COPPER
Multi-Purpose
Liquid Reagent

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
GL533CU	2 x 60 ml	COPPER	15-25°C
	1 x 10 ml	COPPER - Standard	
GL543CU	6 x 60 ml	COPPER	15-25°C
	1 x 10 ml	COPPER - Standard	

INTENDED USE:

In Vitro Diagnostic reagent pack for the determination of Copper in serum and plasma on automated and semi-automated analysers.

PRINCIPLE OF THE TEST: [1]

Copper forms with 4-(3, 5-dibromo-2pyridylazo)-N-ethyl-N-sulfopropylanine a chelate complex. The increase of absorbance of this complex can be measured and is proportional to the concentration of total copper in the sample.

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read and follow instructions for use. Deviations from the described procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Light pink liquid.
Important Note: If stored at 2-8°C precipitation may occur. In this case, store the reagent at 15-25ºC for about 2 hours and mix until reagent is clear.
Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damaged to the bottle and/or cap, resulting in product leakage and/or contamination: do not use the reagent pack and contact your distributor.

Safety Precautions:
CAUTION: Take all necessary precautions required when handling laboratory reagents. Material Safety Data Sheet is available upon request.

Handling precautions:
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration in Tests*
Reagent 1	Acetate Buffer pH 5.0	0.2 mol/l
	4-(-3,5-dibromo-2-pyridylazo) -N-ethyl-N-sulfoprpylaniline	0.02 mmol/l
Standard	Copper	200 µg/dl (31.46 µmol/l)

REAGENT PREPARATION AND STABILITY:

Reagent 1 and standard are ready to use.
Before use, mix reagent by gently inverting each bottle.
If stored and handled properly, components are stable until expiry date stated on label.

INSTRUMENTS:

Instruments application procedures are available upon request.

TYPE OF SPECIMEN: [2]

Use serum or heparin plasma as specimen.

It is recommended to follow NCCLS procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sampling container, with proper specimen identification. Serum/plasma should be separated from cells within 2 hours after collection.
Stability: up to 48 hours at 2-8°C.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
General Chemistry Calibrator	GL983	General Laboratory Equipment	N/A
General Chemistry Control Level 1	GL922	Photometer	N/A
General Chemistry Control Level 2	GL932	Saline solution 0.9 g/l NaCl	N/A

Assay procedure:
Wavelength: 580 nm
Temperature: 37°C
Optical path: 1 cm light path

	Blank	**Calibrator**	**Sample**
Reagent 1	1 ml	1 ml	1 ml
Sample	----	----	50 µl
Calibrator	----	50 µl	----
Gently mix and Incubate at 37°C for 5 minutes. Read Optical Density (OD).			

Calibration:
Using recommended calibrator or standard provided, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Control results are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At some intervals chosen by the laboratory.

CALCULATION:

$$\text{Concentration of Copper} = \frac{OD_{Sample}}{OD_{Calibrator}} \times \text{Concentration of Calibrator}$$

(Conversion factor: µg/dl x 0.157 = µmol/l)

EXPECTED VALUES: [1]

In serum	Adult Man	70 – 140 µg/dl
	Adult Women	80 – 155 µg/dl

Each laboratory should establish its own reference range. Copper results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance evaluation can vary with the instrument used. Data obtained in each individual laboratory may differ from results obtained in-house.

Linearity:
This assay is linear up to 500 µg/dl.
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

BIBLIOGRAPHY:

1. Abe A., Yamashita S., Noma A., Clin Chem., 552-554, 35 (1989)
2. C. A. Burtis, E.R. Ashwood. Tietz Fund. Of Clin. Chem. 5th ed. 30:54 and 973

SYMBOLS:

The following symbols are used in the labelling of Glenbio systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
BUF	Buffer	SUBS	Substrate
CAL	Calibrator	STD	Aqueous Standard
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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