# ZINC

## NITRO-PAPS

**Summary:**
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 α2-macroglobulin, with a small amount associated with transferrin and free amino acids. The major route of zinc excretion is via the feces. Pancreatic secretion accounts for about 25% of total excretion. Biliary losses are small. Urinary losses of zinc, about 0.6 mg/d in an adult consuming about 12 mg Zn/d, seem to be directly related to zinc intake and status. Sweat losses are similar to those in urine but can be appreciable in tropical climates or under physical stress. Nutritional zinc deficiency in humans is fairly prevalent throughout the world. Primary clinical features include retardation of growth and skeletal maturation, testicular atrophy, and hepatosplenomegaly. Growth failure, reduced taste acuity, and hypogonadism in young adults have been ascribed to zinc deficiency. Old age, pregnancy, lactation, and alcoholism are also associated with a higher incidence of poor zinc nutrition. Moderate zinc deficiency is characterized by growth retardation in children and adolescents, hypogonadism in males, mild dermatitis, poor appetite, delayed wound healing, abnormal dark adaptation, mental lethargy, and impaired immune responses. Manifestations of severe cases of zinc deficiency include bullous-pustular dermatitis, alopecia, weight loss, diarrhea, neuropsychiatric disorders, reincurrent infection, and ultimately death if not treated. Pregnant women are at higher risk of acquired zinc deficiency because of the high uptake of zinc by the fetus and associated tissues. Zinc is required for normal fetal development and influences pregnancy outcome. It has been suggested that excessive iron and folic acid supplements, often prescribed during pregnancy, interfere with zinc absorption and utilization and may exacerbate the effects of marginal zinc intakes. The use of oral con- traceptives produces a decrease in plasma zinc with an increase in erythrocyte zinc. The most clearly defined genetic disorder of zinc meta- bolism is acrodermatitis enteropathica. Manifestations of the disease are those of zinc deficiency, including retarded growth, hypogonadism, dermatological and ophthalmic lesions, and gastrointestinal disturbances. The patients exhibit lowered plasma zinc concentrations. Symptoms are completely alleviated with zinc sulfate supplementation. Zinc deficiency is also often associated with sickle cell anemia; zinc supplementation may be of benefit in decrea- sing symptoms and crises of some patients with sickle cell anemia. The determination of plasma or serum zinc concentrations by AAS is the simplest and analytically most reliable test for the routine assessment of zinc. Photometric methods are now available for those laboratories without an AAS instrument, and they give results that are comparable to those obtained by AAS.

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

**Reagent Concentration:**
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.
Reagent 1:
Composition: borate buffer 370 mM pH 8.20, salicylaldoxime 12.5mM, dimethylglyoxime 1.25 mM, surfactants and preservatives.
Reagent 2:
Composizione: Nitro-PAPS 0.40 mM.

**Preparation and stability:**
Reagents are ready for use.
Stability of unopened vials: up to expiration date on labels at 2-8°C.
Onboard stability: R1: 28 days.
R2: 28 days.

**Specimen:**
Mix one vial of reagent 2 with a vial of reagent 1. 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: ≥ 60 days at 2-8°C

**Testing procedure:**
**Applications for automated systems are available on request.**
*Materials provided*
• Working solutions as described above
*Additional materials required*
• Calibrators and controls as indicated below
• 0.9% NaCl

| Manual procedure | | |
|---|---|---|
| Wavelength: | 575 nm, (570 – 582 nm) | |
| Temperature: | +37°C | |
| Cuvette: | 1 cm light path | |
| Zero adjustment: | Reagent blank/each series needs one reagent | |
| | Blank | Sample / Calibrator |
| R1 | 400 µl | 400 µl |
| R2 | 100 µl | 100 µl |
| Sample/Calibrator | 25 µl | 25 µl |
| Mix and incubate 5 minutes. Read the absorbance against blank within 30 minutes. | | |
| Calculation:<br>$\frac{\text{AA sample}}{\text{AA Calibrator}}$ x Calibrator conc. = Zinc in µg/dl | | |

**Measuring range:**
Linearity : 5 µg/dl-1000 µg/dl
Determine samples having higher concentrations via the rerun function. On instruments without rerun function, manually dilute samples with 0.9% NaCl solution(e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2).

