ChemCHEK™

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COPPER

2 x 25 mL
11020001

Intended Use

This reagent is intended for in vitro quantitative determination of Copper in serum or plasma.

- Di-Br-PAESA Methodology

Clinical Significance

Copper is an essential trace mineral in humans, the function of copper is to help to release energy, helps in melanin production in the skin, helps in the production of red blood cells and aid in the absorption and transport of iron. Acquired copper deficiency can cause hematological/neurological manifestations. Wilson disease (copper toxicity) is associated with neurological manifestations and low serum copper, with copper deposited in tissues responsible for the toxicity. The symptoms of acute copper poisoning include nausea, vomiting and abdominal and muscle pain.

Principle

Copper in an acid medium reacts with the chromogen Di-Br-PAESA 4-(3,5-dibromo-2- pyridylazo)-N-ethyl-N-(3-sulphopropyl0aniline.) to form a coloured complex. Intensity of the colour is directly proportional to the amount of Copper present in the sample.

Kit Components

Reagent/ Component	Product Code 11020001	Description
Copper Reagent (R1)	1 x 25 mL	Acetate Buffer (p H 4.9) 0.1M
Copper Reagent (R2)	1 x 25 mL	3,5 Di-Br-PAESA Preservatives
Copper Standard	1 x 4 mL	Copper Standard Concentration 200 µg/dL

Risk & Safety

Material safety data sheets (MSDS) will be provided on request.

Reagent Preparation

Mix in equal parts of Reagent R1& Reagent R2 . Copper Standard is ready to use.

Reagent Storage and Stability

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2 - 8 °C.

Note: Reagent 1 solidifies when kept at 2 - 8 °C. Allow the reagent to melt by keeping at room temperature before use.

Open Vial Stability

Once opened, the reagent is stable up to 4 weeks, if contamination is avoided.

Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the control may also be an indication of reagent instability and associated results are invalid. Sample should be retested, using a fresh vial of reagent.

Precaution

To avoid contamination, use clean laboratory wares. Use clean, dry disposable pipette tips for dispensing. Close reagent bottles immediately after use.

Avoid direct exposure of reagent to light.

Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precaution required for handling all laboratory reagents.

Waste Management

Reagents must be disposed off in accordance with local regulations.

Sample

Serum / Plasma (free of hemolysis). Use heparin as anticoagulant. Highly lipaemic serum may interfere the assay. It is recommended to filter or centrifuge the sample.

Materials Provided

Copper Reagent (R1), Copper Reagent (R2) and Copper Standard

Materials Required but Not Provided

- Pipettes & Tips
- Test Tubes & racks
- Timer
- Incubator
- Analyzer

Test Parameter

Mode of Reaction	End Point
Slope of Reaction	Increasing
Wavelength	580 nm
Temperature	30 °C
Standard Concentration	200 µg/dL
Blank	Reagent
Linearity	500 µg/dL
Incubation Time	10 min
Sample Volume	35 µL
Reagent Volume	500 µL
Cuvette	1 cm light path

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
µg/dL	µmol/L	x 0.1574

Calibration

Copper standard is recommended for calibration of this assay on semi auto analyzers.

Procedure Notes

Laboratory Procedure for Semi Auto Analyzer			
	Blank	Standard	Sample
Working Reagent	500 µL	500 µL	500 µL
Distilled Water	35 µL	-	-
Standard	-	35 µL	-
Sample	-	-	35 µL
Mix and incubate for 10 minute at 30 °C. Read the absorbance (A) of standard & sample against blank at 580 nm. The colour is stable for 30 minutes.			

Calculation

$$\text{Copper Conc. (µg/dL)} = \frac{\text{Absorbance of Sample}}{\text{Absorbance of Standard}} \times 200$$

Quality Control

It is recommended to use control to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

SYMBOLS USED ON THE LABELS

SYMBOLS USED ON THE LABELS: IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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ADS/V.02/060114

CE ISO 9001 : 2008
ISO 13485 : 2003

Reference Range

It is recommended that each laboratory should establish its own reference values.

The following value may be used as guide line.

Men	:	70 - 140 µg/dL
Female	:	80 - 155 µg/dL
Newborns	:	20 - 70 µg/dL
Children	-	
up to 6 years	:	90 - 190 µg/dL
up to 12 years	:	80 - 160 µg/dL

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance

1. Linearity

The reagent is linear upto 500 µg/dL

If the concentration is greater than linearity (500 µg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2.Precision

Accuracy (µg/dL)		
Control	**Expected Value**	**Measured Value**
Control Level 1	112 ± 30.5	103.42
Control Level 2	76 ± 10.2	65.04

Bibliography

1. Pasquinelli, F.; Diagnostica e Tecniche di Laboratorio, (pag.:1099-1102) Rossini Editrice.(1984)
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3. Cuiti, R, Gallia, Giorn.; It. Chim. Clin. 12(2): 91-100 (1987)

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