DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
Hondastrasse, Objekt M55, IZ NOE-Sued, 2351 Wiener Neudorf, Austria,
Phone: +43 (0) 2236 660910-0, Fax: +43 (0) 2236 660910-30, e-mail: office@dialab.at

Liquid reagent – ready to use

Copper

3,5-DiBr-PAESA

Single Reagent

Diagnostic reagent for quantitative in vitro determination of copper in human serum or plasma on photometric systems

REF	Kit Size	Configuration
507101B	**1 x 1 L**	Single Reagent
507140	**5 x 25 mL**	Single Reagent
545911	**5 x 50 mL**	Single Reagent
50447917	**5 x 50 mL**	Single Reagent
5A0821	**5 x 20 mL**	Single Reagent
5T1021	**5 x 20 mL**	Single Reagent
5K0720	**5 x 50 mL**	Single Reagent
5E1821	**5 x 20 mL**	Single Reagent

Additionally offered:

507163SV	1 x 3 mL	Copper Standard	
D98481	12 x 5 mL	Control normal	Diacon N
D14481	5 x 5 mL	Control normal	Diacon N
D98481SV	1 x 5 mL	Control normal	Diacon N
D98482	12 x 5 mL	Control abnormal	Diacon P
D14482	5 x 5 mL	Control abnormal	Diacon P
D98482SV	1 x 5 mL	Control abnormal	Diacon P

TEST PARAMETERS

Method:	Colorimetric, Endpoint, Increasing Reaction, Dibromo-PAESA
Wavelength:	580 nm
Temperature:	37°C
Sample:	Serum, heparin plasma
Linearity:	up to 500 µg/dL (78.65 µmol/L)
Sensitivity:	Lower limit of detection: 3 µg/dL

SUMMARY [1]

Copper contained in food is absorbed within the duodenum, followed by transport to the liver bound to albumin, and for the most art is excreted fecally via the bile. A small portion is bound to apoceruloplasmin in the liver reaching the tissues via the blood stream. 90% of serum copper is present in the form of ceruloplasmin.
Copper is an integral component of at least 16 essential metalloproteins exerts its effects within the body predominantly on connective tissue formation, central nervous system function, and hematopoiesis.
There are two forms of hereditary copper metabolic diseases, e.e. Wilson's disease and Menkes' kinky hair syndrome.
A decrease in serum copper may result from renal losses in ceruloplasmin and from excessive iron or zinc in the food due to absorption-related competition.
Elevated serum copper is normally found during the last trimester of pregnancy and also in estrogen and oral contraceptive intake. Serum copper elevations are usually observed in acute and chronic infections, in various tumors, especially also in cases of liver damage associated with impaired biliary flow, in liver cell cancer , and in conjunction with exocrine pancreatic insufficiency.

TEST PRINCIPLE

At pH 4.7, copper is released from the carrier protein and forms a chelate complex with 4-(3,5-Dibromo-2-pyridylazo)-N-ethyl-N-sulfopropylaniline. The increase of absorbance of this complex is proportional to the concentration of total copper in the sample.

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
Acetate Buffer, pH 5.0	0.22 mol/L
4-(3,5-dibromo-2-pyridylazo)- N-ethyl-N-sulfopropylaniline	0.02 mmol/L

REAGENT PREPARATION

The reagent is ready to use.

REAGENT STABILITY AND STORAGE

Conditions:	protect from light close immediately after use
Storage:	at +2 to +22 °C
Stability:	up to the expiration date

Avoid contamination. Do not use reagent if turbid.

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution 9 g/L
General laboratory equipment

STANDARD

(has to be ordered separately)

Concentration	100 µg/dL (15.73 µmol/L)
Storage:	at 2 – 22 °C
Stability:	up to the expiration date

Avoid contamination! Close immediately after use!

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Standard	Sample
Reagent	1000 µL	1000 µL	1000 µL
Sample	-	-	50 µL
Standard	-	50 µL	-
dist. water	50 µL	-	-
Mix and incubate for 5 minutes at 37 °C. Measure absorbance of the standard and the sample at 580 nm against the reagent blank.			

CALCULATION

$$\text{Copper [µg/dL]} = \frac{\Delta A \text{ sample}}{\Delta A \text{ standard}} \times \text{conc. Standard [µg/dL]}$$

UNIT CONVERSION

µg/dL x 0.157 = µmol/L

REFERENCE RANGES *

Serum/Plasma:		µg/dL	µmol/L
< 4 months		8.9 – 46	1.4 – 7.2
4 – 6 months		25 – 108	4 – 17
6 months – 13 years		51 – 121	8 – 19
14 – 19 years	female	70 – 159	11 – 25
	male	64 – 114	10 – 18
Adults:	female	76 – 152	12 – 24
	male	70 - 140	11 - 22

* Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

LINEARITY, MEASURING RANGE

Measurable range: 3 – 500 µg/dL (0.472 – 78.65 µmol/L).
At higher concentrations dilute sample 1 + 9 with saline (9 g/L NaCl) and multiply the result by 10.

PRECISION

Intra-assay n = 10	Mean [µg/dL]	SD [µg/dL]	CV [%]
Sample 1	72.6	2.41	3.32
Sample 2	121	2.98	2.46
Sample 3	170	1.97	1.16

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Inter-assay n = 15	Mean [µg/dL]	SD [µg/dL]	CV [%]
Sample 1	72.6	0.96	1.32
Sample 2	121	1.06	0.87
Sample 3	170	1.76	1.04

SPECIFICITY/INTERFERENCES

no interference up to:

Bilirubin	15 mg/dL
Hemoglobin	500 mg/dL
Triglycerides	1000 mg/dL

METHOD COMPARISON

A comparison between Dialab Copper (y) and a commercially available test (x) gave the following result:
$y = 1.030 x + 0.0042$; $r = 0.991$.

CALIBRATION

The assay requires the use of a copper standard or calibrator.
We recommend the Dialab **Copper Standard**.
The standard value is traceable to ICP-SFMS.

QUALITY CONTROL

All control sera with Copper values determined by this method can be used.
We recommend the Dialab serum controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the abnormal range).

AUTOMATION

Special applications for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Please refer to the safety data sheet and take the necessary precautions for the use of laboratory reagents.
3. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
4. For professional use only!

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 337-8.
2. Abe A., Yamashita S., Noma A. Sensitive, direct colorimetric assay for copper in serum. Clin. Chem. 35 (4) 552-554 (1989)