Copper Assay Kit (Cu)

Method: PAESA Chromogenic Agent

Cat .No.	Size	Instrument
GB9450E	R1: 1×60 ml R2: 1×20 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS9451E	R1: 1×60 ml R2: 1×20 ml	For Hitachi 917 & OlympusAU640/400/600

INTENDED USE

For the *in vitro* quantitative determination of Copper in serum.

CLINICAL SIGNIFICANCE

The assay kit is for determination of Copper (Cu). As one of the most important trace elements, Copper(Cu) is a part of many metal enzymes and participate in synthesizing melanin, collagen.

The decrease of copper may cause hypogenesis, anaemia of sex of cellule low pigment. The acute toxicity of copper can cause acute renal failure and gastro-enteritis.

ASSAY PRINCIPLE[1,2]

$CER\text{-}Cu^{2+} \xrightarrow{\text{Acidic conditions}} CER+Cu^{2+}$

$Albumin\text{-}Cu^{2+} \xrightarrow{\text{Acidic conditions}} Albumin+Cu^{2+}$

$Cu^{2+}+VC(reduced) \longrightarrow Cu^{+}+VC(oxidized)$

$Cu^{+}+3,5\text{-}DiBr\text{-}PAESA \longrightarrow Complex\ (blue)$

Calculate the copper concectration by the adsorbance at 600 nm.

SAMPLE COLLECTION AND PREPARATION

Serum samples.

Serum samples are stable for a week at 2-8°C,

REAGENT COMPOSITON

Contents	Concentration of Solutions
Reagent 1 (R1) Buffer	
Vc(reduced)	
Reagent 2 (R2)	
3.5-Di-Br-PAESA	0.1mmol/L

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.

Stable up to the expiry date when stored at 2-8°C.

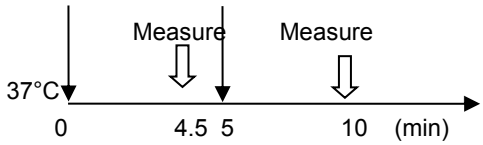
The Cu assay kit reagents are stable for 30 days on board.

ASSAY PROCEDURE

Wave Length (main/sub): 600 nm/700 nm

Sample: 10 µl

R1: 150 µl R2: 50 µl



1. Mix 10 µl sample with 150 µl R1 and incubate at 37℃ for 5 minutes, then read initial absorbance A_1 .
2. Add 50 µl R2 into cuvette, mix and incubate for 5 minutes at 37℃, Read final absorbance A_2 .
3. Calculate the absorbance change $\Delta A=A_2-A_1$.

CALCULATION

$$\text{Concentration}=\frac{\Delta A_{sample}/min}{\Delta A_{calibrator}/min}\times \text{Calibrator value}$$

CALIBRATION

Recommend that this assay should be calibrated using Randox complex Calibrator or Gcell Cu Calibrator.

QUALITY CONTROL

For quality control, use Randox complex Control as daily quality control sera and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.
4. Check the quality of the water used for reagents reconstitution.

REFERENCE VALUE

Female: 12.6-24.4 µmol/L (63.5-150 µg/dl)

Male: 10.0-24.0 µmol/L (80-155 µg/dl)

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geograph-ical location of the population.

UNIT CONVERSION

µg/dl × 0.1574=µmol/L

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 100 µmol/L. Samples above this concentration should be diluted 1+1 with 0.9% NaCl and reassay. Multiply the result by 2.

PRECISION

The CV of the test should be less than 10%

Intra assay precision		
N=20	Level1	Level 2
Mean (µmol/L)	17.18	28.87
SD	0.25	0.33
CV	1.48%	1.14%
Inter assay precision		
N=5	Level1	Level 2
Mean (µmol/L)	17.84	29.70
SD	0.43	0.40
CV	2.42%	1.36%

SENSITIVITY

The minimum detecctable concentration of Cu^{2+} with an acceptable level of precision was determined as 1.97 µmol/L.

INTERFERENCE

A Reagent blank may be performed by replacing sample or standard with double deionized water. The following

Beijing Strong Biotechnologies, Inc.
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analyze were tested up to the levels indicated and found not to interfere:

Hemoglobin:	100 mg/dl
Intralipid:	500 mg/dl
Bilirubin:	100 mg/dl
Uric Acid:	250 mg/dl
D-penicillamine :	250 mg/dl
Sodium heparin :	200 mg/dl

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
Y=1.0513X+0.2096, and a correlation coefficient of 0.9159, 48 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. Solution contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Abc,S.Yamashita, A. Noma, Sensitive, direct colorimetric assay for copper in serum, Clin Chem, 35,552-554(1989)
2. Katarzyna Zawistowska. Copper chelate with 2-pyridylazo ligands as test probes for characterization of micellar effects. COLLOIDS AND SURFACES, 2008, 315: 259-267

INDEX OF SYMBOLS

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
	Authorized Representative in the European Company

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