HƯỚNG DẪN SỬ DỤNG TIẾNG ANH

Tài liệu được xác nhận bằng chữ ký số

Hà Nội, ngày 25 tháng 7 năm 2022

Người đại diện hợp pháp của cơ sở

GIÁM ĐỐC

M.S.D.N: 0106162113 - C.T.T.N.H.H - CÔNG TY TRÁCH NHIỆM HỮU HẠN THIẾT BỊ NHẬT ANH - THÀNH PHỐ HÀ NỘI

Uông Tuấn Phương

COD 31084 1 x 20 mL	COD 31073 1 x 50 mL	COD 31079 1 x 250 mL
STORE AT 2-8ºC		
Reagents for measurement of C3 concentration Only for *in vitro* use in the clinical laboratory		

COMPLEMENT COMPONENT C3

BioSystems REAGENTS & INSTRUMENTS

CE

COMPLEMENT COMPONENT C3

Turbidimetry

PRINCIPLE OF THE METHOD

Complement component C3 in the sample precipitates in the presence of anti-human C3 antibodies. The light scattering of the antigen-antibody complexes is proportional to the C3 concentration and can be measured by turbidimetry[1].

CONTENTS

	COD 31084	COD 31073	COD 31079
A. Reagent	1 x 20 mL	1 x 50 mL	1 x 250 mL

COMPOSITION

A. Reagent: Imidazole buffer 0.1 mol/L, goat anti-human C3 antibodies, sodium azide 0.95 g/L, pH 7.5.

STORAGE

Store at 2-8ºC.

The Reagent is stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during its use.

Indications of deterioration: Presence of particulate material, turbidity, absorbance of the blank over 0.300 at 340 nm.

ADDITIONAL REAGENTS

– Protein Calibrators (BioSystems cod. 31075). The set contains 5 different levels of C3 concentration and it should be used to prepare the calibration curve. The calibrators are supplied ready to use.

REAGENT PREPARATION

Reagents are provided ready to use.

ADDITIONAL EQUIPMENT

– Thermostatic water bath at 37ºC.

– Analyzer, spectrophotometer or photometer with cell holder thermostatable at 37ºC and able to read at 340 ± 20 nm.

SAMPLES

Serum or plasma collected by standard procedures. Use heparin or EDTA as anticoagulants. Lipemic samples are not suitable for testing.

Serum or plasma C3 is stable for 2 days at 2-8°C.

PROCEDURE

1. Bring the Reagents and the instrument to 37ºC.
2. Pipette into a cuvette (Note 1):

Reagent (A)	1.0 mL
Distilled water (Blank), Calibrator or Sample	10 µL

3. Mix and insert cuvette into the instrument. Start stopwatch.
4. Read the absorbance of the Blank, Calibrators and Sample at 340 nm after exactly 5 minutes of sample addition.

CALIBRATION

Calibration curve: Plot the absorbance difference values of each calibrator against its C3 concentration. Use the Blank as the calibrator of 0 concentration. C3 concentration in the sample is calculated by interpolation of its absorbance difference on the calibration curve.

A calibration is recommended at least every 2 months, after reagent lot change or as required by quality control procedures.

REFERENCE VALUES

Serum, adults[2]: 90 - 180 mg/dL = 0.90 - 1.80 g/L.

This range is given for orientation only; each laboratory should establish its own reference range.

QUALITY CONTROL

It is recommended to use the Protein Control Serum level I (Cod. 31211) and II (Cod. 31212) to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

METROLOGICAL CHARACTERISTICS

– Detection limit: 3.7 mg/dL = 0.037 g/L.

– Measurement interval (approximate value dependent on the highest standard concentration): 3.7 - 400 mg/dL = 0.037 - 4.00 g/L. For higher values dilute sample 1/5 with distilled water and repeat measurement.

– Repeatibility (within run):

Mean concentration	CV	n
97 mg/dL = 0.97 g/L	2.9 %	25
227 mg/dL = 2.27 g/L	2.3 %	25

– Reproducibility (run to run):

Mean concentration	CV	n
97 mg/dL = 0.97 g/L	5.0 %	25
227 mg/dL = 2.27 g/L	2.8 %	25

– Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

– Zone effect: > 1500 mg/dL = 15.00 g/L.

– Interferences: Bilirubin (20 mg/dL) and rheumatoid factors (300 IU/mL) do not interfere. Lipemia (triglycerides 2.4 g/L) and hemoglobin (1.6 g/L) may affect the results.Other drugs and substances may interfere[3].

These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure are used.

DIAGNOSTIC CHARACTERISTICS

C3 is a component of the complement system which is involved in both the classical and the alternative pathways of activation.

C3 is often increased as a result of an acute-phase response (inflammation, trauma or tissue necrosis), biliary obstruction and focal glomerulosclerosis.

Plasma C3 levels are decreased in genetic or acquired deficiencies, which are associated with a significantly increased risk for infection, particularly with encapsulated bacteria.

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

NOTES

1. These reagents may be used in several automatic analysers. Instructions for many of them are available on request.

BIBLIOGRAPHY

1. Price CP, Spencer K and Whicher J. Light-scattering immunoassay of specific proteins: a review. *Ann Clin Biochem* 1983; 20: 1-14.
2. Dati F et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference range for 14 proteins in serum based on the standarization against the IFCC/CAP reference material (CRM 470). *Eur J Clin Chem Clin Biochem* 1996; 34: 517-520.
3. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
4. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.