ZINC - Liquid

Nitro-Paps Colorimetric Method

R1: 2 x 40 ml + R2: 2 x 10 ml CL55-100S

INTENDED USE

Kit for quantitative determination of zinc in serum, plasma, urine and semen.

CLINICAL MEANING

Zinc is one of the components of nucleic acids and proteins synthesis. It is therefore a fundamental element for cell replication. An adequate zinc intake is necessary to the correct development of the fetus. Acute zinc deficiency in developing children can cause skin lesions, irritability, hair loss and growth retardation.
A reduced immunologic function is usually associated to zinc deficiency.

PRINCIPLE

In an alkaline solution, zinc ions present in the sample, form a red compound when linked to chromogen NITRO-PAPS. The intensity of the color is proportional to the zinc concentration present in the sample.

SAMPLE

Serum, non hemolyzed plasma and urine.
As anticoagulants, only use heparin. It is recommended to collect the sample on an 8-hours empty stomach. Separate serum from the clot as soon as possible. Shake and bring the samples to room temperature before use.
STABILITY: 7 days at 2-8°C, a month at -20°C.
Seminal fluid: centrifuge the samples at 3000 rpm for 10 minutes. Dilute the surnatant 1:100 with saline solution. Multiply the result by 100.

REAGENTS

Only for in Vitro diagnostics.
Liquid reagents ready to use.

Package content	**CL55-125S**
REAGENT 1 (Liquid) Goods buffer 100 mmol/L, preservatives, stabilizers and surfactants.	2 x 40 ml
REAGENT 2 (Liquid) NITRO-PAPS 0.1 mmol/L, preservatives.	2 x 10 ml
STANDARD(Liquid) Zinc 200 µg/dL.	4 ml

STABILITY: if stored at 2-8°C and kept away from light, reagents are stable up to the expiration date on the label. After opening, reagents are stable up to 60 days if stored at 2-8°C.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

MANUAL ASSAY PROCEDURE

Wavelength	578 nm. (570-582 nm)
Optical path	1 cm
Temperature	37°C
Reaction	increasing endpoint
Ratio (monoreagent)	20/1
Ratio (bireagent) R1/R2/C	16/4/1

PREPARATION OF WORKING REAGENT (for monoreagent procedure only)

Mix 4 parts of Reagent 1 with one part of Reagent 2.
STABILITY: 30 days at 2-8°C and 7 days at room temperature (tightly closed).
Pipette in different cuvettes:

	Blank	Sample	Standard
Working reagent	300 µL	300 µL	300 µL
Distilled water	15 µL		
Sample		15µL	
Standard			15 µL

Mix and incubate for 5 minutes and read sample (As) and standard (Ast) absorbencies against blank reagent.

Bireagent procedure

Pipette in different cuvettes:

	Blank	Sample	Standard
Reagent 1	240 µL	240 µL	240 µL
Distilled water	15 µL		
Sample		15µL	
Standard			15 µL

Mix and incubate for 5 minutes and read sample (Abs) and standard (Abst) extinctions against blank reagent.

Reagent 2	60 µL	60 µL	60 µL

Mix and incubate for 5 minutes and read sample (As) and standard (Ast) extinctions against blank reagent.

The coloration is stable for at least 30 minutes at room temperature.
Reaction volumes can be varied proportionally. Calibration with aqueous standard may cause a systematic error in the usage of some automatic instruments. It's recommended to use a proteic human calibrator.

CALCULATION

Monoreagent procedure

Zinc µg/dL = (Ac/As) x 200 (Standard Value)

Bireagent procedure

$$\text{Zinc µg/dL} = \frac{(As - Abs)}{(Ast - Abst)} \times 200 \text{ (Standard Value)}=$$

Conversion factor: [µg/dL] x 0.153 = Zn [µmol/L]

REFERENCE VALUES

Serum/plasma (adults): 70 - 120 µg/dL
Centrifuged seminal fluid: 2 - 10 mg/dL
These values are only for reference. Each laboratory should define their own parameters.

QUALITY CONTROL – CALIBRATION

At each use of the kit it is necessary to verify that the values obtained fall in the reference range mentioned in the instructions. For this reason it is recommended to use Normal and Pathological control serums.

PERFORMANCE CHARACTERISTICS

Measurement range/Linearity: 6 – 400 µg/dL
Measurable limit: 6 µg/dL
Sensitivity: 2 µg/dL a 580 nm
Precision:

Within run (n=30)	Average (µg/dL)	CV (%)
Sample 1	54.5	2.0
Sample 2	123.3	1.4
Sample 3	182.3	1.3

Between run(n=30)	Average (µg/dL)	CV (%)
Sample 1	54.7	1.5
Sample 2	123.4	1.7
Sample 3	181.3	1.7

Correlation: r = 0.9975
Linear Regression: y = 1.01 x + 5.02

Interferences:

Bilirubin (40 mg/dl) does not interfere.
Triglycerides (1500 mg/dl) do not interfere.
Haemoglobin (300 mg/dl) does not interfere.

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

The compound is not classified as dangerous according to current laws. Total concentration of non active components (preservatives, detergents, stabilisers) is inferior to required limits. Nevertheless, handle the product with care, using the normal precautions expected with correct behaviour in laboratory. Avoid ingestion, contact with skin, eyes and mucous membranes. Samples should be handles as potentially infected by HIV or hepatitis.

REFERENCE

1. Hinggins, T., et al. Clin. Chem., 27, 1619, (1981)
2. Vassault, A.et al. Ann. Biol. Clin., 44,686, (1986)
3. Young D.S., et. al., Clin. Chem. 21 :1D (1975)

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KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalogue number
	temperature limits
	use by
	caution
	consult accompanying documents

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