COPPER

Diagnostic reagent for determination of Copper concentration.

Liquid. Dual Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
CU200 TCU20 NCU20	5 x 25 mL 1842 Tests 267 Tests	SCU20 BYC200	1477 Tests 4091 Tests	KCU20 MCU20	3636 Tests 1675 Tests	LCU20 DMC20	2000 Tests 540 Tests

INTENDED USE

The test is applied for the quantitative determination of Copper concentration in serum and plasma.

TEST PRINCIPLE

3,5-Di-Br-PAESA combines with Cu(II) to form a blue-violet complex, the absorbance of which is measured at 580 nm.

The reaction has high specificity and interference with other cations (that should be avoided), due to their specific pH and environment which they constituted.

TEST PARAMETERS

Method : Colorimetric, Endpoint
Wavelength : 570nm (580-600 nm)
Temperature : 37°C
Sample : Serum, plasma
Linearity : 6 µg/dL - 500 µg/dL.

REAGENT COMPOSITION

Reagent 1: 2 x 25 ml (liquid)

Composition	Final Concentration
Acetate buffer Surfactants Preservatives.	≤ 120 mM pH 4.90,

Reagent 2: 2 x 25 ml (liquid)

Composition	Final Concentration
3,5 Di-Br-PAESA	≤ 12 mM.

REAGENT PREPARATION

Sample Start:
Mix 1 parts of Reagent 1 (Buffer) with 1 part of Reagent 2 (Starter). For example: 1ml Reagent 1 and 1ml Reagent 2. Avoid foaming.
Stability of working reagent: 30 days at 2-8°C, away from light sources.

Working reagents are stable at 2-8ºC in case of closed vials and avoiding contamination after preparation.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

Once opened vials are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum (preferred) and plasma heparinate are collected by standard procedures.
Copper is stable for 7 days at 2-8ºC and 1 month at -20°C.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

Copper µg/dL = Ax/As x 200 (standard value)

Unit Conversion

µg/dL = 0.157 µmol/dL

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Men	: 70 - 140 µg/dL (11.0 - 22.0 µmol/L)
Women	: 80 - 155 µg/dL (12.6 - 24.4 µmol/L)
Pregnant women	: 118 - 302 µg/dL (18.5 - 47.4 µmol/L)
Children 6-12 y	: 80 - 190 µg/dL (12.6 - 29.9 µmol/L)
Infants	: 20 - 70 µg/dL (3.1 - 11.0 µmol/L)

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

All control sera with Copper values determined by this method can be used. We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The use of a Copper Calibrator (for automated Systems) is optional. We recommend
ARCAL Calibrator ("Arcal Auto")
Cat. No. A39050

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 7 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 6 µg/dL.

High Linearity: The method is linear up to 500 µg/dL.

If the limit value is exceeded, it is suggested to dilute sample 1+9 with distilled water and to repeat the test and multiplying the result by 10.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (Intra-assay)

Mean conc.	SD	CV	n
120.00 µg/dL	3.06	2.50%	10
268.50 µg/dL	3.14	1.20%	10

Reproducibility (run to run) (Inter-assay)

Mean conc.	SD	CV	n
120.99 µg/dL	3.36	2.80%	20
265.19 µg/dL	5.73	2.22%	20

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 5 µg/dL.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Interferences: No interference was observed by the presence of:

Hemoglobin	≤ 120 mg/dL
Bilirubin	≤ 50 mg/dL
Lipids interfere	

Methods comparison: A comparison between Archem and a commercially available product gave the following results:

Copper Archem = x
Copper competitor = y
n = 82
y = 1.046x - 6.67 µg/dL r = 0.984

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.

S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

1. Young DS. Effects of Drugs on Clinical Laboratory Tests. 3rd ed. Washington: AACC Press (1990).
2. Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).
3. Clin.Chem. 35/4, 552-554 (1989)
4. Clinical and Laboratory Standards Institute (formerly NCCLS). Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document EP05-A2.
5. K.Ueno, T.Imamura, K.L.Cheng - Handbook of organic analytical reagents - CRC Press (1992).
6. International Federation of Clinical Chemistry, Committee on Reference Systems for Enzymes, Chem Clin Lab Med 2002; 40 (7):718–724.

SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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