ZINC

ZN 0125 CH

5 x 25 ml

INTENDED USE

Reagent for quantitative in vitro determination of zinc in biological fluids.

SUMMARY OF TEST

Zinc is second to iron as the most abundant trace element in the body, 1.4 to 2.3 g being present in the 70-kg adult. Tissues and fluids especially rich in zinc are prostate, semen, liver, kidney, retina, bone, and muscle. Zinc is transported in blood plasma mostly by albumin and by a,-macroglobulin, with a small amount associated with transferrin and free amino acids.

PRINCIPLE OF THE METHOD

Nitro-PAPS reacts with zinc in alkaline solution to form a purple colored complex, the absorbance of which is measured at 575 nm. Interference from copper and iron are virtually eliminated by pH and chelating additives.

KIT COMPONENTS

For in vitro diagnostic use only.

The components of the kit are stable until expiration date on the label

Keep away from direct light sources.

5 x 20 ml (liquid) blue cap

Composition: borate buffer 370 mM pH 8.20, salicylaldoxime 12.5mM, dimethylglyoxime 1.25 mM, surfactants and preservatives.

5 x 5 ml (liquid) red cap ZN R2

Composition: Nitro-PAPS 0.40 mM.

zinc solution 200 μ g/dl - 5 ml Standard:

Store all components at 2-8°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

REAGENT PREPARATION

Mix one vial of reagent R2 with a vial of reagent R1. Stability of working reagent: 30 days at 2-8°C and 7 days at room temperature, well closed.

Stability of unopened vials: up to expiration date on labels at 2-8°C

Stability since first opening of vials: preferably within 60 days at 2-8°C.

PRECAUTIONS

ZN R1: Danger. Causes serious eye damage (H318). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

(P305+P351+P338). Wear eye protection / face protection (P280). Immediately call a POISON CENTER / doctor (P310).

ZN R2: It is not classified as hazardous.

Standard: It is not classified as hazardous.

SPECIMEN

Serum (preferred), plasma heparinate, urine Sample is stable 7 days at 2-8°C and 1 month at -20°C.

TEST PROCEDURE

Wavelenght: Lightpath: Temperature:	1 cm	n (allowed 570 ÷ or 37°C	- 582 nm)
dienoneo:	blank	standard	cample

dispense:	blank	standard	sample
reagent	1 ml	1 ml	1 ml
water	50 μl	-	-
standard	-	50 μl	-
sample	-	-	50 μl

Mix, incubate at 25, 30 or 37°C for 5 minutes.

Read absorbances of standard (As) and samples (Ax) against reagent blank.

RESULTS CALCULATION

serum/plasma sample:

zinc μg/dl = Ax/As x 200 (standard value)

EXPECTED VALUES

70 - 150 μg/dl (10.7 - 22.9 μmol/l) 150 - 1200 μg/24h (2.3 - 18.4 μmol/24h) serum: urine:

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

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

QUANTINORM CHEMA - MULTINORM CHEMA

with normal or close to normal control values

QUANTIPATH CHEMA - MULTIPATH CHEMA

with pathological control values

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity

the method is linear up to 1000 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.

Sensitivity/limit of detection (LOD)

the limit of detection is 5 µg/dl.

Interferences

no interference was observed by the presence of:

hemoglobin ≤ 100 mg/dl bilirubin < 40 mg/dl

Lipids interfere.

Precision

mean (μg/dl)	SD (μg/dl)	CV%
95.20	1.03	1.10
135.70	3.47	2.60
mean (μg/dl)	SD (µg/dl)	CV%
94.28	3.49	3.70
133.40	3.45	2.60
	95.20 135.70 mean (µg/dl) 94.28	95.20 1.03 135.70 3.47 mean (μg/dl) SD (μg/dl) 94.28 3.49

Methods comparison

a comparison between Chema and a commercially available product gave the following results:

> Zinc Chema = x Zinc competitor = v n = 84

 $y = 0.902x + 8.81 \mu g/dl$ $r^2 = 0.966$

WASTE DISPOSAL

This product is made to be used in professional laboratories

P501: Dispose of contents according to national/international regulations.

REFERENCES

 $K. Ueno, \ T. Imamura, \ K. L. Cheng \ - \ Handbook \ of \ organic$ analytical reagents - CRC Press (1992).

Akita Abe, Sumiko Yiamashita, Clin.Chem. 35/4, 552-554 (1989)

Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994)

MANUFACTURER

Chema Diagnostica

Via Campania 2/4

60030 Monsano (AN) - ITALY - EU +39 0731 605064 phone

+39 0731 605672 e-mail: mail@chema.com website: http://www.chema.com

SYMBOLS

IVD in vitro diagnostic medical device

LOT batch code

catalogue number

X temperature limit

Ω use-by date caution

⚠

REF

 \bigcap i consult instructions for use