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Zinc

5-Br-PAPS

(en) English

REF	Content	
507201B	1 x 1 L	Single Reagent
507240	5 x 25 mL	Single Reagent
587911	5 x 50 mL	Single Reagent
50446917	5 x 50 mL	Single Reagent
5A0848	5 x 20 mL	Single Reagent
5T1048	5 x 20 mL	Single Reagent
5K0745	5 x 50 mL	Single Reagent
5E1848	5 x 20 mL	Single Reagent

For professional in vitro diagnostic use only.

INTENDED USE

Diagnostic reagent for quantitative in vitro determination of zinc in human serum, plasma or urine on photometric systems.

DIAGNOSTIC SIGNIFICANCE[1]

Zinc is involved in many enzymatic reactions at the molecular level. It plays an important role in the synthesis of DNA and RNA and exerts a clearly enhancing effect on the immune system. Another important function of zinc is its involvement in the cellular protective function against free radicals and reactive oxygen compounds.
Causes of zinc deficiency may be – among others – malnutrition, malabsorption, diseases of the small intestine, alcoholism, diabetes mellitus, rheumatic disorders, acute and chronic infections, or chronic liver diseases.

TEST PRINCIPLE

Zinc forms with 2-(5-Brom-2-pyridylazo)-5-(N-propyl-N-sulfo-propylamino)-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

COMPONENTS	CONCENTRATION	
Bicarbonate buffer pH 9.4	200	mmol/L
5-Br-PAPS	0.02	mmol/L
Sodiumcitrate	170	mmol/L
Dimethylglyoxime	4	mmol/L
Detergent	1	%

MATERIAL REQUIRED BUT NOT PROVIDED

- Standard or Calibrator, eg.:

REF	Name	Content
507263SV	Zinc Standard	1 x 3 mL

- Controls, eg.:

REF	Name	Content	Description
D98481	Diacon N	12 x 5 mL	control normal
D14481	Diacon N	5 x 5 mL	control normal
D98481SV	Diacon N	1 x 5 mL	control normal
D98482	Diacon P	12 x 5 mL	control abnormal
D14482	Diacon P	5 x 5 mL	control abnormal
D98482SV	Diacon P	1 x 5 mL	control abnormal

- NaCl solution (9 g/L).
- Photometric device with a 500 –600 filter.
- General laboratory equipment.

REAGENT PREPARATION

The reagent is ready to use.

STORAGE AND STABILITY

Conditions:	Store at 18 – 22 °C. Protect from light. Close immediately after use.
Stability:	30 days after first opening of the primary container.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Please refer to the safety data sheet and take the necessary precautions for the use of laboratory reagents.
3. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
4. For professional use only!

SPECIMEN COLLECTION AND STORAGE

Use serum, plasma or urine.
Do not use EDTA plasma, which results in wrong values!

STANDARD

(has to be ordered separately)
Concentration: 200 µg/dL (30.6 µmol/L)
Storage: 18 – 22 °C
Stability: up to the indicated expiration date
Close immediately after use! Avoid contamination! Protect from light!

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Standard	Sample
Reagent	1000 µL	1000 µL	1000 µL
Sample	-	-	50 µL
Standard	-	50 µL	-
dist. water	50 µL	-	-
Mix and incubate for 8 minutes at 25 °C or for 5 minutes at 37 °C. Measure absorbance of the standard and sample at 560 nm against the reagent blank.			

AUTOMATION

Applications for automated systems are available upon request.

INTERPRETATION OF RESULTS

Calculation

$$\text{Zinc [µg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Standard}} \times \text{conc. of Standard [µg/dL]}$$

Unit Conversion
Zinc [µg/dL] x 0.153 = Zinc [µmol/L]

QUALITY CONTROL AND CALIBRATION

All control sera with Zinc values determined by this method can be used.
We recommend the Dialab serum controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the abnormal range).
Each laboratory should establish corrective actions in case of deviations in control recovery.

Calibration
The assay requires the use of a Zinc Standard or a Zinc Calibrator.
We recommend the Dialab **Zinc Standard**.

PERFORMANCE CHARACTERISTICS

Accuracy and precision
CV ≤ 2 % for within- and between-run precision.

Analytical sensitivity
Limit of detection: 2.9 µg/dL (0.444 µmol/L)

Linearity and measuring range
The test has been developed to determine zinc concentrations with a measuring range from 2.9 – 500 µg/dL (0.444 – 76.5 µmol/L). If values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/dL) and the result multiplied by 2.

Analytical specificity
No interferences was observed for:

Bilirubin	≤ 15 mg/dL
Hemoglobin	≤ 160 mg/dL
Triglycerides	≤ 1000 mg/dL

Clinical performance
A method comparison with an approved system using 66 patient samples gave the following results: y = 0.9663 x + 2.6613, r = 0.9911.

Tests were performed on the following instruments: Hitachi 717 Roche or CA-800.

TRACEABILITY

The assigned value of the standard has been made traceable to ICP-SFMS.

EXPECTED VALUES

Serum/Plasma:		[µg/dL]	[µmol/L]
< 4 months		65 - 137	10 - 21
4 – 12 months		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			
	150 - 800	µg/24h	24h collected urine
	15 – 120	[µg/dL]	spontaneous urine

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

LIMITATIONS

NA

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 347-9.
2. 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.

CE IVD 18°C 22°C