

• **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: CA0011	R.1: 6 x 50 ml total 3 · 0 ml	2-8°C
Cat. No.: CA0017	R.1: 5 x 60 ml total 300 ml	2-8°C

• **Intended Use:**

In Vitro Diagnostic reagent pack for the quantitative determination of Calcium in human serum/plasma and urine on automated and semi-automated photometric systems.

• **Summary and Explanation:**

Calcium is an essential in cellular activity. The calcium existence is a critical in muscle contraction, heart activity, neuro transition and blood coagulation. The intercellular muscle contraction and glycogen metabolism and external in mineralization of bone is found.

The 99 to 98 percent of calcium is in a structure of bone and teeth. In plasma 50 percent is found free on blood, 40 percent is attached to the protein and 10 percent is related to anions such as phosphate, citrate and bicarbonate. The hypercalcemia is occurred in 90 to 95 percent is related to some diseases such as carcinoma disease, cancer of breast, lung and pancreas. The rest of it is related to osteoporosis, parathyroid disease, kidney disease also the increase protein on plasma in serum and lack of exercise. The Hypocalcemia mainly is related to hypo parathyroids, malabsorption, kidney failure, liver cirrhosis and decrease of magnesium. The level of the calcium in serum is influenced by protein concentration and in variation disease such as dehydration and carcinoma in kidney and liver is increased. Also, the decrease level of calcium is critical in clinical evaluation.

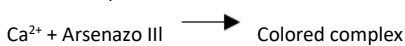
The low concentration of the total calcium is related to the bone disease especially in osteoporosis, kidney disease (dialysis patient), hypo parathyroids and malabsorption in bowel, mal nutrition and vitamin D deficiency.

The high concentration of total calcium is related on hypercalcemia, carcinoma tumors, sarcoidosis, bone disease and vitamin D toxicity.

The measurement of calcium is key for analysis on calcium compound in osteoporosis, activity of para-thyroid, calcium metabolism, situation of kidney patients and malignancy.

**Principle of the Method:**

This method is based on calcium ions in neutral background with Arsenazo activity the color of the complex is blue/purple which measurement on 630 to 660 nm. The intensity of the color will have measured on 630-660 Nano meter wavelength which is correlate with the amount of calcium in sample. on the sample.



• **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 2-8°C, protected from light and contaminations prevented during their use.  
Do not use reagents over the expiration date.  
Do not freeze and protect from light.  
The reagent is dark violet.

**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 Urine, fresh serum, non-hemolysis, plasma heparinized. The stability of Calcium in the samples at 2-8°C for 21 days and at -20°C for 7 months. The calcium stability on room temperature is 7 days.

The serum and plasma should have collected during 8 hours after blood collection. The stability of calcium in urine at room temperature is 2 days. at 2-8°C for 4 days and at -20°C for 21 days. The measurement of calcium in urine should be diluted by milliQ- water 1 in 4 ratios. Then number should multiply on 5. The best result was observed when 10 ml of high concentrate HCL added in 24 hrs urine to prevent interface calcium oxalate. Then warm up the samples and prevent contamination samples.

**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 20mg/dl

**LOQ: 1 mg/dl**

For samples with a higher concentration (20mg/dl), dilute 1:1 with 0.9 % NaCl and re-assay. Multiply result by 2.

**Precision:**

**Intra Assay-Within run Calcium**

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	8.35	0.08	0.95
2	20	14.28	0.08	0.59

**Inter Assay-Between run Calcium**

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	8.58	0.19	2.24
2	20	14.57	0.34	2.31

• **Accuracy:**

Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).

**Correlation coefficient (r):** 0.9506

**Regression equation:** Y = 0.8944 (X) +1.3421 mg/dl

The results of the performance characteristics depend on the analyzer used.

• **Interfering Substances:**

the less concentration of hemoglobin is interfering in this assay.

<b>Bilirubin (mixed isomer)</b>	Less than 10% interference up to 600 µmol/L Bilirubin
<b>Lipaemia</b>	Less than 10% interference up to 2.5 g/L Intralipid.
<b>Haemolysis</b>	Less than 10% interference up to 5g/l Hemoglobin.

• **Reference Values:**



<b>Serum/Plasma</b>	
<b>Adults</b>	<b>8.5-10.5 mg/dl</b>
<b>Children</b>	<b>10-12 mg/dl</b>
<b>Newborns</b>	<b>8-13 mg/dl</b>

<b>Urine</b>	
<b>Adults</b>	<b>50-300 mg/24h</b>
<b>Children</b>	<b>80-160 mg/24h</b>

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

### • Assay Procedure:

Allow reagents to reach working temperature before using.

A proportional variation of the reaction volumes indicated does not change the result

### Assay conditions:

630-660nm	<b>Wavelengths</b>
37 °C	<b>Incubation Temperature</b>
1 cm	<b>Cuvette</b>

Adjust the instrument to zero with distilled water.

<b>Control/Sample/Calibrator</b>	<b>Blank</b>	
1000 µl	1000 µl	<b>R</b>
10 µl	-	<b>Control/Sample/Calibrator</b>
<p><b>Gently mix and incubate for 2 minute at 37°C.</b> then measure the absorbance from sample and A calibrator. The absorbance of sample and calibrator against the blank. The stability of color is 30 minutes. Avoiding in direct light.</p>		

### • Calculations:

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

$$\text{Calcium in Urine(mg/dl)} = \frac{\text{Abs. sample}}{\text{Abs. STD./Cal.}} \times \text{Cal./STD.Conc(mg/dl)} \times 11$$

$$\text{Calcium in Urine (mg/24h)} = \frac{\text{Urine calcium(mg/dl)} \times \text{Urine Volume (ml)}}{100}$$

### Conversion units:















$$\text{Calcium (mg/dl)} \times 0.2495 = \text{Calcium (mmol/L)}$$

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

### • References:

- 1-Farell E C. Calcium. Kaplan A et al. Clin Chem the C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1051-1255 and 418.
- 2-Kessler G. et al. Clin Chem Vol 10, No 8 1964; 686-706.
- 3-Connerty H. V. et al. Am J Clin Path Vol 45, No 3 1996; 200-296.
- 4-Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
- 5-Young DS. Effects of disease on Clinical Lab. Tests, 4th ed. AACC 2001.
- 6-Burtis A. et al. Tietz Textbook of Clinical Chemistry, 3rd ed. AACC 1999.
- 7-Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed. AACC 1995.

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

 In Vitro Diagnostics	 Contains sufficient for <n> tests
 Batch Code	 Temperature limit
 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



Rev 01: Issued on 20 February 2023