GENESIS

Instructions For Use

Zinc Single Reagent

Cat no.	size
1315 101	2*25
1315 102	4*25

INTENDED USE

Quantitative determination of Zinc in human serum, Plasma or Urine.

DIAGNOSTIC CHARACTERISTICS

Zinc is an essential trace metal, which is second only to Iron. It is present in Zinc metalloenzymes e.g. carbonic anhydrase, alkaline Phosphatase, R.N.A and D.N.A polymerases, thimidine kinase, carboxypeptidases and alcohol dehydrogenase. Hypozincemia is a condition where insufficient zinc is available for metabolic needs. The deficiency may lead to Anorexia, Diarrhea and Pneumonia or cognitive and motor function impairment in children. Zinc deficiency during pregnancy can negatively affect both the mother and fetus.

PRINCIPLE OF THE METHOD

Colorimetric Method with 5-Bromo-PAPS.

Zinc forms with 2-(5-Brom-2-pyridylazo)-5-(N-propylNsulfopropylamino) -phenol a red chelate complex. The increase of absorbance can be measured and is proportional to the concentration of total zinc in the sample.

COMPOSITION

BUFFER(R1)	Bicarbonate buffer, pH 9.4	200 mmol/L
	5-Br-PAPS	0.02 mmol/L
	Sodium citrate	170 mmol/L
	Dimethylglyoxime	4 mmol/L
	Detergent	1 %
STANDARD(S)		200 µg/dl (30.6 µmol/L)

STORAGE.

Store at 2-8ºC.

Reagents and Standard are stable until the expiry date shown on the Vial label when stored tightly closed and if contaminations are prevented during their use.

REAGENT PREPARATION

The reagent and standard are ready to use.

ADDITIONAL EQUIPMENT

− Analyzer, spectrophotometer able to read at 546 nm

SPECIMEN

Serum (preferred), plasma heparinate , urine.

Sample is stable 7 days at 2-8°C and 1 month at -20°C.

PROCEDURE

1. Pipette into labeled test tubes:

	Blank	Standard	Sample
Working Reagent	1.0 mL	1.0 mL	1.0 mL
Standard (S)	-	50 µL	-
Sample	-	-	50 µL

2. Mix thoroughly and incubate the tubes for **10 minutes** at room temperature.

3. Measure the absorbance (A) of the Standard and Sample at 546 nm against the blank.

CALCULATIONS

The concentration in the sample is calculated using the following general formula:

$$\frac{\text{A Sample}}{\text{A Standard}} \times \begin{matrix} 200 \\ 30.6 \end{matrix} \begin{matrix} = \mu g/dl \\ = \mu mol/l \end{matrix}$$

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by
	Consult instructions for use		Temperature Limit

REFERENCE VALUES

Serum or plasma	
Adults (male)	72.6 - 127 µg/dl (11.1 - 19.5 µmol/l)
Adults (female)	70.6 - 114 µg/dl (10.7 - 17.5 µmol/l)
Children	63.8 - 110 µg/dl (9.8 - 16.8 µmol/l)
Newborns	49.5 - 99.7 µg/dl (7.6 - 15.3 µmol/l)
Urine:	
300 - 800 mg/24h 24h collected urine 15 - 120 µg/dL spontaneous urine	

During pregnancy and menstruation the concentration of zinc can be very low .

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

It is recommended to use the Control Serum level I and II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control .

METROLOGICAL CHARACTERISTICS

Detection limit 2.9 µg/dL (0.445 µmol/L).

Linearity limit: 500 µg/dL (76.5 µmol/L).

Samples with higher concentrations have to be diluted 1 + 1 with physiological saline (0.9 %). Multiply the result by 2..

Precision

− **Repeatability (within run):**

Mean Concentration [µg/dL]	cv	n
240	2.5 %	20
322.1	1.46 %	20

− **Reproducibility (run to run):**

Mean Concentration [µg/dL]	cv	n
215.6	2.2 %	20
321.0	1.6 %	20

INTERFERENCES

Interferences: Bilirubin (<15 mg/dL), hemolysis (hemoglobin < 500 mg/dL) and (triglycerydes < 1000 mg/dL) do not interfere.Drugs and substances may interfere.

BIBLIOGRAPHY

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 347-9.

2. Johnsen and R.Eliasson. Evaluation of a commercially available kit for the colorimetric determination of zinc. International Journal of Andrology, 1987, April 10 (2): 435-440.

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CE

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