



ZINC (2–8°C)

CATALOGUE NUMBER	KIT SIZE (ml)
MPRZN02	2x50ml/1x5ml

Intended Use:

For *In Vitro* diagnostic use by trained professionals only.

This reagent is intended for the quantitative determination of zinc in human serum, plasma and urine.

Clinical Significance:

Zinc is a component of over 200 metalloenzymes, among which are those involved in nucleic acid and protein synthesis. It is therefore a necessary component for cell replication. Adequate zinc supply is essential for healthy development. Zinc deficiency can become apparent with skin lesions, loss of hair, retarded growth and is associated with impaired immunological function.

Test Principle:

Zinc reacts with the 5-Br-PAPS to form a stable complex, the formation of which is directly proportional to the level of zinc in the sample and can be measured spectrophotometrically. Interference from iron and copper are eliminated from the reaction by assay conditions and masking agents.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
Zinc Reagent R1 (Br-PAPS)	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%
Standard	Zinc	30.6 µmol/l (200 µg/dl)

Reagent Preparation and Stability:

R1: Liquid, ready to use

Standard: Liquid, ready to use

R1 and Standard are stable to the expiry date when stored unopened at 2 – 22°C.

Dispose of reagents carefully in line with local guidelines.

Sample / Sample Preparation / Sample Stability:

Collect serum and Li-heparin plasma by standard venepuncture technique. Do not use EDTA as an anticoagulant as it sequesters the substrate 5-Br-PAPS in the assay.

Assay Procedure:

Pre-rinse all glassware with 1M HCl prior to use

WAVELENGTH	546 nm
TEMPERATURE	25°C / 37°C
CUVETTE	1cm Path Length
BLANK	Reagent Blank

	Blank	Standard	Sample
Sample	-	-	50 µl
Standard	-	50 µl	-
Distilled water	50 µl	-	-
Reagent	1000 µl	1000 µl	1000 µl
Mix and incubate for 5 minutes at 37°C or 10 minutes at 25°C. Read the absorbance (Δ Abs) of Sample/Standard against the Reagent Blank.			

Calculation:

Concentration = $\frac{\Delta \text{Abs Sample}}{\Delta \text{Abs Standard}} \times \text{Concentration of Standard}$

Performance Characteristics:

Measuring range:

4 - 2000 µg/dl (0.6 - 306 µmol/l)

Dilute samples with higher concentrations using Normal saline 1+9 and rerun the assay. Multiply the result by the dilution factor (for 1+9 dilution, the dilution factor is 10)

Analytical Sensitivity: (Lowest detection limit):

4 µg/dl (0.6 µmol/l)

Imprecision

Intra-Assay Precision:

Sample	Mean (µg/dl)	SD (µg/dl)	CV %
LEVEL 1	70.70	1.94	2.74
LEVEL 2	112.5	4.08	3.62
LEVEL 3	172.5	2.77	1.61

Inter-Assay Precision:

Sample	Mean (µg/dl)	SD (µg/dl)	CV %
LEVEL 1	120.9	1.13	0.93
LEVEL 2	176.8	3.20	1.81

Interferences:

Icterus: No significant interference up to 15 mg/dl of Bilirubin.

Haemolysis: No significant interference up to 500 mg/dl of Haemoglobin.

Lipemia: No significant interference up to 1000 mg/dl of Triglycerides.

Reference Range:

Male	72.6 – 127 µg/dl (11.1 – 19.4 µmol/l)
Female	70 – 114 µg/dl (10.7 – 17.5 µmol/l)
Child	63.8 – 110 µg/dl (9.76 – 16.8 µmol/l)
Newborn	49.5 – 99.7 µg/dl (7.57 – 15.3 µmol/l)
Urine	300 – 800 mg/24 hr

Each laboratory should establish its own mean reference range according to the population.

Limitations of the Test:

Do not use EDTA as a plasma anticoagulant.

The result from this test should not be used as the sole criteria for the diagnosis of zinc deficiency, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Automated systems:

Contact AMS UK Technical Department for applications on a wide range of automated analysers.

For automation we recommend the use of a serum based calibrator.

Quality Control and Calibration Material:

Calibration Serum: QCCCAL1 / QCCCAL2

Human Assayed Control Normal: QCCHAN1 / QCCHAN2

Human Assayed Control Elevated: QCCHAE1 / QCCHAE2

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

REF	Catalogue number	LOT	Temperature limitation
IFU	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device	LOT	Use by Date
MAN	Manufacturer		

