SBio COPPER KIT

(Colorimetric Method)

(For invitro diagnostic use only)

REF	90400025
Pack Size	25 ml

CE

8C 2C Store at 2-8°C	Manufacturer	IVD *In vitro* Diagnostic Medical Device	L1 Buffer Reagent	Colorimetric Colorimetric Method
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number	L2 Colour Reagent	
Date of Manufacture	REF Catalogue Number	EC REP Authorised Representative in the European Community	S Copper Standard (200 µg/dl)	This way up

INTENDED USE

Copper Kit is used for the determination of Copper in serum.

PRINCIPLE OF THE TEST

Copper, released from ceruloplasmin in an acidic medium, reacts with Di-Br-PAESA to form a coloured complex. Intensity of the complex formed is directly proportional to the amount of Copper present in the sample.

Copper + Di-Br-PAESA —(Acidic / Medium)→ **Coloured complex**

CLINICAL SIGNIFICANCE

Copper is widely distributed in the various organs of the body. The highest concentration is found in the liver followed by the brain and kidneys. It plays an important part in the iron metabolism by converting the ferrous ions to a ferric state. Over 90% of the copper in plasma are bound to the protein ceruloplasmin.

Increased levels are found in chronic / malignant diseases e.g. leukemia, cirrhosis, various infections and in patients on oral contraceptives and estrogens. Decreased levels are found in Wilson's disease, decreased synthesis of ceruloplasmin, malabsorption, malnutrition, and nephrotic syndrome.

PRESENTATION

	25 ml
L1 : Buffer Reagent	12.5 ml
L2 : Colour Reagent	12.5 ml
S : Copper Standard (200 µg/dl)	2 ml

COMPOSITION

Acetate Buffer 50 mM pH 4.9; Di-Br-PAESA; Reducing Agents and Preservatives.

STORAGE / STABILITY

Contents are stable at 2-8°C till the expiry mentioned on the labels.

SAMPLE REQUIRED

Serum, free from hemolysis. Copper is reported to be stable in the sample for 6 days when stored at 2-8°C.

REAGENT PREPARATION

Reagents are ready to use. Protect from bright light.

The cold Buffer (L1) when retrieved from 2-8° C may have a particulate suspension.

The suspension clears up once the buffer attains a temperature over 25°C.

Working reagent: For larger assay series a working reagent may be prepared by mixing equal volumes of L1 (Buffer Reagent) and L2 (Colour Reagent).

The Working reagent is stable at 2-8°C for at least 3 weeks. Keep tightly closed.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

This product requires the handling of human specimens. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimens, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength / filter : 580 nm (Hg 578 nm) / Yellow

Temperature : R.T.

Light path : 1 cm

MATERIALS REQUIRED BUT NOT PROVIDED

Photometer with appropriate filter, Control material, Type II water, Saline (0.85 - 0.90 %) if desired for specimen dilution.

Pipette into clean dry test tubes labelled as Blank (B), Standard (S), and Test (T):

Addition Sequence	B (ml)	S (ml)	T (ml)
Buffer Reagent (L1)	0.5	0.5	0.5
Colour Reagent (L2)	0.5	0.5	0.5
Distilled Water	0.05	-	-
Copper Standard (S)	-	0.05	-
Sample	-	-	0.05

Mix well and incubate at R.T. (25° C) for 10 mins. Measure the absorbance of the Standard (Abs.S), and Test Sample (Abs.T) against the Blank, within 30 mins.

CALCULATIONS

$$\text{Copper in µg/dl} = \frac{\text{Abs.T}}{\text{Abs.S}} \times 200$$

QUALITY CONTROL

The following process is recommended for QC during the assay of Copper. *Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:

This procedure is linear upto 500 µg/dl. If the value exceeds this limit, dilute the serum with normal saline (NaCl 0.9%) and repeat the assay. Calculate the value using the proper dilution factor.

Limit of detection:

The limit of detection for Copper is 5 µg/dl.

Interferences:

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

Precision:

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	177.17	2.05	184.48	1.23	361.65	3.28
Control 2	100.34	4.68	100.34	4.68	200.68	9.36

Method comparison:

Comparative studies were done to compare our reagent with another commercial Copper Assay. No significant differences were observed. Details of the comparative studies are available on request.

REFERENCE RANGE

Serum (Males) : 80 - 140 µg/dl

(Females) : 80 - 155 µg/dl

(Newborns) : 12 - 67 µg/dl

(Childrens upto 10 yrs) : 30 - 150 µg/dl

It is recommended that each laboratory establish its own normal range representing its patient population.

NOTE

In vitro diagnostic reagent for laboratory and professional use only Not for medicinal use. The reagent contain sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water. Only clean and dry glassware must be used. Chelating agents such as EDTA, Oxalate and Citrate, present even in traces, prevent the formation of the colour complex, hence necessary care should be taken during the assay.

Highly lipemic samples could interfere and should be cleared by centrifugation or filtration before use.

The assay can be run at 600 nm however the absorbances would be approx. 30% lower as compared to 570 nm.

The reagent may be used in several automated analyzers. Instructions are available on request. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

1. Akita Abe, Yiamashita, S., (1989) Clin. Chem. 35/4: 552-554.

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EC REP

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