PATHOZYME DIAGNOSTICS

COMPLEMENT C4

(TURBIDIMETRY METHOD)

CAT No.: C4T

Reagent kit for quantitative estimation of Complement C4 in Serum or Plasma.

DIAGNOSTIC SIGNIFICANCE:

C4 is the complement component essential for classical pathway activation. Most individuals with C4 deficiency do not have problems with infection, suggesting that the alternative pathway can compensate for the lack in the classical pathway activation in removal of bacterial agents. Hepatic cells synthesize C4, although in less proportion may be synthesized by monocytes and other tissues. Increased and decreased levels of C4 both have clinical significance. Increased levels are closely related with acute-phase response (trauma, inflammatory process). Decreased levels are related with genetic deficiency (autoimmune or collagen vascular disease, particularly Systemic Lupus Erythematosus), or acquired deficiency as a consequence of the consumption in immunocomplexes formation, autoimmune hemolytic anemia and autoimmune nephritis.

PRINCIPLE:

C4 at is a quantitative turbidimetric assay for the measurement of the component complement C4 in human serum or plasma. Anti-human C4 antibodies form insoluble complexes when mixed with samples containing C4. The scattering light of the immunocomplexes depends of the C4 concentration in the patient sample, and can be quantified by comparison from a calibrator of known C4 concentration.

SPECIMEN COLLECTION:

Fresh serum and EDTA or heparinized Plasma. C4 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 lipemic samples are not suitable for testing.

KIT PRESENTATION:

PACK SIZE	1 X 20 ml	2 X 20 ml
Complement C4 Reagent	1 X 20 ml	2 X 20 ml
Complement C4 Calibrator	1 No	1 No

REAGENT PREPARATION:

C4 Reagent and Calibrator are ready to use.

REAGENT STORAGE AND STABILITY:

C4 reagent and Calibrator are stable at 2-8°C until the expiry date stated on the label. Does not use the reagent after the expiry date.
NOTE: *Bring the reagent and calibrator at Room Temperature before use.*

ASSAY PARAMETERS:

Reaction	: End point	Sample Volume	: 25 µl
Wavelength	: 340 nm	Reagent Volume	: 1000 µl
Flow Cell Temp.	: 37 °C	Calibrator Conc.	: As on vial
Zero Setting	: Dist. Water	Linearity	: 100 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 C4 - Reagent	1000 µl	1000 µl
Complement C4 Calibrator	25 µl	--
Sample	--	25 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 C4 (mg/dl) = Abs T ÷ Abs C X Calibrator Conc.

NORMAL VALUES:

Adults : 10 - 40 mg/dl

Newborn : 13 - 38 mg/dl

Each laboratory should establish its own reference range.

LINEARITY:

This method is linear up to 100 **mg/dl**. For values above 100 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 0.5 mg/dl give non-reproducible results.
Analytical sensitivity: Using this reagent and method an ΔA of 9.34 mA at 340 nm is equivalent to 1 mg/dl of C4 at a concentration of 47.6 mg/dl.
Prozone effect: Up to 200 mg/dl.

INTERFERENCES:

Bilirubin (10 mg/dL), and rheumatoid factors (400 UI/ml) do not interfere. Hemoglobin (4 g/L) and lipemia (6 g/L) may affect the results. 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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