ZINC

Diagnostic reagent for determination of Zinc concentration.

Liquid. Mono Reagents. Store at 18°C - 22°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
ZN2270	5 x 25 mL	EZ10	1000 Tests	MZN70	1675 Tests	SZN70	1176 Tests
BY2270	4091 Tests	HT2270	2211 Tests	NZN70	800 Tests	TZN70	1842 Tests
DMZ70	540 Tests	LZN70	2000 Tests	NZN71	400 Tests		

INTENDED USE

The test is applied for the quantitative determination of Zinc in serum, plasma or urine.

TEST PRINCIPLE

Nitro-PAPS reacts with zinc in alkaline solution to form a purple colored complex, the absorbance of which is measured at 546 nm. Interference with copper and iron are virtually eliminated by pH and chelating additives.

Clinical Significance: Zinc is an essential trace metal, which is second only to Iron. It is present in Zinc metalloenzymes. (e.g. carbonic anhydrase, alkaline phosphatase, RNA and DNA polymerases, thimidine kinase, carboxypeptidases and alcohol dehydrogenase)

TEST PARAMETERS

Method	: End point
Wavelength	: Main: 570 nm (540-580nm) Sub: 650-750nm
Temperature	: 37°C
Sample	: Serum, plasma heparinate, urine
Linearity	: 4 µg/dL – 1500 µg/dL

REAGENT COMPOSITION

Reagent 1: (Mono Reagent)

Compositions:	
Bicarbonate Buffer	≤ 400 mmol/L
5-Br-PAPS	≤ 0.08 mmol/L
Sodium Citrate	≤ 245 mmol/L
Detergent.	%1

REAGENT PREPARATION

Reagents are ready to use.

REAGENT STABILITY AND STORAGE

Stability of unopened vials is up to expiration date on labels at room temperature.

Once opened vials (reagent 1) are stable for 60 days at 2-8°C and 30 days at room temperatures.

On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum (preferred), plasma heparinate, urine (Sample with EDTA cannot be used) are collected by standard procedures.
Sample is stable for 7 days at 2-8ºC and 1 month at -20°C.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

$$\frac{\text{A Sample}}{\text{A Standard}} \times \text{conc. of standard}$$

= Zinc in sample (µg/dL)

Unit Conversion

µmol/L × 6.51=µg/dL

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Men Serum:	72.6 - 127 µg/dL
WomenSerum:	70 - 114 µg/dL
School children:	63.8 - 110 µg/dL
Newborn:	49.5 - 99.7 µg/dL

(Zinc values could be low during menstruation and pregnancy)

Urine: 300 - 1200 µg/24h

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used. We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The assay requires the use of a Zinc Standard (Calibrator). Any commercially available Standard or Calibrator suitable for this method may be used. We recommend:

ARCHEM Standard

Cat.No. ZNC05 (Conc. value is on label)

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 1 week.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 4 µg/dL

High Linearity: The method is linear up to 1500 µg/dL.

If the limit value is exceeded, it is suggested to dilute sample 1+9 with distilled water and to repeat the test, multiplying the result by 10.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (Intra-assay)

Mean conc.	SD	CV	n
95.20 µg/dL	1.53	1.40%	10
135.70 µg/dL	3.47	1.90%	10

Reproducibility (run to run) (Inter-assay)

Mean conc.	SD	CV	n
94.28 µg/dL	3.1	2.70%	20
133.40 µg/dL	3.2	2.40%	20

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection of the test is 3 µg/dL.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Methods Comparison: A comparison between Archem and a commercially available product gave the following results:
Zinc Archem = x
Zinc competitor = y
n = 84
$y = 0.902x + 8.81$ µg/dL $r^2 = 0.966$

Interferences: No interference was observed by the presence of:

Hemoglobin	≤ 500 mg/dL
Bilirubin	≤ 15 mg/dL

Lipids interfere: ≤ 1000 mg/dL

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell,

seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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