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

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COD 31085 1 x 20 mL	COD 31074 1 x 50 mL	COD 31080 1 x 250 mL
STORE AT 2-8ºC		
Reagents for measurement of C4 concentration Only for *in vitro* use in the clinical laboratory		

COMPLEMENT COMPONENT C4

BioSystems
REAGENTS & INSTRUMENTS

CE

COMPLEMENT COMPONENT C4
Turbidimetry

PRINCIPLE OF THE METHOD

Complement component C4 in the sample precipitates in the presence of anti-human C4 antibodies. The light scattering of the antigen-antibody complexes is proportional to the C4 concentration and can be measured by turbidimetry[1,2].

CONTENTS

	COD 31085	COD 31074	COD 31080
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 C4 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 C4 concentration and it should be used to prepare the calibration curve. The calibrators are supplied ready to use.

REAGENT PREPARATION

Reagent is 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 C4 is stable for 2 days at 2-8ºC.

PROCEDURE

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

Reagent (A)	1.0 mL
Distilled water (Blank), Calibrator or Sample	25 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 10 minutes of sample addition.

CALIBRATION

Calibration curve: Plot the absorbance values of each calibrator against its C4 concentration. Use the Blank as the calibrator of 0 concentration. C4 concentration in the sample is calculated by interpolation of its absorbance 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]: 10 - 40 mg/dL = 0.10 - 0.40 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: 1.0 mg/dL = 0.010 g/L.

– Measurement interval (approximate value dependent on the highest standard concentration): 1.0 - 90 mg/dL = 0.010 - 0.90 g/L. For higher values dilute sample 1/5 with distilled water and repeat measurement.

– Repeatibility (within run):

Mean concentration	CV	n
21 mg/dL = 0.21 g/L	2.2 %	20
50 mg/dL = 0.50 g/L	1.7 %	20

– Reproducibility (run to run):

Mean concentration	CV	n
21 mg/dL = 0.21 g/L	3.7 %	25
50 mg/dL = 0.50 g/L	1.9 %	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: > 700 mg/dL = 7.00 g/L.

– Interferences: Bilirubin (20 mg/dL) and rheumatoid factors (300 IU/mL) do not interfere. Lipemia (triglycerides 2.0 g/L) and hemoglobin (2.4 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

C4 is a component of the complement system which is essential for activation of the classical pathway.

Plasma levels are modestly increased by the acute-phase response (inflammation, trauma or tissue necrosis).

A complete C4 genetic deficiency is associated with a very high prevalence of autoimmune or collagen vascular disease, particularly Systemic Lupus Erythematosus. Levels of C4 are also depressed because of consumption due to immuno complex formation.

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.