ZINC – (Single Reagent)

Diagnostic reagent for the in-vitro quantitative determination of Zinc in human serum and plasma and urine on manual systems.

REF: V/ZN02.025	50 test	REF: V/ZN02.050	100 test

CLINICAL SIGNIFICANCE

Zinc is present in various organs and is a component of many enzymes. Zinc found in serum is totally bound to protein with over 60 % being bound to albumin.
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.

METHOD PRINCIPLE

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

REAGENT COMPOSITION

R1: Standard	200 µg/dl (30.6 µmol/l)
R2: Reagent 5-Br-PAPS Bicarbonate buffer pH 9.8 Sodium Citrate Dimethylglyoxime Detergent	 0.02 mmol/L 200 mmol/L 170 mmol/L 4 mmol/L 1 %

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the **Lab.Vie**. zinc reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

Lab.Vie. Zinc reagents are supplied ready-to-use. All reagents are stable until expiration date stated on label when stored at 2-8°C. Protect from light.

Deterioration
The**Lab.Vie**. zinc reagent is normally clear, do not use reagent if turbid.

SPECIMEN COLLECTION AND PRESERVATION

Use serum or Heparinized plasma or urine.

SYSTEM PARAMETERS

Wavelength	560 nm
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample Reagent Ratio e.g.: Reagent volume Sample volume	1:20 1 ml 50 µl
Temperature	25-37°C
Incubation time	8 min at 25°C 5 min at 37°C
Zero adjustment	Reagent blank
Sensitivity	2.9 µg/dl
Linearity	500 µg/dl

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes, automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

	Blank	Standard	Specimen
Reagent	1.0 ml	1.0 ml	1.0 ml
Standard		50 µl	
Specimen			50 µl

Mix, incubate for 8 minutes at 25°C, or 5 min at 37°C Measure absorbance of specimen and standard against reagent blank.

CALCULATION

$$\text{zinc concentration (µg/dl)} = \frac{\text{Abs. specimen}}{\text{Abs. standard}} \times 200$$

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact **Lab.Vie**. technical support.

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	20	20	20	20
Mean µg/dl	93.1	348.6	94.1	355.5
SD.	1.15	5.05	1.28	5.95
CV. %	1.23	1.45	1.36	1.67

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

Accuracy (Methods Comparison)
Result obtained from **Lab.Vie**. zinc reagent compared with commercial reagent of the same methodology performed on 20 human sera give a correlation of 0.991.

Sensitivity
When run as recommended, the minimum detection limit of the assay is 2.9 µg/dl.

Linearity
The reaction is linear up to concentration of 500 µg/dl. Specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result×2).

INTERFERING SUBSTANCES

Haemoglobin
No significant interference up to 500 mg/dl.
Icterus
No significant interference up to a bilirubin level of 15 mg/dl.
lipemia
No significant interference up to a Triglycerides level of 1000 mg/dl.

EXPECTED VALUES

Serum / Plasma	µg/dl	µmol/l
<4 months	65 – 137	10 – 21
4 – 12 monthes	65 – 130	10 – 20
1 – 5 years	65 – 118	10 – 18
6 – 9 years	78 – 105	12 – 16
10 – 13 years,male	78 – 98	12 – 15
female	78 – 118	12 – 18
14 – 19 years,male	65 – 118	10 – 18
female	59 – 98	9 – 15
Adults	46 – 150	7 - 23

Urine	
24h collected urine	150 – 800 µg/24h
Spontaneous urine	15 – 120 µg/dl

DYNAMIC RANGE

2.9 – 500 µg/dl.

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.
2. Tietz, text book of clinical chemistry and molecular diagnostics ISBN 0-7216-0189-8.

SYMBOLS IN PRODUCT LABELLING			
IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		