

# Copper

## Intended Use

For In Vitro Diagnostic use in the automated, quantitative determination of Copper in serum or plasma.

## Method Principle

Under acid conditions, protein unraveling agents free the copper ions. The dissociated copper ions then engage in a subsequent reaction with 4-(3,5-dibromo-2-pyridylazo)-N-ethyl-N-sulfopropylaniline (DiBr-PAESA) to produce a colored chelate complex with maximum absorption at 580nm. The intensity of the color thus produced is directly proportional to the Copper ions in the serum sample. The reaction scheme depicts the steps that occur in this Bromide method.



## Method Performance Characteristics

**Sensitivity:** 0.0016 - 0.0024 per ug/dL should be obtained using a path length of 1 cm.

**Linear Range:** 10 - 355 ug/dL.

**Precision:** Precision data was obtained using three levels of protein-based controls and following the NCCLS EP5-TS procedure. The following results were observed:

Copper	Within-Run Precision		Day-to-Day Precision	
	SD	CV	SD	CV
µg/dL	µg/dL	%	µg/dL	%
50.6	3.0	5.9	3.3	6.5
97.6	2.3	2.4	2.5	2.6
165.4	2.5	1.5	2.7	1.6

## Correlation

Correlation studies were carried out between this automated Copper method (Y) and reference Atomic Absorption method (X). Serum samples were assayed and the results compared by the least squares regression. The following statistics were observed:

Correlation Data	
Parameter	Data Observed
N	30
Range	37 - 179
Regression	$Y = 0.91x - 0.503$
Correlation	$r = 0.9847$
$S_{y,x}$	0.995