ISE S.r.l.

CUSTOMISED SOLUTIONS
FOR YOUR LABORATORY

Calcium – Instructions for use

CE

IVD

R1: 4x 17,5 mL **R3330000012**

REF

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

TEST PARAMETERS

Method:	Colorimetric, Endpoint, increasing reaction, Arsenazo III
Wavelength:	650 nm, Hg 623 nm, (630 – 670 nm)
Temperature:	20 – 25 °C, 37 °C
Sample:	Serum, heparin plasma or urine do not use EDTA plasma.
Linearity:	up to 20 mg/dL (5 mmol/L)
Sensitivity:	The lower limit of detection 0.04 mg/dL (0.01 mmol/L)

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
Phosphate buffer, pH 7.5	50 mmol/L
8–Hydroxyquinoline-5-sulfonic acid	5 mmol/L
Arsenazo III	120 µmol/L
Detergents	

REAGENT PREPARATION

The reagent is ready for use.

REAGENT STABILITY AND STORAGE

Conditions:	Close immediately after use Avoid contamination Do not freeze the reagent.
Storage:	at 2 – 8 °C
Stability:	up to the indicated expiration date

SAMPLE PREPARATION

Urine: add 10 ml of concentrated HCl to 24 h Urine and heat the specimen to dissolve calcium oxalate.

SAMPLE STABILITY AND STORAGE [5]

In serum/plasma:	at 20 – 25 °C	7 days
	at 4 – 8 °C	3 weeks
	at -20 °C	8 months
In urine:	at 20 – 25 °C	2 days
	at 4 – 8 °C	4 days
	at -20 °C	3 weeks

Discard contaminated specimens. Freeze only once!

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

STANDARD

(not included in the kit; has to be ordered separately)

Concentration	10 mg/dL (2.5 mmol/L)
Storage:	2 – 25 °C
Stability:	up to the indicated expiration date

PROTECT FROM LIGHT. CLOSE IMMEDIATELY AFTER USE!

INTERFERING SUBSTANCES

no interference up to:

Ascorbic acid	30 mg/dL
Bilirubin	40 mg/dL
Hemoglobin	500 mg/dL
Triglycerides	2000 mg/dL
Magnesium	15 mg/dL

Strontium salts in medicine may lead to strongly increased calcium values.

For further information on interfering substances refer to Young DS [6].

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Std./Cal.	Sample
Reagent	1000 µL	1000 µL	1000 µL
Sample	-	-	10 µL
Std./Cal.	-	10 µL	-
Dist. water	10 µL	-	-
Mix, Incubate for 5 minutes at 20 – 25 °C / 37 °C and read absorbance against reagent blank.			

CALCULATION

$$\text{Calcium [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{conc. of Std/Cal [mg/dL]}$$

UNIT CONVERSION

Calcium [mg/dL] x 0.2495 = Calcium [mmol/L]
Calcium (urine) [mg/24h] x 0.025 = Calcium (urine) [mmol/24h]

REFERENCE RANGE [4] *

Serum/plasma [2]:	mg/dl	mmol/L
	8.6 - 10.3	2.15 – 2.57
Urine [1]:	mg/24h	mmol/24h
Females:	< 250	< 6.24
Males:	< 300	< 7.49

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

SUMMARY [1,2]

Calcium plays an essential role in many cell functions: intracellularly in muscle contraction and glycogen metabolism, extracellularly, in bone mineralization, in blood coagulation and in transmission of nerve impulses. Calcium is present in plasma in three forms: free, bound to proteins or complexed with anions as phosphate, citrate and bicarbonate. Decreased total calcium levels can be associated with diseases of the bone apparatus (especially osteoporosis), kidney diseases (especially under dialysis), defective intestinal absorption and hypoparathyroidism. Increased total calcium can be measured in hyperparathyroidism, malignant diseases with metastases and sarcoidosis. Calcium measurements also help in monitoring of calcium supplementation mainly in the prevention of osteoporosis.

TEST PRINCIPLE

At neutral pH, calcium forms a blue coloured complex with arsenazo III. The intensity of the colour is proportional to the calcium concentration. Interference by magnesium is eliminated by addition of 8-hydroxyquinoline-5-sulfonic acid.

I.S.E S.r.l.
Via Delle Driadi, 45 – 00133 Roma
Tel.+39 0774579365; FAX +39 0774579305
www.logotech-ise.com E-mail: info@logotech-ise.com

Revision A R3330000012 11-2018

ISE S.r.l. **Calcium** – Instructions for use

CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

CE IVD

R1: 4x 17,5 mL **R3330000012** REF

PERFORMANCE CHARACTERISTICS

Linearity, Measuring rane

The test has been developed to determine calcium concentrations within a measuring range from 0.04 – 20 mg/dL (0.01 – 5 mmol/L). When values exceed this range samples should be diluted 1+1 with NaCl solution (9 g/L) and the results multiplied by 2.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 0.04 mg/dL (0.01 mmol/L)

Precision (AT 20 – 25 °C)

Intra-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	8.79	0.09	1.04
Sample 2	12.5	0.15	1.20
Sample 3	14.0	0.24	1.73

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	8.82	0.18	2.01
Sample 2	12.3	0.11	0.90
Sample 3	13.7	0.26	1.92

Method Comparison

A comparison of this Calcium (y) with a commercially available assay (x) using 70 samples gave following results:
y = 1.02 x – 0.20 mg/dL; r = 0.999.

QUALITY CONTROL

All control sera with Calcium values determined by this method can be used. We recommend our serum controls Normal control serum (control serum with values in the normal range) and Pathological control serum (control serum with values in the abnormal range).
Each laboratory should establish corrective action in case of deviations in control recovery.

CALIBRATION

The assay requires the use of a calcium standard or a calcium calibrator.
We recommend our Multicalibrator which method has been standardized against the reference method Atomic Absorption Spectrometry (AAS).

AUTOMATION

Special adaptations for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

1. As calcium is an ubiquitous ion, essential precaution must be taken against accidental contamination. Only use disposable materials.
2. Traces of chelating agent, such as EDTA can prevent the formation of the coloured complex.
3. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
4. In very rare cases, samples of patients with gammopathy might give falsified results. (7)
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
6. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
7. For professional use only!

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p.231-41.
2. Endres DB, Rude RK. Mineral and bone metabolism. In: Burtis CA, Ashwood ER. editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B. Saunders Company; 1999. p.1395-1406.
3. Michaylova V, Ilkova P. Photometric determination of micro amounts of calcium with arsenazo III. Anal chim Acta 1971; 53:194-8.
4. Bauer PJ. Affinity and stoichiometry of calcium binding by arsenazo III. Anal Biochem 1981;110:81-72.
5. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p.20-1 and p.50-1.
6. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
7. Bakker AJ, Mucke M. Gammopathy interference in clincal chemistry assays: mechanism, detection and prevention. ClinChemLabMed 2007; 45 (9): 1240-1243.

Symbols on labels and packaging

IVD = In vitro diagnostic medical device

REF = Catalog Number

LOT = Lot Number

= Manufacturer

= Expiration date

= Temperature limitation

= Instruction for use

I.S.E S.r.l.
Via Delle Driadi, 45 – 00133 Roma
Tel.+39 0774579365; FAX +39 0774579305
www.logotech-ise.com E-mail: info@logotech-ise.com

Revision A R3330000012 11-2018