Zinc (Zn)
(5-Br-PAPS Method)

- **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: **ZN0011**	R. Zinc-Reagent: 2 x 50 ml total 100 ml	15-25°C
Cat. No.: **ZN0017**	R. Zinc-Reagent: 2 x 50 ml total 100 ml	15-25°C

- **Intended Use:**
In Vitro Diagnostic reagent pack for the quantitative determination of Zinc in human serum, plasma and urine on automated and semi-automated photometric systems.

- **Summary and Explanation:**
Zinc is the second most abundant trace element in humans. It is an integral part of more than two hundred enzymes. Nutritional zinc deficiency is fairly prevalent and symptoms include retardation growth and skeletal maturation, testicular atrophy and hepatosplenomegaly. Decreased levels are found in patients with hepatic cirrhosis gastrointestinal disease, intestinal bypass and Crohn's disease. Decreased levels have also been found in patients with renal disease due to proteinuria. 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.

- **Principle of the Method:**
Direct colorimetric test without deproteinization of the sample. Zinc forms with 5-Br-PAPS a red chelate complex. The increase of absorbance can be measured and is proportional to the concentration of total zinc.

- **Reagent Preparation and Stability:**
Reagent is ready for use.
Before use, mix reagent by gently inverting each bottle.
Reagent is stable until the expiration date on the label when stored tightly closed at 15-25°C, protected from light and contaminations prevented during their use.
The color of reagent is light orange.
Do not use reagent over the expiration date.
Do not freeze and protect from light.

- **Waste Management:**
Refer to local legal requirements for chemical disposal regulations.
Warning: Handle waste as potentially biohazardous material.
Dispose of waste according to accepted laboratory instructions and procedures.

- **Warnings and Precautions:**
For In Vitro Diagnostics Use Only.
For Professional Use Only.
Carefully read instructions for use.
In case of serious damage to the bottle or cap, resulting in product leakage or contamination, do not use the reagent pack and contact your distributor.
Take all necessary precautions required when handling laboratory reagents.
Do not use components past the expiry date stated on the Bottles.
Do not interchange caps among components as contamination may occur and compromise test results. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.

- **Type of Specimen:**
Use fresh and non-haemolysed serum or heparin plasma (collecting the blood in Fasting stage) or 24h urine, as specimen.
Do not use EDTA plasma.
Specimen must be completely cleared before assay.
Centrifuge turbid urine samples before performing assay.
Stability: 7 days at 2-8°C and -20°C in 14 days.

- **Materials Required but not Supplied:**
General chemistry calibrator from TKS or other valid calibrators.
General chemistry control Level 1 & 2 from TKS or other valid controls.
Saline solution 0.9 % NaCl
General laboratory equipments

- **Notes:**
Carefully read instructions for use.
It is recommended to use disposable material. If glassware is used the material should be scrupulously cleaned with hydrochloric acid 1 N and then thoroughly rinsed it with distilled water.
Use clean disposable pipette tips for its dispensation.
Disposable and glassware material used must be free of metals, ions and detergents.

- **Performance Characteristics:**
Performance results can vary with the instrument used.
Data obtained in each individual laboratory may differ from these values.

Maximum determination in this assay is 400 µg/ dl
For samples with a higher concentration (400 µg/dl), dilute 1:1 with 0.9 % NaCl (0.9 %) and re-assay. Multiply result by 2.
LOD: 5 µg/ dl

Precision:

Intra assay-Within run Zinc

Sample	n	Mean (µg/dl)	SD (µg/dl)	CV (%)
1	20	103.92	1.28	1.23
2	20	201.3	2	0.99

Inter assay-Between run Zinc

Sample	n	Mean (µg/dl)	SD (µg/dl)	CV (%)
1	20	147.05	1.57	1.06
2	20	283	2.33	0.82

- **Accuracy:**
Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).
The results obtained using 80 samples were the following:
Correlation coefficient (r): 0.995
Regression equation: Y = 1.002 (X) + 1.136 µg/dl
The results of the performance characteristics depend on the analyzer used.

