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COPPER FLUID AUTO

Diagnostic Single reagent for the in-vitro quantitative determination of copper in human serum, plasma or urine on both manual and automated systems.

REF: BS.1/CU02.025.0050	50 test	REF: BS.1/CU02.050.0100	100 test

CLINICAL SIGNIFICANCE

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 absorption 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 (increase transferase) and/or changes in mood and behavior because of accumulation of Cu in Central Neurons.

METHOD PRINCIPLE

Colorimetric with Dibrom-PAESA
At PH of 4.7 copper is released from the carrier protein and forms with 4-(3,5-Dibromo-2-pyridylazo)-N-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.

REAGENT COMPOSITION

R1: Standard	100 µg/dl (15.73 µmol /l)
R2: Reagent - Acetate buffer PH 5.0 - 4-(3,5-Dibromo-2-pyridylazo)-N-sulfopropylaniline	 0.22 mol/L 0.02 mmol/L

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent (R) contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- 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.
- Respect country requirement for 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.

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

REAGENT PREPARATION, STORAGE AND STABILITY

Bioscien COPPER reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored refrigerated at 2–8˚C.
The COPPER reagent could precipitate during refrigerator storage. It suggested to let it to redissolve at room temperature before use (15 minutes). Mix well after redissolving.

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.

SYSTEM PARAMETERS

Wavelength	580 nm (578 nm)
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)

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes and automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

I-Determination of copper in serum

	Blank	*Standard*	*Specimen*
Reagent	1.0 ml	1.0 ml	1.0 ml
Standard		50 µl	
Specimen			50 µl

Mix and incubate for 5 minutes at 37°C. Measure absorbance of specimen "A" and standard "A" against reagent blank.

CALCULATION

$$\text{Serum concentration (µg/dl)} = \frac{(\text{A specimen}) \times 100}{(\text{A standard})}$$

$$\text{Serum concentration (µmol/l)} = \frac{(\text{A specimen}) \times 15.7}{(\text{A standard})}$$

Fits your perfection

I-Determination of copper in urine

Dilute standard 10 times (Example 100 µl + 900 µl normal saline), then follow the method below:

	Blank	*Standard*	*Specimen*
Reagent		1.0 ml	1.0 ml
Standard		750 µl	
Specimen			750 µl
Dist. H2O	1.0 ml		

Mix and incubate for 5 minutes at 37°C. Measure absorbance of specimen "A" and standard "A" against reagent blank.

CALCULATION

Urine concentration (µg/dl) = $\frac{\text{(A specimen)} \times 10}{\text{(A standard)}}$

Urine concentration (µmol/l) = $\frac{\text{(A specimen)} \times 1.57}{\text{(A standard)}}$

concentration (µg/urine 24 h) = $\frac{\text{(A specimen)} \times 10 \text{ x dl of urine 24h}}{\text{(A standard)}}$

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact ***Bioscien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision

	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	20	20	20	20
Mean µg/dl	101.3	189.9	89.5	256
SD.	1.06	2.23	1.55	5.93
CV. %	1.05	1.17	1.74	2.32

The results of the performance characteristics depend on the analyzer used.

Accuracy (Methods Comparison)

Result obtained from ***Bioscien*** Copper reagent compared with commercial reagent of the same methodology performed on 20 human sera give a correlation of 0.993.

Sensitivity

When run as recommended, the minimum detection limit of the assay is 10 µg/dl

Linearity

The reaction is linear up to 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 [3]

No significant interference from bilirubin (<15 mg/dl), Hemoglobin (<500 mg/dl), Triglycerides (<1000 mg/dl).

EXPECTED VALUES [4]

Serum and plasma	***µg/dl***	***[µmol/L]***
Infants	20-70	[3.14-11]
Children (6-12 years)	80-190	[12.5-29.8]
Adult males	70-140	[11-22]
Adult females	80 -155	[12.5-24.3]
Females in pregnancy	120-300	[18.8-47]
In 24 hrs Urine	***10-30***	***[µg/24hrs]***

REFERENCES

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

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		