In vitro diagnostic reagent for direct colorimetric determination of zinc in serum, plasma and urin. Store at room temperature.

REF: ZIN-032B

Summary:

Zinc is necessary for cell replication. 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.

Principle:

Direct colorimetric mesurement without deproteinization of the sample. Zinc forms a stable colored complex with 5-Br-PAPS which colour intensity is proportional to the amount of Zinc in the sample.

Composition

R1: 5-Br-PAPS - 0.02 mmol/l, Bicarbonate buffer pH 9.8 - 200 mmol/l, Sodium citrate - 170 mmol/l, Dimethylglyoxime - 4 mmol/l, Detergent - 1% **Zinc standard**: 200 μ g/dl (30.6 μ mol/l)

Reagent Stability And Storage:

The sealed reagent is stable up to the indicated expiry date if stored at +18° to +22°C. The reagent can be stored at 2-8°C after opening.

Precautions:

In addition to the possible risk indications regarding the reactive components, reagents may contain non-reactive components such as preservatives (i.e. sodium azide of other) and detergents.

Samples:

Serum, Plasma, Urine

Equipment:

Usual laboratory equipment

Procedure:

1. Assay conditions:

 Wavelength:
 .546 nm

 Cuvette:
 .1 cm. light path

 Temperature
 .+ 25°C / + 37°C

	Standard	Sample		
R1 (μL)	1000	1000		
Serum or Plasma (µL)	-	50		
Standard (µL)	50	-		

2.Mix and incubate for 10 minutes at 25°C or 5 minutes at 37°C. Measure the absorbance of the sample $\rm A_{(S)}$ and of the standard $\rm A_{(STD)}$ against the reagent blank $\rm A_{(RR1)}$

$$\Delta A_{(S)} = A_{(S)} - A_{(RBL)}$$

$$\Delta A_{(STD)} = A_{(STD)} - S_{(RBL)}$$

Calculations:

 ΔA sample x 200 = Conc. g/dl zinc

 ΔA sample ΔA standard $\times 30.6 = Conc. mol/l zinc$

Quality control:

All clinical laboratories should establish an Internal Quality Control program. Check instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program. Controls should be assayed:

- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At pre-established intervals following the Q.C. Laboratory recommandations.

Reference Values:

Expected range:

Men: 72.6 - 127µg/dl (11.1-19.5µmol/l) Women: 70.0 - 114µg/dl (10.7-17.5µmol/l)

During pregnancy and menstruation the concentration of zinc could be low.

Children: 63.8 - 110µg/dl (9.8-16.8µmol/l) New born: 49.5 - 99.7µg/dl (7.6-15.3µmol/l)

Urine: 300 - 800mg/24h

Performance characteristics:

Measuring and reportable range:

4 - $2000~\mu g/dl$. Samples with zinc concentration higher than $2000~\mu g/dl$ (306 $\mu mol/l)$ must be diluted 1:10 with normal saline and result multiplied by 10.

Linearity:

Up to 2000 g/dl (306 µmol/l)

Precision:

	Intra-assay				Inter-assay			
	Mean (µg/dL)	SD	%CV		Mean (µg/dL)	SD	%CV	
L1	70.70	1.94	2.74	ĺ	120.90	1.13	0.93	
L2	112.50	4.08	3.62		176.80	3.20	1.81	
L3	172.50	2.77	1.61		N/A	N/A	N/A	

Sensitivity (Lower detection limit):

Detection limit: 4 µg/dl

The lower detection limit represents the lowest measurable zinc activity that can be distinguished from zero.

Interferences:

EDTA anticoagulant masks zinc to 5-Br-PAPS chromogenic system. The test is not affected by the presence of conjugated and non-conjugated bilirubin up to 15 mg/dl, hemoglobin up to 500 mg/dl and triglycerides up to 1000 mg/dl.

Notes:

For in vitro diagnostic use.

Use disposable test tubes and glassware washed with hydrochloric acid 1N solution and distilled water.

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

Working solution must be limpid; do not use if turbid.

R1 contains urea as additive. In the sample order setting, do not input urea test immediately after zinc in "random access" automatic analyzers.

References

1. Johnsen and R.Eliasson: Evaluation of a commercially available kit for the colorimetric determination of zinc. International Journal of Andrology, 1987, April 10 (2): 435-440.

