SPECTRUM

The Creative Approach to Bioscience

Ceruloplasmin

Turbidimetry

REF: 574 001 50 test
REF: 574 002 100 test

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Intended Use

Spectrum Diagnostics Ceruloplasmin reagent is intended for Quantitative turbidimetric determination of Ceruloplasmin in human serum or plasma.

Background

Ceruloplasmin (CER) is a glycoprotein which is synthesized mostly in the liver. It is one of the acute phase protein in inflammation and it is the most important carrier of copper (Cu) in plasma. The Ceruloplasmin molecule binds 6-8 Cu atoms. Ceruloplasmin has antioxidative effect. The most important physiological functions of Ceruloplasmin are the regulation of transport, availability, and redox potential of iron (Fe) as a result of its ferroxidase activity; the antioxidative effect of lipids in the cell membrane, due to the prevention of metal ion-catalyzed oxidation; and the transport of copper.

Assay Principle

Anti-human Ceruloplasmin antibodies when mixed with samples containing Ceruloplasmin, forms insoluble complexes. These complexes cause an absorbance change, dependant upon the Ceruloplasmin concentration of the patient sample, that can be quantified by comparison from a calibrator of known Ceruloplasmin concentration.

Reagent

Diluent (R1)
Tris buffer 20 mmol/L,PEG 8000, pH 8.3.
Sodium azide 0.95 g/L

Antibody (R2)
Goat serum, anti-human Ceruloplasmin, pH 7.5
Sodium azide 0.95 g/L

Calibrator
available upon request

Reagent Preparation, Storage and Stability

Spectrum Ceruloplasmin reagents are stable up to the expiry date labeled on the bottles when stored at 2 - 8°C and contaminations are prevented during their use.

Deterioration

Do not use the Spectrum Ceruloplasmin reagents if presence of particles and turbidity.
Do not freeze; frozen Antibody or diluent could change the functionality of the test.

Specimen Collection and Preparation

Fresh serum or plasma. EDTA or heparin should be used as anticoagulant. stable 7 days at 2 - 8°C or 3 months at -20°C.
Samples with presence of fibrin should be centrifuged.
Do not use highly hemolized or lipemic samples.

Procedure

Wavelength	340 nm
Temperature	37°C
Cuvette	1cm light path
Zero adjustment	distilled water

Bring the reagents at 37°C and pipette:

	Calibrator	Sample
Reagent (R1)	800 µl	800µl
Calibrator	7 µl	---
Sample	---	7 µl

Mix and measure absorbance immediately (A1) after the sample or calibrator addition, then immediately pipette:

Reagent (R2)	200 µl	200 µl

Mix and measure absorbance (A2) of calibrators and sample exactly 2 minutes after R2 addition.

Adaptation sheets for several automatic analyzers are available upon request.

Calculation

$$\frac{(A2 - A1)\text{sample}}{(A2 - A1)\text{calibrator}} \times \text{Calibrator concentration} = \text{mg/dL Ceruloplasmin}$$

Expected Values

Normal values are between 15 - 60 mg/dL.
Each laboratory should establish its own reference range.

Sensitivity

When run as recommended, the minimum detection limit of the assay is 3.27 mg/dL.

Linearity

Up to 120 mg/dL.
specimens showing higher concentration should be diluted 1/5 using physiological saline and repeat the assay.

Interfering Substances:

Haemoglobin	up to 20 g/L.
Bilirubin	up to 40 mg/dL.
Lipemia	up to (< 2.5 g/L)
Rheunatoid Factor	up to 800 IU/mL

Dynamic Range

3.27 - 120 mg/dL.

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Clinical Guide to laboratory tests, Edited by NW Tietz W B Saunders Co. Philadelphia, 483, 1983.

2. Dati F et al. Eur J Clin Chem Clin Biochem 1966; 14: 401-406.

3. Young DS. Effedts of disease on clinical laboratory tests, 3rd ed. AACC Pres.1997.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
574 001	50 test
574 002	100 test

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