Zinc Assay Kit (Zn)

Method: PAPS Reagent

Cat .No.	Size	Instrument
GB430E	R1: 2×40 ml R2: 1×20 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS431E	R1: 2×40 ml R2: 1×20 ml	For Hitachi917 & OlympusAU640/400/600
GH431E	R1: 2×40 ml R2: 1×20 ml	For Hitachi902
GX431E	R1: 1×80 ml R2: 1×20 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-8
GD431E	R1:24×4.3 ml R2: 6×4.3 ml	For DATE DEMENSION

INTENDED USE
For the *in vitro* quantitative determination of Zinc in serum.

CLINICAL SIGNIFICANCE[1]
Zinc is an essential trace metal, which is second only to Iron. It is present in Zinc metalloenzymes e.g. Carbonic anhydrase, alkaline phosphatase, R.N.A and D.N.A polymerases, thimidine kinase, carboxypeptidases and alcohol dehydrogenase.

ASSAY PRINCIPLE[2]
Zinc present in the sample is chelated by Nitro-PAPS in the reagent. The formation of this complex is measured at a wavelength of 570 nm.

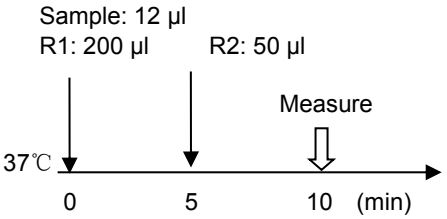
SAMPLE COLLECTION AND PREPARATION
Serum.
Serum samples are stable for one week at 4℃.

REAGENT COMPOSITON

Contents	Concentration of Solutions
R1	
borate buffer, pH 8.20	370 mmol/L
salicylaldoxime	12.5 mmol/L
dimethylglyoxime	1.25 mmol/L
surfactants	
preservatives	
R2	
Nitro-PAPS	0.40 mmol/L
Calibrator	200 μg/dl

STABILITY AND PREPARATION OF REAGENTS
All reagents are ready to use.
Unopened kit: Up to the expiry date at 2-8℃.
The reagents are stable for 1 month after opening and kept at 2-8℃.

ASSAY PROCEDURE
Test Procedure for Analyzers (HITACHI 917)
Assay Mode: End Point, 34
Wave Length (main): 570 nm



1. Mix 12 μl sample with 200 μl R1 and incubate at 37℃ for 5 minutes.
2. Add 50 μl R2 into cuvette, mix and incubate for another 5 minutes at 37°C
3. Measure the absorbance of the sample (A_{sample}) and calibrator ($A_{calibrator}$) against reagent blank.

CALCULATION
$$\text{Concentration} = \frac{A_{sample} - A_{blank}}{A_{calibrator} - A_{blank}} \times \text{Calibrator value}$$

CALIBRATION
Recommend that this assay should be calibrated using Gcell Calibrator (Cat .No: GC-Zn）.

QUALITY CONTROL
Randox Assayed Multi-sera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE
Serum :70-115 μg/dl (10.7-17.7 μmol/L)

CONVERSION FACTORS
μmol/L× 6.51=μg/dl

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY
The method is linear up to 500 μg/dl. If the concentration exceeds the top value, further dilute the sample 1+1 with 0.9% NaCl solution and repeat assay. Multiply the result by 2.

PRECISION
The CV of the test should be less than 5%.

Intra assay precision		
N=20	Level 1	Level 2
Mean	24.76	20.55
SD	0.78	0.96
CV	3.13%	4.66%
Inter assay precision		
N=5	Level1	Level 2
Mean	24.51	21.07
SD	0.94	0.92
CV	3.84%	4.37%

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SENSITIVITY

The minimum detectable concentration of Zn with an acceptable level of precision was determined as 6.92 ug/dl.

INTERFERENCE

Bilirubin ≤50 mg/dl, Ascorbic Acid ≤ 200 mg/dl,
Heparin sodium ≤ 100 U/ml, without interference;
Intralipid ≤500 mg/dl , Interference.

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
Y=1.073X-1.609, R^2=0.997; 237 patient samples were analyzed.

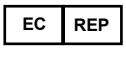
SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. The reagents contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. M. Saito, T. Makino et al., Clinica Chimica Acta, 120(1982) 127-135.
2. R. Homster, B. Zak, Clin. Chem. 31/8, 1310-1313(1985).

INDEX OF SYMBOLS

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
	Authorized Representative in the European Company

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