QUANTON BIOLIFE SCIENCES

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Copper Test Kit
Colorimetric

QBL/PDS/Cu_011

Quantitative determination of Copper in human Serum / Plasma / other body fluids. Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Pack Size
COPMONO 25	25 X 1 ml
COPMONO 50	50 X 1 ml
COP 100	1X100 ml
COP 1000	1X1000 ml
COP 5000	1X5000 ml
COP 10000	1X10000 ml

CLINICAL SIGNIFICANCE
The assay kit is for determination of Copper (Cu). As one of the most important trace elements, Copper (Cu) is a part of many metal enzymes and participate in synthesizing melanin, collagen. The decrease of copper may cause hypogenesis, anaemia of sex of cellule low pigment. The acute toxicity of copper can cause acute renal failure and gastro-enteritis.

Method
Colorimetric

PRINCIPLE
$CER\text{-}Cu^{2+} \xrightarrow{\text{Acidic conditions}} CER + Cu^{2+}$

$Albumin\text{-}Cu^{2+} \xrightarrow{\text{Acidic conditions}} Albumin + Cu^{2+}$

$Cu^{2+} + VC\ (reduced) \longrightarrow Cu^{+} + VC\ (oxidized)$

$Cu^{+} + 3,5\text{-DiBr-PAESA} \longrightarrow Complex\ (blue)$

REAGENT
Reagent 1 : Copper Reagent
Copper Standard : 100 µg/dl

REAGENT PREPARATION
The Reagent is ready to use.

REAGENT STORAGE AND STABILITY
Reagent is stable till expiry when stored at 2-8°C
Store protected from light.

WARNING AND PRECAUTIONS
- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT
Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED
- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION
Serum samples are stable for a week at 2-8°C
Freeze only once! Discard contaminated specimens!

ASSAY PROCEDURE
Operating Instructions
- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	578 nm
Reaction Type	End Point
Cuvette	1 cm light path
Reaction Temperature	37°C
Reaction Type	Increasing
Measurement	Against Reagent Blank
Sample Volume	50µl
Reagent Volume	1000µl
Incubation	10 minutes
Blank Absorbance Limit	< 0.500
Low Normal	80 µg/dl
High Normal	170 µg/dl
Linearity	500 µg/dl

MANUAL ASSAY PROCEDURE
Pipette into Test Tubes

	BLANK	STD	SAMPLE
Sample	-	-	50µl
Standard	-	50µl	-
Reagent	1000µl	1000µl	1000µl

Mix & Incubate for 10 min. at 37°C Measure absorbance of Sample (AT) and Standard (AS) against Reagent Blank at 546 nm.

SAMPLE DILUTIONS
- This method is linear upto a concentration of 500 µg/dl
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION
Results are calculated, usually automatically by the instrument, as follows:

Copper (µg/dl) = AT/AS x Conc. of Standard

CLIBRATORS AND CONTROLS
For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of the **Copper Standard** have been made traceable to the reference method Atomic Absorption Spectrometry (AAS).

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS
WITHIN RUN

Sample	Mean Concentration	SD	CV %
Randox 2	99.74	0.32	0.33%
Randox 3	161.52	0.58	0.36%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Randox 2	99.55	0.57	0.57%
Randox 3	161.13	0.44	0.27%

LINEARITY
The method is linear upto a concentration 400 µg/dl. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Copper is 0.1 µg/dl.

METHOD COMPARISON
A comparison of Copper with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.991$

REFERENCE VALUES
Female: 12.6-24.4 µmol/L (63.5-150 µg/dl)
Male: 10.0-24.0 µmol/L (80-155 µg/dl)
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geograph-ical location of the popula
The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE
- Hemoglobin: No interference found upto 100 mg/dL.
- Bilirubin: No interference found upto 100 mg /dL.
- Lipemia: No interference found upto 40 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY
1. Abc,S.Yamashita, A. Noma, Sensitive, direct colorimetric assay for copper in serum, Clin Chem, 35,552-554(1989)
2. Katarzyna Zawistowska. Copper chelate with 2- pyridylazo ligands as test probes for characterization of micellar effects. COLLOIDS AND SURFACES, 2008, 315: 259-26

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2,
Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

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