

SERUM PROTEIN



C4

1 x 30/1 x 5/1 mL
51820001

INTENDED USE

This reagent is intended for in vitro quantitative determination of complement C4 in human serum.

- Turbidimetric Immunoassay
- Linear up to 80 mg/dL
- Ready to use reagents
- Multipoint calibration

CLINICAL SIGNIFICANCE

C4 is a constituent of C3 convertase & C5 convertase.

Decreased levels are found in hereditary angioneurotic edema, immune complex disease and congenital deficiencies.

PRINCIPLE

The reagents containing polyclonal goat antihuman C4 when mixed with the serum sample containing C4 cause changes in absorbance, due to the development of turbidity, which is directly proportional to the concentration of C4 in the sample.

REAGENT COMPOSITION

C4 R1	1 x 30 mL
Phosphate buffered saline	(pH7.43)
Polyethylene glycol	(40 g/L)
Sodium azide	(0.95 g/L)
C4 R2	1 x 5 mL
Phosphate buffered saline	(pH 7.43)
Polyclonal goat anti-human C4C	(variable)
Sodium azide	(0.95 g/L)
CALIBRATOR	1 x 1 mL

Calibrator concentration is mentioned on vial label

STORAGE AND STABILITY

The reagents are stable until expiry date when kept at 2-8°C.

NORMAL RANGE

It is recommended that each laboratory establish its own reference values.

The following values may be used as guide line.

Serum : 9 - 36 mg/dL

PRECAUTION

To avoid contamination, use clean laboratory wares. Use clean, dry disposable pipette tips for dispensing. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light.

SAMPLE

Use fresh serum. If the test cannot be carried out on the same day, the serum may be stored at 2-8°C for 48 hours.

GENERAL SYSTEM PARAMETERS	FOR SEMI AUTO	FOR FULLY AUTO
Mode of reaction	End point	End point
Slope of reaction	Increasing	Increasing
Wavelength	340 nm	340 nm
Temperature	37 °C	37 °C
Calibrator concentration	As on vial label x Dilution factor	
Linearity	80 mg/dL	80 mg/dL
Blank	Reagent Blank	Reagent Blank
Incubation time	5 min +5 min	5 min +5 min
Sample volume	5 µL	3µL
Reagent 1 volume	450 µL	200 µL
Reagent 2 volume	75 µL	30 µL
Cuvette	1 cm light path	1 cm light path

CALIBRATION

PREPARATION OF CALIBRATION CURVE

Prepare the following calibrator dilution using NaCl as diluent. Multiply the concentration of the C4 calibrator by the corresponding factors stated in the table below to obtain the C4 concentration of each dilution.

Dilution	1	2	3	4	5	6
dil.Cali. (µL)	-	10	10	25	50	100
Saline (µL)	100	150	70	75	50	-
Dil. factor	0	0.0625	0.125	0.25	0.5	1.0

LABORATORY PROCEDURE FOR FULLY AUTO ANALYZER

	Blank	Calibrator	Sample/control
C4 R 1	200 µL	200 µL	200 µL
Dil. Calibrator	-	3 µL	-
Dil.Sample/control	-	-	3 µL

Mix and incubate for 5 minutes at 37°C. Read the absorbance (A1) at 340 nm.

C4 R 2	30 µL	30 µL	30 µL
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Mix and incubate for 5 minutes at 37°C. Measure the absorbance (A2) at 340 nm.

ALTERNATIVE PROCEDURE FOR SEMI AUTO ANALYZER:

	Blank	Calibrator	Sample/control
C4 R 1	450 µL	450 µL	450 µL
Dil. Calibrator	-	5 µL	-
Dil.Sample/control	-	-	5 µL

Mix and incubate for 5 minutes at 37°C.

C4 R 2	75 µL	75 µL	75 µL
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Mix and incubate for 5 minutes at 37°C. Measure the absorbance against reagent blank at 340 nm.

CALCULATION

Multipoint calibration

Calculate the ΔAbs, plot a standard curve and read the concentration of controls and samples.

PERFORMANCE CHARACTERISTICS:

Measuring Range:- 2 –80 mg/dL.

If the concentration is greater than linearity (80 mg/dL), dilute the diluted(1/10) sample with normal saline and repeat the assay. Multiply the result with dilution factor.

Prozone Effect:- >1000mg/dL

Precision in CV%:-

	Low	Medium	High
Intra - Run	4.54	2.18	3.96
Inter - Run	4.17	3.08	

Accuracy in mg/dL

Control	Assigned value	Measured value
Level 1	12.7(10.1-15.2)	12.11
Level 2	28.3(22.7-34.0)	27.4
Level 3	41.8(33.5-50.2)	39.9

Interference:-

No interference for

Hemoglobin	upto	1000 mg/dL
Na-citrate	upto	1000 mg/dL
Heparin	upto	50 mg/dL
Turbidity	upto	5%
Bilirubin	upto	20 mg/dL
Triglyceride	upto	2500 mg/dL

BIBLIOGRAPHY

1. Dati, F. et al., Lab. Med.13, 87 (1989)
2. Muller-Eberhard, H.H., Ann. Rev.Biochem.44, 697(1975)

SYMBOLS USED ON THE LABELS: IN VITRO DIAGNOSTIC USE SEE PACKAGE INSERT FOR PROCEDURE LOT NUMBER MANUFACTURER'S ADDRESS MANUFACTURING DATE EXPIRY DATE TEMPERATURE LIMIT

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