

ZINC

INTENDED USE

In Vitro Diagnostic reagent for the determination of Zinc in serum and urine on automated and semi-automated analysers.

SUMMARY AND BACKGROUND OF THE CLINICAL UTILITY

Zinc is the second most abundant trace element in humans. It is an integral part of more than two hundred enzymes. Nutritional zinc deficiency is fairly prevalent and symptoms include retardation growth and skeletal maturation, testicular atrophy and hepatosplenomegaly. Decreased levels are found in patients with hepatic cirrhosis gastrointestinal disease, intestinal bypass and Crohns disease. Decreased levels have also been found in patients with renal disease due to proteinuria.

TEST PRINCIPAL

Zinc forms with 2-(5-Brom-2-pyridylazo)-5-(N-propylN-sulfopropylamino)-phenol, (5-Bromo-PAPS), a red chelate complex. The increase of absorbance can be measured and is proportional to the concentration of total zinc in the sample.

KIT COMPOSITION

Monoreagent (ready for use)

5-Br-PAPS	0.02 mmol/l
Buffer pH 9.8	200 mmol/l
Sodiumcitrate	170 mmol/l
Dimethylglyoxime	4 mmol/l
Detergent	1 %

Standard: Conc. printed on the vial label

REAGENT STABILITY

Reagent is stable up to the date of expiry indicated on the kit, if stored at 2–8 °C and contamination is avoided. Protect from light. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION

Human serum or urine. Discard contaminated specimens.

TEST MANUAL PROCEDURE

Wavelength:	560 nm
Temperature:	37 °C
Cuvette:	1 cm light path
Direction:	Increase
Zero adjustment:	Reagent blank

	Sample	Standard
Sample	50 µL	-
Standard	-	50 µL
Reagent R1	1000 µL	1000 µL

Mix, incubate for 10 min, read the absorbance of standard, control and samples.

CALCULATION

The concentration of zinc in unknown samples and controls is obtained using:

$$\text{Zinc } (\mu\text{g/dL}) = \frac{\Delta A_{\text{sample}} \times STD_{\text{conc}}}{\Delta A_{\text{standard}}}$$

QUALITY CONTROL

For quality control use adequate control materials, available from AMS.

REFERENCE VALUES

Serum

Men: 72 – 127 µg/dL

Women: 70 – 114 µg/dL

(During pregnancy and menstruation the concentration of zinc can be very low)

Children: 63 – 110 µg/dL

Newborn: 49 – 99 µg/dL

Urine

300 – 800 µg/24h

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

PERFORMANCE DATA

Linearity: The method is linear up to 400 µg/dL.

The limit of detection: 5 mg/dL.

Method comparison:

$$y = 0.959x - 4.3 / r = 0.972$$

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