## ZINC

5 x 25 ml

ZN 0125 CH

## **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  $\alpha_{\rm z}$ -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.

## ZN R1 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.

ZN R2 5 x 5 ml (liquid) red cap

Composition: Nitro-PAPS 0.40 mM.

Standard: zinc solution 200  $\mu$ g/dl - 5 ml

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).

Causes skin irritation (H315). Wear protective gloves. Eye protection (P280). IF ON SKIN: Wash with plenty of water (P302+P352). IF IN

EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). Immediately call a 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: 575 nm (allowed 570 ÷ 582 nm)

Lightpath: 1 cm

Temperature: 25, 30 or 37°C

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  $\mu$ g/dl = Ax/As x 200 (standard value)

#### EXPECTED VALUES

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

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

with normal or close to normal control values

## **QUANTIPATH CHEMA**

with pathological control values.

Please contact Customer Care for further information.

# TEST PERFORMANCE

#### Linearity

the method is linear up to 1000  $\mu g/dl$ .

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  $\leq 100 \text{ mg/dl}$ bilirubin  $\leq 40 \text{ mg/dl}$ 

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
		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)

### Methods comparison

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

Zinc Chema = x Zinc competitor = y 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

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## **SYMBOLS**

IVD in vitro diagnostic medical device

LOT batch code

catalogue number

temperature limit



REF

X

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consult instructions for use