Complement C4
Turbidimetric Immunoassay

REF : 520 001 (2 X 10 ml) + 0.5 ml High calibrator **(40 test)**
REF : 520 002 (2 X 25 ml) + 0.5 ml High calibrator **(100 test)**

Intended Use
For the quantitative determination of Complement C4 (C4C) in human serum by turbidimetric immunoassay for manual and automated chemistry analyzers.

Background
C4C is a constituent of C3 convertase and C5 convertase.Decreased levels are found in hereditary angioneurotic oedema, immune complex diseases and congenital deficiencies.

Method
Antigen-antibody reaction using endpoint method.

Reagent (R)
1. Polyclonal goat anti-human C4C antiserum stabilised in phosphate buffered saline (pH 7.43) with polymer enhancer (20g/l).
2. Sodium azide (0.95 g/L).

Reagents required but not supplied
1. 0.9 g % sodium chloride
2. Calibrators and Controls

Reagent Preparation, Storage and Stability
The reagent is 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.

Specimen Collection and Preservation
Use fresh serum. If the test can not be carried out on the same day, the serum may be stored at 2 - 8°C for 48 hours. If stored for a longer period, the sample should be frozen.

Procedure
Sample/Control: ready for use
Reference curve: Generate a reference curve by diluting the standard high level successively 1:2 in saline (9 g/L NaCl). Use saline (9 g/L NaCl)as zero point

Test:

	Samples	Standards	Controls
Samples	15 µl	.....	.....
Standards	.....	15 µl	.....
Controls	.....	.....	15 µl
Reagent	450 µl	450 µl	450 µl

Mix and incubate for 5 minutes at room temperature.
Read optical density (OD) of samples, standards and control(s) at 340 nm. Plot a standard curve and read the concentration of controls and samples.

Reference Values
9-36 mg/dL
These values are for reference only. Each laboratory should establish its own reference values.

Performance Characteristics
1-Dynamic Range
0 - 80 mg/dL

2-Detection Limit
8 mg/dL

3-Hookeffect
> 300 mg/dL

4-Sensitivity:
0.0053 ABS units/concentration unit

5-Specificity
Monospecific

6-Interferences:
No interference for: Haemoglobin (1000 mg/dL), Na-citrate (1000 mg/dL), Heparin (50 mg/dL), Turbidity (5%), Billirubin (20 mg/dL) and Triglyceride (2500 mg/dL)

7-Precision (CV%)

	Low	Medium	High
Intra run	0.85	0.73	0.69
Inter run		2.99	

8- Methods Comparison
A comparison between Spectrum Diagnostics C4 reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.984 was obtained.

Precautions and warnings
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.

References
1. Dati, F. et al., Lab. Med. 13, 87 (1989).
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

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