SPECTRUM

The Creative Approach to Bioscience

Copper

REF: 242 001 (2 x 25 ml) 50 test
REF: 242 002 (4 x 25 ml) 100 test

Intended Use

Spectrum Copper reagent is intended for in-vitro quantitative, diagnostic determination of Copper in human serum on both manual and automated systems.

Background

Copper (Cu) is an important trace element and is associated with a number of metalloproteins and it is a catalytic component of numerous enzymes and also a structural component of other important proteins. Copper is involved in many vital processes in the body; energy production, connective tissue formation, iron metabolism, melanin synthesis, normal function of CNS, regulation of gene expression and has antioxidant function . Excess Cu ingestion interfere with absorbtion of zinc and can lead to Zinc deficiency, which is frequently characterized by slow healing. The classical presentation of Cu toxicosis is represented by the genetic disease of Cu accumulation known as Wilson's disease. This disease is typified by hepatocellular damage (increased transferase) and/or changes in mood and behavior because of accumulation of Cu in Central Neurons.

Method

Colorimetric with Dibromo-PAESA

Assay Principle

Copper forms with 4-(3,5-dibromo-2-pyridylazo)-N-ethyl-sulfopropylaniline a chelate complex. The increase of absorbance of this complex can be measured and is proportional to the concentration of total copper in the sample.

Reagents

Standard (ST)
100 µg/dL 15.7 µmol/L

Reagent 1

Acetate buffer pH 5.0 100 mM

Reagent 2

4-(3,5-dibromo-2-pyridylazo)-N-ethyl-sulfopropylaniline 10 mM

For further information, refer to the Copper reagent material safety data sheet.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Avoid contamination by using clean laboratory material (pipette, plastic vial for analyzers,...)

Reagent Preparation

Warning: The reagent R1 could precipitate during refrigeration. ~~It is highly~~ recommended to incubate the neeeded amount of R1 after well mixing in 37°C for at least 1 hr before starting assay (till complete dissolve).

Working Solution:
Mix equal amounts of both reagents R1 and R2. The working is stable for one month at 2-8°C

Reagent Storage and Stability

Reagent are stable up to the expiry date labeled on the bottles. Once opened, the opened vial is stable for 2 months at 2-8 °C.

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		

Specimen collection and preparation

Serum (free from haemolysis)

System Parameters

Wavelength	580 nm (Hg 578)
Optical path	1 cm
Assay type	End-point
Direction	Increase
Temperature	37 °C
Zero adjustment	Reagent blank
Linearity	500 µg/dl (78.65 µmol/l)

Procedure

I- Determination of copper in serum

	Blank	Standard	Sample
Working Solution	1.0 ml	1.0 ml	1.0 ml
Standard	.....	50 µl	.....
Sample	.....	.....	50 µl

Mix and incubate for 5 minutes at 37 °C. Measure the absorbance of the sample As and of the standard Astd against the reagent blank A_{RBL} .

$\Delta As = As - A_{RBL}$
$\Delta Astd = Astd - A_{RBL}$

Calculation

$$\text{Serum Copper conc. (µg/dL)} = \frac{\Delta As}{\Delta Astd} \times 100$$

$$\text{Serum Copper conc. (µmol/l)} = \frac{\Delta As}{\Delta Astd} \times 15.7$$

Performance Characteristics

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (µg/dL)	92	200
SD	2.3	3.6
CV%	2.5	1.8

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (µg/dL)	88	192
SD	2	3.4
CV%	2.27	1.77

Methods Comparison

A comparison between Spectrum copper reagent and a commercial reagent of the same methodology was performed on 200 human serum.A correlation of 0.982 was obtained.

Quality Control

Normal and abnormal commercial control serum of known concentrations should be analyzed with each run.

Sensitivity

When run as recommended, the minimum detection limit of the assay 4 µg/dl

Linearity

The reaction is linear up to a Copper concentration of 500 µg/dl (78.65 µmol/l)
Specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result × 2).

Interfering Substances

Triglycerides (1000 mg/dL) does not affect the results.
Hemoglobin (>500 mg/dL) does not affect the results.
Bilirubin (>40 mg/dL) does not affect the results.
Other drugs and substances may interfere.

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the reults is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Expected Values

In Serum

Adult males	70 - 140 µg/dl	(11 - 22 µmol/l)
Adult females	80 - 155 µg/dl	(12.5 - 24.3 µmol/l)
Females in pregnancy	120 - 300 µg/dl	(18.8 - 47 µmol/l)
Children (6-12 years)	80 - 190 µg/dl	(12.5 - 29.8 µmol/l)
Infants	20 - 70 µg/dl	(3.14 - 11 µmol/l)

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. Abe A., Yamashita S., Noma A., Clin. Chem., 552-554-35 (1989)
2. Richmond. N., Clin. Chem. 1973; 19: 1350-1356.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
242 001 242 002	50 Test 100 Test

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