

Complement C3 (2nd Generation)

Turbidimetric Immunoassay

REF: 519 001 (2 X 10 ml) + 0.5 ml High calibrator (40 test)

REF: 519 002 (2 X 25 ml) + 0.5 ml High calibrator (100 test)

Intended Use

For the quantitative determination of Complement C3 (C₃C) in human serum by turbidimetric immunoassay for manual and automated chemistry analyzers.

Background

C₃C is the central point of the classic and alternative complement pathway. It is a constituent of C₅ convertase. On activation split products of C₃C have important biological functions, where C₃b is an opsonin and involved in immune adherence, while C₃a is an anaphylatoxin and a chemotoxin.

C₃C behaves as an acute phase protein, therefore increased levels may be found in acute inflammatory reactions. On the other side Decreased levels are reported in complex disease, recurrent immune infections with pyrogenic bacteria, various glomerulonephritides and in congenital deficiencies.

Method

Antigen-antibody reaction using endpoint method .

Reagent (R)

Polyclonal goat anti-human C₃C stabilised in saline supplemented with accelerator.

Sodium azide (0.95 g/L).

Reagents required but not supplied

1. Saline (9 g/L NaCl)
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 cannot 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: dilute 1:10 in saline 9g/L

Reference curve: Generate a reference curve by diluting the standard high level 1:10, 1:20, 1:40, 1:80 and 1:160 with saline (9 g/L NaCl) Use saline (9 g/L NaCl) as zero point.

Test:

| | Diluted samples | Diluted standards | Diluted controls |
|-------------------|-----------------|-------------------|------------------|
| Diluted Samples | 15 µl | | |
| Diluted Standards | | 15 µl | |
| Diluted Controls | | | 15 µl |
| Reagent | 500 µl | 500 µl | 500 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

75 - 135 mg/dL

These values are for reference only. Each laboratory should establish its own reference values.

Performance Characteristics

1-Dynamic Range

0 - 353 mg/dL

2-Detection Limit

20 mg/dL

3-Hookeffect

> 3530 mg/dL

4-Sensitivity:

0.00070 ABS units/concentration unit

5-Specificity

Monospecific

6-Interferences:

-No interference for: Na-citrate (1000 mg/dL), Heparin (50 mg/dL), Triglyceride (2500 mg/dL) and EDTA (5mg/dL).

-Haemoglobin (1000 mg/dL) and Bilirubin (60 mg/dL) interfere with the test.

7-Precision (CV%)

| | Low | Medium | High |
|-----------|------|--------|------|
| Intra run | 0.62 | 0.81 | 0.73 |
| Inter run | 2.83 | 3.51 | 2.9 |

8- Methods Comparison

A comparison between Spectrum Diagnostics C3 reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.991 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