Spectrum For Diagnostic Industries

Copper
(Colorimetric Test with Dibromo-PAESA)

IVD

REF.	Pack size
206 01 050	(1 x 50 ml) 50 tests
206 02 030	(2 x 30 ml) 60 tests
206 05 030	(5 x 30 ml) 150 tests

Intended Use

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

Introduction

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 Dibrom-PAESA

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

Reagnt

Acetate buffer (pH 5.0)	0.2 mol/L
Dibrom-PAESA	0.02 mmol/L

Standard

100 µg/dL	15.7 µmol/L

Reagent preparation, storage and stability

Copper reagent is supplied ready-to-use and stable up to the expiry date labeled on the bottles, Once opened, the reagent and the standard vials are stable for 3 months at specified temperature.

Deterioration

Failure to recover control values within assigned range may indicate reagent deteriortion

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,...)

Specimen collection and preservation

Serum or Plasma (free from haemolysis)

24 hours Urine:
Refrigerate or add 10 ml of 3 mol/L HCL to the container before collection.

Procedure

Wavelength	580 nm (Hg 578)
Optical path	1 cm
Assay type	End-point
Direction	Increase
Temperature	37 °C
Zero adjustment	Reagent blank
Reagent Blank Limits	Low 0.00 AU High 0.17 AU
Linearity	500 µg/dL (78.65 µmol/L)

I- Determination of copper in serum

	Blank	Standard	Sample
Reagent	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 Specimen and of the standard against the reagent blank .

Calculation

$$\text{Serum Copper conc. (µg/dL)} = \frac{\Delta A\text{specimen}}{\Delta A\text{standard}} \times 100$$

II- Determination of copper in urine

Dilute Standard 20 Times (Example: 50 µl standard + 950 µl normal saline), then follow the method below :

	Blank	Standard	Urine Sample
Reagent	……	1.0 ml	1.0 ml
Diluted Standard	……	750 µl	……
Sample	……	……	750 µl
Dist.H2O	1.0 ml	……	……

Mix and incubate for 5 minutes at 37 °C. Measure the absorbance of the Specimen and of the standard against the reagent blank .

$$\text{Serum Copper conc. (µg/dL)} = \frac{\Delta A\text{specimen}}{\Delta A\text{standard}} \times 5$$

Quality control

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

Interfering Substances

Interferences are found according to the literatures.

Expected Values

Serum

1-Adult	
a) males	70 - 140 µg/dL (11 - 22 µmol/L)
b) females	80 - 155 µg/dL (12.5 - 24.3 µmol/L)
2-Females in pregnancy	120 - 300 µg/dL (18.8 - 47 µmol/L)
3-Children (6-12 years)	80 - 190 µg/dL (12.5 - 29.8 µmol/L)
4-Infants	20 - 70 µg/dL (3.14 - 11 µmol/L)

24 hours Urine	10 - 30 µg/24hour

Performance characteristics

Accuracy
Results obtained using this reagents (y) did not show systematic differences when compared with other commerical reagents (x).
The results obtained using 92 samples were the following :
correction coefficient (r) : 0.986
Regression equation : y =4.4+0.920x.
The results of the performance characteristics depend on the analyzer used.

Sensitivity

When run as recommended, the minimum detection limit of this assay is 1.0 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).

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
2. Richmond. N., Clin. Chem.

SYMBOLS IN PRODUCT LABELLING

IVD For in-vitro diagnostic use
LOT Batch Code/Lot number
REF Catalogue Number
Consult instructions for use
Temperature Limitation
Use by/Expiration Date
CAUTION. Consult instructions for use
Manufactured by

Spectrum For Diagnostics Industries - Free Zone
Ismailia Free Zone, Block 5 .
Cairo- Port said Avenue.
Ismailia,Egypt
Tel: +2 064 3488 013 - +2 064 3488 014 Fax: +2 064 3488 015
www.sdi-fz.com

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EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany
CE