COPPER

Colorimetric Di-Br-PAESA method.
Kit for measurement of copper concentration in serum and in plasma.

IVD REF **10500** Σ **3x30 mL (R1)**
1x10 mL (R2)
1x5 mL (STD)

CE

PRINCIPLE OF THE METHOD

Under acid enviroment, cupric ions present in the sample reacts with Di-Br-PAESA. to form a coloured complex . The intensity of the coloured complex is proportional to the copper concentration in the sample.
The method doesn't need de-proteinization , neither sample blank.

TEST PREFORMANCE

Precision

Intra-assay (n=10)	Mean (µg/dL)	SD (µg/dL)	CV (%)
Sample 1	98,9	2,494	2,52
Sample 2	165,5	4,179	2,53

Inter-assay (n=30)	Mean (µg/dL)	SD (µg/dL)	CV (%)
Sample 1	101,93	2,856	2,80
Sample 2	169,25	4,940	2,92

Method comparison
Results obtained on the same samples with an equivalent method have done the following data:

y=5,1431x+1,0303

R =0,9935
n= 18

Sensitivity/limit of detection
The method is able to discriminate until 8 µg/dL.

Linearity
The method is linear up to 500 µg/dL.

SAMPLE

Serum, plasma with lithium heparin as anticoagulant.

Note:
- Avoid use of hemolyzed sample.
- Copper in the sample is stable for 8 days at +2-8°C.
- Strong lipemic serum can interfere with the measurement . Centrifuge or filtrate the sample before testing.

REFERENCE VALUE

SERUM AND PLASMA

MAN	80 – 140	µg/dL	12.59 – 22.03	µmol/L
WOMAN	80 – 155	µg/dL	12.59 – 24.39	µmol/L
NEWBORN (BABIES)	12 – 67	µg/dL	1.89 – 10.54	µmol/L
CHILDREN (up to 10 years)	30 – 150	µg/dL	4.72 – 23.60	µmol/L

REAGENTS - INITIAL CONCENTRATION

Reagent 1	Acetatum buffer 100 mmol/L pH 4,90 Reducing agents and preservatives.	3x30 mL	REF: 1050001
Reagent 2	3,5 Di-Br- PAESA (4-(3,5-dibromo-2-pyridylazo)-N-ethyl-N-sufopropylaniline)	1x10 mL	REF: 1050002
Standard	Standard ion Copper 200 µg/dL	1x5 mL	REF: 1050003

REAGENTS -STORAGE AND STABILITY

Kit: Store at +2-8°C.
Stable until the expiry date shown on the label.

Opened reagents: Reagents are stable after opening until the expiry date shown on the bottles when are protected from direct light, tightly closed, and stored at reported temperature.

REAGENTS - PREPARATION

Reagents are liquid ready to use .

REAGENTS – PRECAUTION AND WARNING

- This method describes the manual use of this kit. For use with automatic analyzer see the specific applications.
- Quality control data sheet of the reagents are available upon request. Refer to the batch number on the label.

ADDITIONAL EQUIPMENT

Pipettes
Spectrophotometer
Cuvettes with 1 cm lightpath.

SAFETY PRECAUTIONS

Reagent 1

Caution

- Causes serious eye irritation [H319]
- Wear protective gloves/protective clothing/eye protection/face protection. [P280]
- If eye irritation persists get medical advice/attention.. [P337+313]

Reagent 2 The product is not classified as dangerous

Standard The product is not classified as dangerous

WASTE MANAGEMENT

Please refer to local legal requirements.

ANALYTICAL PROCEDURE

Wavelength	λ = 580(570 or 590) nm
Lightpath	1 cm
Temperature	+37°C
Measurement	Against reagent blank
Reaction	end point (increase)

Allow reagents to reach working temperature before using.

	BLANK	STANDARD	SAMPLE	
Reagent 1	900	900	900	µL
Distilled water	60	-	-	µL
Sample	-	-	60	µL
Standard	-	60	-	µL

Mix thoroughly and incubate for 5 minutes at +37°C.
Measure the absorbance of the Sample and the Standard against the blank (ABS1).

Reagent 2	100	100	100	µL

Mix thoroughly and incubate for 5 minutes at +37°C.
Measure the absorbance of the Sample and the Standard against the blank (ABS2).
The colour is stable for at least 30 minutes if protected from direct light.

CALCULATIONS

Serum, plasma:

$$\text{Copper } (\mu g/dL) = \frac{\text{ABS2 Sample} - (\text{ABS1 Sample} \times 0{,}906)}{\text{ABS2 Standard} - (\text{ABS1 Standard} \times 0{,}906)} * [\text{Standard}]$$

Conversion factor :
Copper (µg/dl) x 0.1574 = Copper (µmol/l)

QUALITY CONTROL

Each laboratory should estabilish its own internal Quality control scheme and procedures fpr corrective action if controls do not recover within the acceptable tolerances.

BIBLIOGRAPHY

1. Pasquinelli F., Diagnostica e Tecniche di Laboratorio, (pag..: 1099-1102) Rossini Ed. (1984).
2. Akita Abe, Sumico yiamashita, Clin. Chem. 35(4): 197, 552-554 (1989).
3. Ciuti R., Galli A., Giorn. It. Chim. Clin. 12 (2): 91-100 (1987).
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SYMBOLS

Read use istruction

Manufactured by

Size/number of tests

In Vitro Diagnostic Medical Device

CE mark declaring compliance with the In Vitro Diagnostics Medical Device Directive, 98/79/EC

Catalogue number

Store at +15-25°C

Batch number

Store at +2-8°C

Vial content