Zinc

Color 5 Br-PAPS

Quantitative determination of zinc

CE IVD

PACKAGING

Ref.: 101-0590	Cont.: 5 x 10 mL

Store at 2 - 8º C

CLINICAL SIGNIFICANCE

Nutritional zinc deficiency in humans is fairly prevalent throughout the world, deficiency is characterized by growth retardation in children and adolescents, hypogonadism in males, mild dermatitis, poor appetite, delayed wound healing, abnormal dark adaptation, and mental lethargy and impaired immune responses.
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE OF THE METHOD

Direct colorimetric test without deproteinization of the sample. End point increase. At pH 8.6, in a buffered media, zinc reacts with the specific complexant 5-Br-PAPS, forms a stable coloured complex.
The colour intensity is proportional to the amount of zinc present in the sample.

REAGENTS

R 1 Buffer	Good. pH 8.6	0.2 mol/L
R 2 Color	5-Br-PAPS	1.1 mmol/L
R 3 Reducing acid	Ascorbic acid (powder)	
ZINC CAL	Zinc primary standard 200 µg/dL	

Optional (not included in the kit)

Contro-N	Ref.: 101-0252	4 x 5 mL	Lyophilized human control serum
	Ref.: 101-0083	20 x 5 mL	
Contro-P	Ref.: 101-0253	4 x 5 mL	Lyophilized human control serum
	Ref.: 101-0084	20 x 5 mL	

CALIBRATION

The ZINC CAL value is verified using NIST (National Institute of Standards and Technology) traceable reference Standard.

PREPARATION AND STABILITY

- Working reagent (WR): Add (→) one dose (dispense using the enclosed spoon) of R3 to one vial of R1. Cap and mix gently to dissolve contents. (WR) is stable after reconstitution 30 days at 2-8ºC when stored tightly closed and contaminations prevented during their use. Do not use if appears turbid.
- R2: Ready to use. After opening, is stable 90 days 2 - 8º C, if contamination avoided and vial recapped immediately after use.
- ZINC CAL: Ready to use.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2 - 8º C, protected from light and contaminations prevented during their use.
Do not use reagents over the expiration date.
Signs of reagent deterioration:
- Presence of particles and turbidity.

ADDITIONAL EQUIPMENT

- Spectrophotometer or colorimeter measuring at 560 nm.
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment(Note 1).

SAMPLES

- Serum or plasma[1]: Not hemolyzed. Use only heparin salts as anticoagulants. Stability: 7 days at 2 - 8º C.
- Seminal fluid: Centrifuge the sample at 3000 r.p.m. for 10 - 15 minutes. Dilute supernatant 1/100 with NaCl (9 g/L) and multiply the result by 100. Stability: 7 days at 2 - 8º C.
- 24 h urine.

PROCEDURE

Notes: CHRONOLAB SYSTEMS has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.
ZINC CAL: Proceed carefully with this product because due its nature it can get contamined easily.
It is recommended to use disposable material. If glassware is used the material should be scrupulously cleaned with hydrochloric acid 1 N and then thoroughly rinsed it with distilled water.
Use clean disposable pipette tips for its dispensation.

1. Allow reagents to reach working temperature before using. A proportional variation of the reaction volumes indicated does not change the result.
2. Assay conditions:
   Wavelength: . . . . . .560 nm (550 - 580)
   Cuvette: . . . . . 1 cm light path
   Temperature . . . . . 25 / 30 / 37º C
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

	Blank	Standard	Sample
WR (mL)	1.0	1.0	1.0
Distilled water	50	-	-
Standard(Note 2) (µL)	--	50	--
Sample (µL)	--	--	50

5. Mix and read the absorbance (A_1) of the samples against the Blank. Add:

	Blank	Standard	Sample
R2 (µL)	100	100	100

6. Mix and read the absorbance (A_2) of sample and standard against Blank. The colour is stable for at least 1 hour.

CALCULATIONS

$$\frac{(A_2 - A_1)\ \text{Sample} - (A_2 - A_1)\ \text{Blank}}{(A_2 - A_1)\ \text{Standard} - (A_2 - A_1)\ \text{Blank}} \times 200\ (\text{Standard conc.}) = \mu g/dL\ \text{zinc in the sample}$$

Conversion factor: µg/dL x 0,153 = µmol/L.

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures.
If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES[1]

Serum or plasma:	68 - 107 µg/dL ≅ 10.4 – 16.4 µmol/L
Centrifuged seminal fluid:	2 – 10 mg /dL ≅ (0.31 – 1.53 mmol/L)
24 h urine	150 - 1200 µg/L

These values are for orientation purpose; each laboratory should establish its own reference range.

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PERFORMANCE CHARACTERISTICS

Measuring range: From detection limit of 4 µg/dL to linearity limit of 2000 µg/dL.

If the results obtained were greater than linearity limit, dilute the sample 1/10 with NaCl (9 g/L) and multiply the result by 10.

Precision:

	Intra-assay (n=20)			Inter-assay (n=20)		
Mean (µg/dL)	76.7	199	307	77.6	203	301
SD	2.35	4.36	4.70	2.29	4.60	3.38
CV (%)	3.06	2.20	1.53	2.95	2.27	1.13

Accuracy: Results obtained using CHRONOLAB reagents (y) did not show systematic differences when compared with other commercial reagents (x).

The results obtained using 60 samples were the following:

Correlation coefficient (r): 0.99.

Regression equation: 1.027x – 2.7873.

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

No interferences were observed to bilirubin up to 15 mg/dL, hemoglobin up to 0.5 g/dL and triglycerides up to 1000 mg/dL.

EDTA interfere in the test.

A list of drugs and other interfering substances with zinc determination has been reported by Young et. al[3,4].

BIBLIOGRAPHY

1. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
2. Kaplan A et al. Clin Chem The C.V. Mosby Co.1984.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
4. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.

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