

BioMed-Zinc

Colorimetric, Endpoint



REF: ZN130120 (2x50)

INTENDED FOR USE:

For the determination of Zinc in serum, plasma, urine or seminal fluid

PRINCIPLE :

The zinc produces with the specific complexant 5-Br-PAPS [(2-5-bromo-2-pyridylazo)-5-(N-propyl-N-sulfo-propylamino) phenol] a stable coloured complex which colour intensity is directly proportional to the amount of zinc in the sample. The interferences due to the oligoelements (iron, copper, cobalt) present in the sample, are eliminated using specific masking agents

SPECIMEN :

Serum or plasma not hemolyzed. Use only heparin salts as anticoagulants. 24h-Urine diluted 1:10.

Seminal fluid. Centrifuge the sample at 3000 rpm for 10-15 minutes.

Dilute supernatant 1:100 with physiological solution. Multiply result by dilution factor.

Shake and bring the samples at room temperature (+15-25°C) before using

REAGENTS COMPOSITION:

Reagent (A) Zn Liquid Vol. = 2x50mL	Buffer Complexants 5-Br-PAPS	200 mmol/L < 0.1% < 0.1%
Standard (B) Zn Liquid - Vol. = 10mL	Zinc	200 µg/dL 30.6 µmol/L

PACKAGE : Collection and Storage .

Store at +2-8°C .

Stable until the expiration date reported upon the package.

After the unsealing and the taking of the reagent , it is advised to close up the bottle immediately in order to avoid evaporation , direct light exposure and bacteric contamination .

PRECAUTION & WARNINGS :

Avoid pipette by mouth .

The preparation , according to current regulation . pipette is classified as not dangerous.

The total concentration of non active components (preservatives , detergents , stabilizers) is below the minimum required for citation .

Anyway handle with care , avoid ingestion , avoid contact with eyes , skin and mucous membranes

The samples must be handle as potentially infected from HIV or Hepatitis .

REAGENT PREPATION & STABILITY :

Ready to use liquid reagents. Reagents must be at room temperature (+15-25°C) before using. Stable until the date reported on the label.

The Reagent is limpid and yellow/orange; do not use if turbid..

REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and instrumentations.

PROCEDURE :

Wavelength 560 nm (565)
Optical path : 1 cm light path
Temperature : +25/30/37°C
Reading : Against blank reagent
Assay tipe : Endpoint
Sample/reagentRatio: 1/20

Procedure : Pipetting in tubes :

	BLANK	STANDARD	SAMPLE	
Reagent (A)	1000	1000	1000	µL
Distilled Water	50			µL
Calibrator		50		µL
Sample			50	µL

Mix, incubate for 10 min at room temperature (+15-25°C); read sample and standard extinction against blank reagent.

Colour is stable at least 15 min at room temperature..

Volumes can be proportionality modified .

This methodology describes the manual procedure to use the kit .

For automated procedure, ask for specific application .

CALCULATION :

$$\text{Zinc: } \mu\text{g/dL} = \frac{(\text{E}) \text{ sample}}{(\text{E}) \text{ Standard}} \times 200 \text{ (Standard value)}$$

Standard Concentration 200 µg/dL (30.6 µmol/L)

In the urine multiply result by Vol (dl) of 24h-Urine by 10 (dilution factor).

In the seminal fluid multiply result by 100 (dilution factor).

EXPECTED VALUES :

Men:	72.6 - 127 µg/dL	11.1 - 19.5 µmol/L
Women	70 - 114 µg/dL	10.7 - 17.5 µmol/L
Seminal fluid	2 - 10 mg/dL	0.3 - 1.5 mmol/L
Youth	63.8 - 110 µg/dL	9.8 - 16.8 µmol/L
baby	49.5 - 99.7 µg/dL	7.6 - 15.3 µmol/L
Urine	280 - 900 µg/24h	42.8 - 137.7 µmol/L

the above mentioned values are to be considered as a reference.

It is strongly recommended that each laboratory establish its own normal range according to its geographic area , according to IFCC protocol .

WASTE DISPOSAL :

The disposal of the product must be in accordance with local regulation concerning waste disposal .

QUALITY CONTROL :

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

REFERENCES :

Bohuon, C.; Clin.Chim.Acta, 16,155(1957).
Vassault,A. et al. Ann.Biol.Clin.,44,686,(1986)

PERFORMANCE :

MEASURE INTERVAL INEARTY :	5 -1000 µg/dL
DETECTION LIMIT (2DS):	5 µg/dL

INTER-ASSAY PRECISION: n=20

LOW LEVEL	M = 60.50	C.V = 2.9%
MEDIUM LEVEL	M = 115.34	C. V = 2.5%
HIGH LEVEL	M = 176.46	C.V = 1.8%

INTER-ASSAY PRECISION: n=20

LOW LEVEL	M = 60.82	C.V = 2.9%
MEDIUM LEVEL	M = 116.22	C.V = 2.5%
HIGH LEVEL	M = 175.39	C.V = 1.8%
CORRELATION	r = 0.97	n=10
LIN. REGRESSION	y= 0.983 x- 3.4	n=10

INTERFERENCE: (In Accordance With Raccomandation SFBC)

Interferences are negligible up to :			
Hemoglobin	500 mg/dL	Copper	1000 µg/dl
Triglycerids	500 mg/dL	Iron	1000 µg/dl
Bilirubin	15 mg/dL	Cobalt	500 µg/dl

METHOD LIMITATIONS:






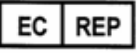

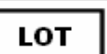

It is impossible to read at 546 nm and at 578 nm.

During the pregnancy and during the menstruation, the concentrations can be reach subnormal values.

For concentration higher than 1000 µg/dl repeat the measure on a sample diluted 1:2 with saline solution e multiply the results by 2.

Do not use haemolyzed sera. Turbid and itteric sera can interfere in the reaction raising the values.

Do not use plasma obtained from EDTA

	Consult Instructions for Use
	Caution, consult accompanying Documents
	In Vitro Diagnostic Medical Device
	Temperature limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue number
	Batch code
	Use by

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