ISE S.r.l. Zinc (100 test) – Instructions for use

CUSTOMISED SOLUTIONS
FOR YOUR LABORATORY

CE IVD

R1: 2x 10 mL **R3330000055** REF

Diagnostic reagent for quantitative in vitro determination of zinc in human serum, plasma or urine on photometric systems

TEST PARAMETERS

Method:	Colorimetric, Endpoint, Increasing Reaction, Br-PAPS
Wavelength:	560 nm
Temperature:	25 °C / 37 °C
Sample:	Serum, heparin plasma, urine (do not use EDTA plasma!)
Linearity:	up to 500 µg/dL (76.5 µmol/L)

SUMMARY [1]

Zinc is involved in many enzymatic reactions at the molecular level. It plays an important role in the synthesis of DNA and RNA and exerts a clearly enhancing effect on the immune system. Another important function of zinc is its involvement in the cellular protective function against free radicals and reactive oxygen compounds.
Causes of zinc deficiency may be – among others – malnutrition, malabsorption, diseases of the small intestine, alcoholism, diabetes mellitus, rheumatic disorders, acute and chronic infections, or chronic liver diseases.

TEST PRINCIPLE

Zinc forms a red chelate complex with 2-(5-Bromo-2-pyridylazo)-5-(N-propyl-N-sulfo-propylamino)-phenol. The increase of absorbance of this complex is proportional to the concentration of total zinc in the sample.

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
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 %

REAGENT PREPARATION

The reagent is ready to use.

REAGENT STABILITY AND STORAGE

Conditions:	protect from light!
	close immediately after use
Storage:	at 18 – 22 °C
Stability:	up to the expiration date

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution 9 g/L
General laboratory equipment

STANDARD

(has to be ordered separately)

Concentration	200 µg/dL (30.6 µmol/L)
Storage:	at 18 – 22 °C
Stability:	up to the expiration date

Avoid contamination! Close immediately after use!

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into	Blank	Standard	Sample
test tubes			
Reagent	1000 µL	1000 µL	1000 µL
Sample	-	-	50 µL
Standard	-	50 µL	-
dist. water	50 µL	-	-
Mix and incubate for 8 minutes at 25°C or for 5 minutes at 37°C. Measure absorbance of the standard and the sample at 560 nm against the reagent blank.			

CALCULATION

$$\text{Zinc [µg/dL]} = \frac{\Delta A \text{ sample}}{\Delta A \text{ standard}} \times \text{conc. Standard [µg/dL]}$$

UNIT CONVERSION

µg/dL x 0.153 = µmol/L

REFERENCE RANGES *

Serum/Plasma:		µg/dL	µmol/L
< 4 months		**65 – 137**	**10 – 21**
4 – 12 months		65 – 130	10 – 20
1 – 5 years		65 – 118	10 – 18
6 – 9 years		78 – 105	12 – 16
10 – 13 years	male	78 – 98	12 – 15
	female	78 – 118	12 – 18
14 – 19 years	male	65 – 118	10 – 18
	female	59 – 98	9 – 15
Adults:		46 – 150	7 – 23

Urine:	300 - 800	mg/24h	24h collected urine
	15 - 120	µg/dL	spontaneous urine

* Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

LINEARITY, MEASURING RANGE

Measurable range: 2.9 – 500 µg/dL (0.445 – 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

Intra-assay n = 10	Mean [µg/dL]	SD [µg/dL]	CV [%]
Sample 1	249.8	5.04	2.02
Sample 2	320.9	5.98	1.86

Inter-assay n = 18	Mean [µg/dL]	SD [µg/dL]	CV [%]
Sample 1	218.6	4.85	2.22
Sample 2	322.0	6.81	2.11

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SPECIFICITY/INTERFERENCES

no interference up to:

Bilirubin	15 mg/dL
Hemoglobin	500 mg/dL
Triglycerides	1000 mg/dL

METHOD COMPARISON

A comparison between Dialab Zinc (y) and a commercially available test (x) using 18 samples gave the following results: y = 0.9808 x – 9.4977; r= 0.9988.

CALIBRATION

The assay requires the use of a Zinc Standard or a Zinc Calibrator.
We recommend the our **Zinc Standard**.
The standard value is traceable to ICP-SFMS.

QUALITY CONTROL

All control sera with Zinc values determined by this method can be used.
We recommend the our serum controls (control serum with values in the normal and abnormal range).

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Please refer to the safety data sheet and take the necessary precautions for the use of laboratory reagents.
3. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
4. For professional use only!

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

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.

Symbols on labels and packaging

IVD = In vitro diagnostic medical device

REF = Catalog Number

LOT = Lot Number

= Manufacturer

= Expiration date

= Temperature limitation

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