- **Interfering Substances:**
No interferences were observed to:

Ascorbic acid	200 mg/dl
Hemoglobin	750 mg/dl
Bilirubin	< 50 mg/dl
Triglycerides	< 500 mg/dl

EDTA interfere in the test.

- **Reference Values:**

Serum/Plasma		
< 4 months	65-137 µg/dl	10-21 µmol/L
4-12 months	65-130 µg/dl	10-20 µmol/L
1-5 years	65-118 µg/dl	10-18 µmol/L
6-9 years	78-105 µg/dl	12-16 µmol/L
10-13 years (Male)	78-98 µg/dl	12-15 µmol/L
10-13 years (Female)	78-118 µg/dl	12-18 µmol/L
14-19 years (Male)	65-118 µg/dl	10-18 µmol/L
14-19 years (Female)	59-98 µg/dl	9-15 µmol/L
Men	73-127 µg/dl	
Women	70-114 µg/dl	
Urine 24h	0.2-1.3 mg/24h	

Each laboratory should establish its own expected values. The Zinc results should always be reviewed with the patient's medical examination and history.

نشانی کارخانه: کیلومتر ۵۴ جاده تهران–سمنان، شهرک صنعتی پایتخت، بلوار نخل، بلوارتوسکا، نیلوفر۶ **نشانی دفتر مرکزی:** تهران، یوسف آباد، خیابان اسد آبادی، کوچه سی و دوم، پلاک ۵
تلفن: ۹ الی ۸۸۵۴۹۷۵۴ – ۰۲۱ **ارتباط با پشتیبانی:** ۰۹۱۲۹۵۷۹۴۰۹ – ۰۹۱۲۹۵۷۹۴۰۸
www.tksmed.com info@tksmed.com

- **Assay Procedure:**

Allow reagents to reach working temperature before using.
A proportional variation of the reaction volumes indicated does not change the result.

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Assay conditions:

560nm	**Wavelengths**
25-30-37 °C	**Incubation Temperature**
1 cm	**Cuvette**

Adjust the instrument to zero with distilled water.

Control/Sample/Calibrator	**Blank**	
1000 µl	1000 µl	**R**
50 µl	-	**Control/Sample/Calibrator**
Gently mix and incubate for 5 minutes at 37°C. or 10 minutes at 25°C Absorbance against blank would be apply		

- **Calculations:**

$$\text{Zinc (µg/dl)} = \frac{\text{Abs. Sample}}{\text{Abs. STD./Cal.}} \times \text{Cal./STD. Conc. (µg/dl)}$$

$$\text{Urine Zinc (µg/24h)} = \frac{\text{Urine zinc (mg/dl) x Urine volume (ml)}}{100000}$$

- **Conversion Factor:**

Zinc (µg/dl) x 0.153 = Zinc (µmol/L)

TOSE'E KIMIS SA'ADAT has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

- **References:**

1-M. Saito, T. Makino et al., Clinical Chimica Acta, 120 (1982) 127-135.
2-Lokitch G. Trace elements in Pediatric. JIFCC 1996; 9:46-52.
3-Fuentes J. et.al.; Simple colorimetric method for plasma, seminal Zinc assay; ANDROLIGIA 14/4(1982) 322-327.
4-R. Homster, B. Zak, Clin.Chem.31/8, 1310-1313 (1985).

ISO 13485:2016
ISO 9001:2015

IVD

- **Symbols:**

The following symbols are used in the labelling of TOSE'E KIMIS SA'ADAT systems:

IVD	In Vitro Diagnostics		Contains sufficient for <n> tests
LOT	Batch Code		Temperature limit
REF	Catalogue No.		Consult instruction for use
	Expiry Date		Caution
	Date of Manufacture		Keep dry
	Manufactured by		This way up
	Biological Risks		Keep away from sunlight

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