**Reference value:**
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.

**Analytical sensitivity (lower detection limit):**
The limit of detection is 5 µg/dl.
The lower detection limit represents the lowest measurable calcium concentration that can be distinguished from zero. It is calculated as three standard deviations of the lowest standard.

**Interferences:**
No interference was observed by the presence of:
hemoglobin ≤ 100 mg/dl
bilirubin ≤ 40 mg/dl
Lipids interfere.

**Precision:**

| intra-assay (n=10) | mean (µg/dl) | SD (µg/dl) | CV% |
|---|---|---|---|
| sample 1 | 95.20 | 1.03 | 1.10 |
| sample 2 | 135.70 | 3.47 | 2.60 |
| inter-assay (n=20) | mean (µg/dl) | SD (µg/dl) | CV% |
| sample 1 | 94.28 | 3.49 | 3.70 |
| sample 2 | 133.40 | 3.45 | 2.60 |

**Method comparison:**
A comparison of the BIOANALYTIC Zinc (y) with a commercial obtainable assay (x) gave the following result:
y = 0.902x + 8.81µg/dl;
$r^2$ =0.966

**Quality Control:**
Control Serum:

| | | |
|---|---|---|
| BIOCON N | 5 x 5 ml | #B10814 |
| BIOCON P | 5 x 5 ml | #B10817 |

The control intervals and limits must be adapted to the individual laboratory and country-specific requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

**Calibration:**
S1: 0.9% NaCl
S2: BIOCAL H 5 x 3 ml #B11895

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**Calibration frequency:**

A two-point-calibration is recommended in case of:
1-change of lot
2- quality control requirements

**Literature:**

1. Doumas B.T., Watson W.A., Biggs H.G.. Albumin standards and the measurement of serum albumin with bromcresol green. Clin Chim Acta 1971 ;31 :87-96.
2. Glick M.R., Ryder K.W., Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem 1986;32:470-474.
3. Grant G.H., Silverman L.M., Christenson R.H.. Amino acids and proteins. In: Tietz N.W. (ed.). Fundamentals of Clinical Chemistry, 3rd Philadelphia, Pa: W.B. Saunders, 1987:328-330.
4. Marshall WJ (ed.). Illustrated Textbook of Clinical Chemistry,3rd . London: Gower Medical Publishing, 1989:207-218.
5. Tietz NW (ed.). Clinical Guide to Laboratory Tests, 3rd . Philadelphia, Pa: WB Saunders, 1895:22-24.

**Order information (Cat No.) :**

| | | | | | |
|---|---|---|---|---|---|
| CC515 | SH515 | B21305 | B27305 | B32305 | B36305 |
| OL515 | CR515 | B22305 | B28305 | B33305 | B37305 |
| AB515 | BZNC250 | B24305 | B30305 | B34305 | B80305 |
| KL515 | BZNC125 | B25305 | B31305 | B35305 | |

**Manufacturer**

Diaclinica Diagnostik Kimya.San.Tic.Ltd.Şti
Adress : İkitelli O.S.B Mutsan San.Sit. M4 Blok No:17-19 Başakşehir/İSTANBUL
Tel:+90(212) 549 33 88- Fax:+90 (212) 549 55 50
Web :www.diaclinica.com

## SYMBOLS

| | |
|---|---|
| IVD | for in vitro diagnostic use only |
| LOT | lot of manufacturing |
| REF | code number |
| | storage at temperature interval |
| | expiration date (year/month) |
| | warning, read enclosed documents |
| | Read the directions |

ISO 9001:2015
ISO 13485:2016