COPPER (2-8°C)

(Di-Brom PAESA Method)

CATALOGUE NUMBER	KIT SIZE (ML)
MPRCU02	2x50ml / 1x5ml

Intended Use:
For *In Vitro* diagnostic use by trained professionals only.
Copper reagent is intended for the quantitative estimation of copper in serum and plasma.

Clinical Significance:
The major function of copper metalloproteins involve oxidation-reduction: most known copper containing enzymes bind and react directly with molecular oxygen. In plasma approximately 95% of copper is bound to the alpha-2-globulin, ceruloplasmin an oxidase with ferroxidase activity. There is evidence that marginal copper deficiency is associated with heart disease, bone and joint osteoarthritis and osteoporosis. Also, decreased antioxidant protection is a result of decreased level of copper.

Test Principle:
At a pH of 4.7 copper is released from its carrier protein, ceruloplasmin, and chelates with 4-3,5 Di Br PAESA to form a stable coloured complex. The colour intensity of this complex is proportional to the amount of copper in the sample and can be measured spectrophotometrically.

Reagent Composition:

REAGENT	COMPONENT	CONCENTRATION
Copper Colour Reagent R1	Acetate Buffer pH 5.0	0.2 mol/l
	4-(3,5 dibromo-2-pyridylazo)-N-ethyl-N-sulphopropylaniline	0.02 mmol/l
Copper Standard	Copper	100 µg/dl (15.73 µmol/l)

Reagent Preparation and Stability:
R1: Liquid, ready to use.
Standard: Liquid, ready to use.
R1 and R2 are stable to the expiry date stated when stored unopened at 2 - 8°C.
Exercise the normal precautions associated with the handling of laboratory reagents and dispose of carefully according to local guidelines.

Sample Collection, Preparation and Stability:
Collect serum and plasma by standard venepuncture technique.

Assay Procedure:

WAVELENGTH	580 nm
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Reagent Blank

	Blank	Standard	Sample
Sample	-	-	50 µl
Standard	-	50 µl	-
Copper Colour Reagent	1000 µl	1000 µl	1000 µl
Mix and incubate 5 minutes at assay temperature. Read absorbance of Sample/Standard against the Reagent Blank.			

Calculation:
Copper Concentration (µg/dl) = $\frac{\Delta Abs\ Sample}{\Delta Abs\ Standard}$ x Concentration of Standard

Performance Characteristics:
Measuring range:
3.0 µg/dl – 500 µg/dl (0.471 µmol/l – 78.65 µmol/l)
Dilute samples with concentration higher than 500 µg/dl using Normal saline 1/10 and rerun the assay. Multiply the result by the dilution factor (for 1+9 dilution, the dilution factor is 10).

Analytical Sensitivity: (Lowest detection limit):
Analytical sensitivity = 0.3 µg/dl. The lower detection limit represents the lowest measurable copper concentration that can be distinguished from zero.

Intra-Assay Precision:

Sample	Mean (µg/dl)	SD (µg/dl)	CV %
Pool 1	72.60	1.66	2.28
Pool 2	121.20	1.19	0.98
Pool 3	170.0	1.52	0.89

Inter-Assay Precision:

Sample	Mean (µg/dl)	SD (µg/dl)	CV %
Pool 1	101.7	2.78	2.73
Pool 2	111.9	3.06	2.73

Method Comparison:
A comparison of the Prestige Diagnostics Copper (y) with a commercial assay (x) gave the following result:
y = 1.0003x + 1.962, r = 0.997

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

Reference Range:

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

Each laboratory should establish its own mean reference range according to the population.

Application for Automated systems:
For applications on automated systems – contact the technical department.

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

Quality Control and Calibration Material:
It is recommended that a laboratory uses reference control sera to verify the reagent performance. Results obtained should fall within the specified ranges.
Prestige recommend the following calibrator and controls
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

Notes:
- Use disposable test tubes and glassware washed with hydrochloric acid 1N solution and distilled water.
- R1 contains urea as additive. In the sample order setting, do not input urea test immediately after copper in 'random access' automatic analysers.
- Handle reagents carefully. Do not ingest and avoid contact with eyes, skin and mucous membranes and to use laboratory reagents according to good laboratory practice.
- The result from this test should not be used as the sole criteria for diagnosis, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

References:

1. Abe A., Yamashita S, Noma A: Clin Chem., 35 (1989) 552-554.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

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