Bialex®

71341	R1:2x48ml + R2:2x16 ml
Test for in vitro diagnostic of Copper by Colorimetric Method	

Copper(Cu) Test Kit (Colorimetric)

PRICIPLE OF THE METHOD

This reagent is intended for the in vitro quantitative determination of Copper(Cu) in human serum. Copper is a trace element widely distributed in the body. Serum Cu exists in two types (ceruloplasmin copper – copper and albumin –Cu $^{2+}$ form). Copper is an important role in cells, respiratory, nervous and endocrine function. The concentration of copper in the blood can be used to diagnose Wilson's disease, Menkes síndrome, bone disease, liver and gallbladder diseases.

METHODOLOGY

In acidic condition, the copper is dissociates out of the blue protein and albumin copper, ascorbic acid (reduced) will make the dissociated out copper ion (II) rever tinto copper ion(I), the copper ion(I) and chromogenic agent 3,5 – DiBr – PAESA generated into blue complex, by measuring the absorbance of blue copper complex can calculate the concentration of copper.

acidic condition

ceruloplasmin-Cu2+ ⟶ ceruplasmin +Cu2+

acidic condition

albumin-Cu2+ ⟶ albumin+Cu2+

Cu2+ + ascorbic acid (reduced) ⟶ Cu+ +ascorbic acid (Oxidation)

Cu++3,5-DiBr-PAESA ⟶ blue copper complex

STABILITY AND STORAGE

Unopened, avoid light preservation in 2~8 °C, until expiration date
Opened, avoid contamination preservation in 2~8 °C, valid for 1 month.
Reagent is not allowed frozen.

SPECIMEN COLLECTION AND HANDLING

No hemolytic serum specimens.
Fat of blood specimen will enable higher results
In sample serum, bolirubin ≤100mg/L; D-penicillamine ≤250mg/L; Uric acid ≤250mg/L; Heparin sodium ≤200mg/L; hemoglobin ≤100mg/L, no obvious disturb.

APPLICABLE INSTRUMENT

Fully automaticbiochemical analyzer.

SYSTEM PARAMETERS

The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group

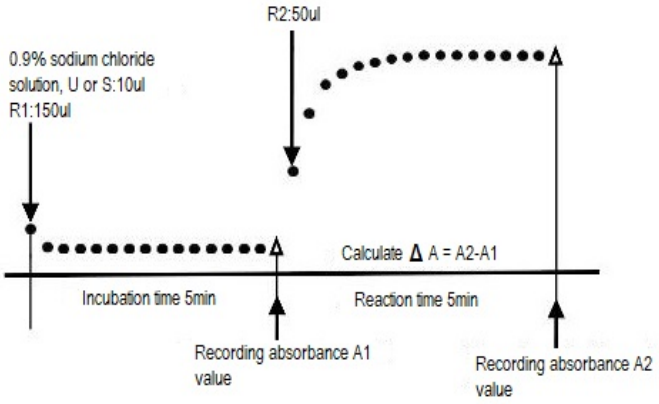
Temperature	37° C
Cuvette light path	1.0cm
Primary Wavelength	600 nm
Secondary Wavelength	800 nm
Assay Type	Two Point End
Direction	Increase
Sample: Reagent1:Reagent2 Ratio	10:150:50

eg: Sample Vol	10μL
Reagent R1 Vol	150μL
Reagent R2 Vol	50μL

Linearity	0~79μ mol/L
Testing	Deducting the reagent blank

OPERATION STEPS

R1: Reagent 1 R2: Reagent 2 S: Calibrator U: Sample



CALCULATION

$$\text{Cu sample concentration} = \frac{\text{Sample } \triangle A}{\text{Calibrator } \triangle A} \times \text{Standard concentration}$$

REFERENCE RANGE

10.0~24.4μ mol/L or 63.5-155μg/dl
By clinical trials, choose no less than 100 newborn or adults blood specimens, tested by automatic biochemical analyzer, and then processing the testing value with statistical method, calculating out the reference range.
Recommendation: The laboratory set up its own reference range!

THE LIMITATION OF TEST RESULTS

Copper(Cu) testing is just one of the standard that clinicist diagnose the patient. Clinical physicians should according to patients' bodies, History and other diagnsotic program, to get comprehensive judgment.

THE INTERPRETATION OF TEST RESULTS

Human error, the processing of specimen, analysis instrument deviation, etc. all can affect the measurement result; When one sample deviates from the expected value too far, need to be tested again.

PERFORMANCE INDEX

1.Reagent blank absorbance ≤0.8, (600nm, 1cmoptical path)
2.Precision repeatability CV≤10% batch variations R<10%.
3.Accuracy: relative deviation≤10%.
4.Linearity range: 0~79μ mol//L, r>0.990.
5.Stability: All package reagent, non corrosive gas and avoid light, preservation in 2~8 °C, stable 12 months.

ATTETION

1.When the simultaneous determination of sodium and potassium Project, please first test Na.
2. Different batches reagents cannot mix, when replacing reagents batch number, please calibration again.
3.The Opened reagent should be airtight store according to the specified method, never use expired.
4.Liquid waste disposal: Suggest follow local regulations.

Product Designed and Developed in The U.S.A.
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