

Quantitative determination of Zinc in human Serum / Plasma / other body fluids. Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Pack Size
ZINMONO 25	25 X 1 ml
ZINMONO 50	50 X 1 ml
ZIN 100	1X100 ml
ZIN 1000	1X1000 ml
ZIN 5000	1X5000 ml
ZIN 10000	1X10000 ml

CLINICAL SIGNIFICANCE

Zinc is important in human for growth and sexual development. It is present in various organs and is a component of many enzymes. Zinc found in serum is totally bound to protein with over 60% being bound to albumin. Increased levels are found in patients associated with gastrointestinal disorders accompanied with nausea, vomiting, high fever and a metallic taste. Decreased levels are found in cirrhosis lung carcinomas, sickle cell anemia, acute myocardial infarction, renal failure, corticosteroid and oral contraceptive therapy.

Method

Colorimetric

PRINCIPLE

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

REAGENT

Reagent 1 : Zinc Reagent
Zinc Standard : 200 µg/dl

REAGENT PREPARATION

The Reagent is ready to use.

REAGENT STORAGE AND STABILITY

Reagent is stable till expiry when stored at 2-8°C
Store protected from light.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum, plasma or urine
Do not use EDTA plasma.

Stability:

in serum/plasma: 7 days at 4 – 8°C

1 year at –20°C

in urine: 3 days at 4 – 8°C

1 year at –20°C

Freeze only once! Discard contaminated specimens!

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28°C, prior to analysis.

AUTOMATED PARAMETERS

Wavelength	546 nm
Reaction Type	End Point
Cuvette	1 cm light path
Reaction Temperature	37°C
Reaction Type	Increasing
Measurement	Against Reagent Blank
Sample Volume	50µl
Reagent Volume	1000µl
Incubation	05 minutes
Blank Absorbance Limit	< 0.500
Low Normal	72.6 µg/dl
High Normal	127 µg/dl
Linearity	400 µg/dl

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	BLANK	STD	SAMPLE
Sample	-	-	50µl
Standard	-	50µl	-
Reagent	1000µl	1000µl	1000µl

Mix & Incubate for 05 min. at 37°C Measure absorbance of Sample (AT) and Standard (AS) against Reagent Blank at 546 nm.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 400 µg/dl
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION

Results are calculated, usually automatically by the instrument, as follows:

Zinc (µg/dl) = AT/AS x Conc. of Standard

CLIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of the **Zinc Standard** have been made traceable to the reference method Atomic Absorption Spectrometry (AAS).

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Randox 2	147.06	1.52	1.04%
Randox 3	233.02	1.98	0.85%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Randox 2	147.36	1.47	1.00%
Randox 3	232.42	1.11	0.48%

LINEARITY

The method is linear upto a concentration 400 µg/dl. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Zinc is 0.1 µg/dl.

METHOD COMPARISON

A comparison of Zinc with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.991$

REFERENCE VALUES

Serum/Plasma

Men: 72.6 – 127 µg/dl (11.1-19.5 µmol/l)

Women: 70.0 – 114 µg/dl (10.7-17.5 µmol/l)

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

Children: 63.8 – 110 µg/dl (9.8-16.8 µmol/l)

New born: 49.5 – 99.7 µg/dl (7.6-15.3 µmol/l) Urine 300 - 800 µg/24h

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.






INTERFERENCE

- Hemoglobin: No interference found upto 500 mg/dL.
- Bilirubin: No interference found upto 40 mg /dL.
- Lipemia: No interference found upto 40 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

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

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight



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