma.

DIAGNOSTIC SIGNIFICANCE:

C3 is the complement component of highest concentration in plasma and the most functionally linked between the classical and alternative pathway activations. Hepatic cells synthesize C3, although bacterial endotoxins induce synthesis through monocytes and fibroblasts. Increased and decreased levels of C3 **both** have clinical significance. Increased levels are closely related with acute-phase response (trauma, inflammatory process), biliary obstruction and focal glomerulosclerosis. Decreased levels are related with genetic deficiency (risk for infection, particularly by encapsulated bacteria), or acquired deficiency (collagen vascular diseases and severe infections).

PRINCIPLE:

C3 is a quantitative turbidimetric assay for the measurement of the component complement C3 in human serum or plasma. Anti-human C3 antibodies form insoluble complexes when mixed with samples containing C3. The scattering light of the immunocomplexes depends of the C3 concentration in the patient sample, and can be quantified by comparison from a calibrator of known C3 concentration.

SPECIMEN COLLECTION:

Fresh serum and EDTA or heparinized Plasma.C3 in serum or plasma is stable for 7 days at 2-8°C or 3 months at –20°C. Samples with presence of fibrin should be centrifuged before testing. Hemolyzed or contaminated samples are not suitable for testing.

KIT PRESENTATION:

PACK SIZE	1 X 20 ml	2 X 20 ml
Complement C3 Reagent	1 X 20 ml	2 X 20 ml
Complement C3 Calibrator	1 No	1No

REAGENT PREPARATION:

C3 Reagent and Calibrator are ready to use.

REAGENT STORAGE AND STABILITY:

C3 reagent and Calibrator are stable at 2-8°C until the expiry date stated on the label. Do not use the reagent and calibrator after the expiry date.

NOTE: Bring the reagent and calibrator at Room Temperature before use.

ASSAY PARAMETERS:

Reaction	: End point	Sample Volume	: 10 µl
Wavelength	: 340 nm	Reagent Volume	: 1000 µl
Flow Cell Temp.	: 37 °C	Calibrator Conc.	: As on vial
Zero Setting	: Dist. Water	Linearity	: 500 mg/dl
Incubation	: 2 mins. at 37 °C	Unit	: mg/dl

PROCEDURE: Bring the Reagent and Calibrator at R.T. before use.

Pipette into TT	Calibrator	Test
Complement C3 Reagent	1000 µl	1000 µl
Complement C3 Calibrator	10 µl	--
Sample	--	10 µl

Mix & Incubation for 2 mins at 37 °C. Read Abs of Test (T) and Calibrator(C) against Distilled Water at 340 nm.

CALCULATION:

Complement C3 (mg/dl) = Abs T ÷ Abs C X Calibrator Conc.

NORMAL VALUES:

Adults : 90 - 180 mg/dl.

Newborn : 70 - 196 mg/dl

Each laboratory should establish its own reference range.

LINEARITY:

This method is linear up to 500 **mg/dl**. For values above 500 mg/dl diluted the sample suitably with 0.9 % saline, and repeat the assay. Apply correction due to dilution to arrive at a final result.

Detection limit: Values less than 4.2 mg/dl give non-reproducible results.

Analytical sensitivity: Using this reagent and method an ΔA of 3.42 mA at 340 nm is equivalent to 1 mg/dL of C3 at a concentration of 192 mg/dl.

Prozone effect: Up to 800 mg/dl.

INTERFERENCES:

Bilirubin (10 mg/dL), hemoglobin (4 g/L) and rheumatoid factors (300 UI/ml) may affect the results. Lipemia (12 g/L) does not interfere. Other substances may interfere.

NOTES:

1.This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.

2.The linearity limit depends on the sample/reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

3.Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCES:

1. Tietz textbook of clinical chemistry 3rd*Ed.*Burtis CA, Ashwood ER. WB Saunders Co., (1999)
2. Young DS. Effects of drugs on clinical laboratory tests. 3th ed. AACC Press (1997).
3. Friedman and Young. Effects of the disease on clinical laboratory tests, 3th ed. AACC Press, 1997.

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Expiry Date | IVD In-Vitro Diagnostics Use | Storage | Mfg. Date | LOT Batch Number | REF Catalogue Number | See Package Insert

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An ISO 9001:2015, ISO 13485:2016, CE & GMP Certified Company

A-115, Kagal Five Star MIDC, Kagal, Dist. Kolhapur-416 216.

Tel: 0231-2305072, Cell: +91 88058 67810, E-mail: contactus@pathozyme.com, Website: www.pathozyme.com