# Copper

## Color Di Br-PAESA. Liquid Reagent

CE

In vitro diagnostic reagent for quantitative determination of copper in serum or plasma.
Store at 2-8 °C.

**REF: RCO-100**

### Summary:

The major functions of copper metalloproteins involve oxidation-reduction; most known copper containing enzymes bind and react directly with molecular oxygen. Specific diseases associated with copper include head disease, bone and joint osteoarthritis and osteoporosis and Menkes syndrome, Wilson's disease and others. Elevated levels of copper can also be toxic.

### Principle:

In a pH 4.7 buffer system, copper is released from its carrier protein, the ceruloplasmin, and forms with the specific complexant 3,5-DiBr-PAESA a stable coloured complex. The colour intensity of this complex is proportional to the amount of copper in the sample.

### Composition:

**R1**: Acetate buffer pH 5.0 - 0.2 mol/l,
3,5-DiBr-PAESA - N-ethyl-N-sulfopropylaniline - 0.02 mmol/l, Standard - 100 µg/dl (15.73 µmol/l)

### Reagent Stability And Storage:

The sealed reagent is stable up to the indicated expiry date if stored at 4°C.

### Samples:

Serum, Plasma

### Procedure:

1. Assay conditions:
Wavelength: . . . . . 580 nm
Cuvette: . . . . . .1 cm. light path
Temperature . . . . . .+ 37°C

| | Standard | Sample |
|---|---|---|
| R1 (µL) | 1000 | 1000 |
| Serum or Plasma (µL) | - | 50 |
| Standard (µL) | 50 | - |

2.Mix and incubate for 5 minutes at 37°C.
Measure the absorbance of the sample $A_{(S)}$ and of the standard $A_{(STD)}$ against the reagent blank $A_{(RBL)}$

$\Delta A_{(S)} = A_{(S)} - A_{(RBL)}$

$\Delta A_{(STD)} = A_{(STD)} - A_{(RBL)}$

### Calculations:

$$\frac{\Delta A \text{sample}}{\Delta A \text{standard}} \times 100 = \mu g/dl \text{ copper}$$

$$\frac{\Delta A \text{sample}}{\Delta A \text{standard}} \times 15.71 = \mu mol/l \text{ copper}$$

**Calibration Frequency:**
Two-point calibration is recommended:
- after reagent lot change
- as required following quality control procedures

### Quality control:

All clinical laboratories should establish an Internal Quality Control program. Check instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At pre-established intervals following the Q.C. Laboratory recommandations.

### Reference Values:

Male: 70-140 µg/dl (11.0 -22.0 µmol/l)
Female: 80 -155 µg/dl (12.6 -24.4 µmol/l)

### Performance characteristics:

**Measuring and reportable range:**

3 – 500 µg/dl. Samples with copper concentration higher than 500 µg/dl (78.65 µmol/l) must be diluted 1:10 with normal saline and result multiplied by 10.

**Linearity:**

Up to 500 µg/dl (78.65 µmol/l)

**Precision:**

| | Intra-assay | | | Inter-assay | | |
|---|---|---|---|---|---|---|
| | Mean (µg/dL) | SD | %CV | Mean (µg/dL) | SD | %CV |
| L1 | 72.60 | 1.66 | 2.28 | 101.7 | 2.78 | 2.73 |
| L2 | 121.20 | 1.19 | 0.98 | 111.9 | 3.06 | 2.73 |
| L3 | 170 | 1.52 | 0.89 | N/A | N/A | N/A |

**Method comparison:**

A comparison of the mti-diagnostics Copper LS (y) with a commercial obtainable assay (x) gave the following result:
$y = 1.003x + 1.9621$
$R^2 = 0.9977$

**Sensitivity (LOD)**:

0.3 µg/dl
The lower detection limit represents the lowest measurable copper concentration that can be distinguished from zero.

**Interferences:**

The test is not affected by the presence of conjugated and non-conjugated bilirubin up to 15 mg/dl, hemoglobin up to 0.5 g/dl and triglycerides up to 1000 mg/dl.

### Notes:

For in vitro diagnostic use.
Please follow the normal precautions required for handling all laboratory reagents.
Use disposable test tubes and glassware washed with hydrochloric acid 1N solution and distilled water.
Working solution must be limpid; do not use if turbid
R1 contains urea as additive. In the sample order setting, do not input urea test immediately after copper in "random access" automatic analyzers.
In addition to the possible risk indications regarding the reactive components such as preservatives (i.e. sodium azide or other) and detergents. The total concentration of these components is lower than the limits reported by the 67/548/EED and 88/379/EEC directives and following modifications and amendments about classification, labelling and packaging of dangerous preparations (reagents). However, it is recommended to handle reagents carefully, to avoid ingestion and contact with eyes, skin and mucous membranes and to use laboratory reagents according to good laboratory practice

### References:

1. L. Thomas: Labor und Diagnose, 2005, 6 Auflage.
2. Guder, W.; Zawta, B.: Die Qualität diagnostischer Proben, Empf. der Arbeitsgr. Präanalytik der DGKC und der DGLM 2002, 3. Aufl.
3. Abe A., Yamashita S., Noma A.: Clin. Chem., 35 (1989) 552-554.



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