

BioMed-Copper



Colorimetric, Endpoint

REF: CU127100 (2x50)

INTENDED FOR USE:

For the quantitative determination of copper in serum ..

PRINCIPLE

The copper in presence of a buffer at acid-PH , is released from ceruplasmin and albumin .
The copper so obtained react with 5-Br-PADAP to produce a stable coloured complex which colour intensity is directly proportional to the amount of copper in the sample .

SPECIMEN :

Non haemolyzed sera .
Copper in serum is stable at least 3 days in refrigerant (+2-8°C) .
Remove serum from clot as soon as possible.
Shake and bring the sample at room temperature (+15-25°C) before using .

REAGENTS COMPOSITION:

Reagent(A) Cu Liquid Vol. = 2 x 50 mL	Buffer complexants 5-Br-PADAP	200 mmol/L < 0.1% < 0.1%
Decolourant (B) Liquid-Vol. = 1 x 10 mL	EDTA	10 mmol/L
Standard © Cu Liquid- Vol. = 10mL	Copper	200 µg/dL 35µmol/L

PACKAGE : Collection and Storage .

Store at +2-8°C..
Stable until the expiration date reported upon the package.
After the unsealing and the taking of the reagent , it is advised to close up the bottle immediately in order to avoid evaporation , direct light exposure and bacteric contamination .

PRECAUTION & WARNINGS :

Avoid pipetting by mouth .
The preparation , according to current regulation . is classified as not dangerous.
The total concentration of non active components (preservatives , detergents ,stabilizers) is below the minimum required for citation .
Anyway handle with care , avoid ingestion , avoid contact with eyes , skin and mucous membranes
The samples must be handle as potentially infected from HIV or Hepatitis .

REAGENT PREPARATION & STABILITY

Ready to use liquid reagents , stable until the date reported on the label .
The reagent is limp and yellow/orange .

REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and instrumentations .

PROCEDURE :

Wavelength : 595 nm
Optical path : 1 cm light path
Temperature : + 25/30/37°C
Reading : Against blank reagent
Assay type : End Point

Pipetting in tubes :

	BLANK	STANDARD	SAMPLE
Reagent (A)	1000 µL	1000 µL	1000 µL
Distilled Water	100 µL		
Standard		100 µL	
Sample			100 µL

MIX, incubate for 10 min at room temperature (+15-25°C) ; read sample and standard extinction against blank reagent .

Colour is stable at least 15 min at room temperature ;
Volumes can be proportionality modified .

This methodology describes the manual procedure to use the kit .
For automated procedure, ask for specific application .

CALCULATION:

$$\text{copper : } \mu\text{g/dL} = \frac{(\text{E}) \text{ Sample}}{(\text{E}) \text{ Standard}} \times 200 (\text{ standard value })$$

standard concentration 200 µg/dL (31.48 µmol/L)

to convert µg/dL in µmol/L multiply by 0.1574

EXPECTED VALUES :

Men	70-145 µg/dL	11-22.8 µmol/L
Women	80-155 µg/dL	12.6-24.4 µmol/L

the above mentioned values are to be considered as a reference.
It is strongly recommended that each laboratory establish its own normal range according to its geographic area , according to IFCC protocol .

WASTE DISPOSAL :

The disposal of the product must be in accordance with local regulation concerning waste disposal .

QUALITY CONTROL :

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

For this purpose the use of test serum REF , 6000(Normal ambit) and REF , 6001(Pathologic ambit) is advised .

PERFORMANCE :

MEASURE INTERVAL INEARTY :	5-800 µg/dL
DETECTION LIMIT (2DS)	5 µg/dL

INTRA-ASSAY PRECISION : n=20

LOW LEVEL	M = 60.50	C.V = 2.9%
MEDIUM LEVEL	M = 115.34	C>V = 2.5%
HIGH LEVEL	M = 176.46 U/L	C.V = 1.8%

INTER-ASSAY PRECISION : n=20

LOW LEVEL	M = 60.82	C.V = 2.9%
MEDIUM LEVEL	M = 116.22	C.V = 2.5%
HIGH LEVEL	M = 175.39	C.V = 1.8%
CORELATION	r = 0.97	n=10
LIN. REGRESSION	y = 0.983 x + 3.4	n = 10

INTERFERENCE:

Interferences are negligible up to :			
Hemoglobin	500 mg/dL	Zinc	1000 µg/dL
Triglycerides	500 mg/dL	iron	1000 µg/dL
Bilirubin	10 mg/dL	cobalt	500 µg/dL

METHOD LIMITATIONS:

The test is impossible on urine samples .

In case of itteric sera , a blank sample is advised , Put in the sample and in the blank reagent 50 µl of decolourant , wait 2', read and subtract.

For concentration higher than 800 µg/dL repeat the measure on a sample diluted 1:2 with saline solution and multiply the result by 2 .










Readings but advised wavelenghts are impossible .

For through evaluation of the interfering substances ,consult : Young , D. S ,et al , Clin , Chem , 21:1D (1975) .

REFERENCES :

1) T , Makino , M , Kiyonaga, Clin , Chim, Acta , 171,19 (1988) .

2) Stookey L ; Anal Chem , 42: 779 , (1970) .

	Consult Instructions for Use
	Caution, Consult accompanying
	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue Number
	Batch Code
	Use by

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