Calcium AS FS

Calcium Reagent test Kit

Intended use
Diagnostic reagent for in vitro quantitative determination of calcium in human serum or urine on photometric analyzers.

Reagent Kits

Item Code	Packsize
111309934840	R: 4 x 60 mL

Summary
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.

Method
Photometric test using arsenazo III

Principle
Calcium with arsenazo III at neutral pH yields a blue colored complex, whose intensity is proportional to the calcium concentration. Interference by magnesium is eliminated by addition of 8-hydroxyquinoline-5-sulfonic acid.

Storage Instructions and Reagent Stability
Reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagent! Protect the standard from light!

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagent and the standard are ready-to-use.

Traceability
This method has been standardized against the reference method Atomic Absorption Spectrometry (AAS).

Reagent Components

Phosphate buffer	pH 7.5	50 mmol/L
8-Hydroxyquinoline-5-sulfonic acid		5 mmol/L
Arsenazo III		120 µmol/L

Materials required but not provided
NaCl solution 9 g/L.
General laboratory equipment

Specimen
Serum, heparin plasma or urine Do not use EDTA plasma. Stability [5]

in Serum/Plasma:	7 days	at	20 – 25°C
	3 weeks	at	4 – 8°C
	8 months	at	–20°C
in Urine:	2 days	at	20 – 25°C
	4 days	at	4 – 8°C
	3 weeks	at	–20°C

Add 10 mL of concentrated HCl to 24 h urine and heat the specimen to dissolve calcium oxalate.
Discard contaminated specimens. Freeze only once!

Assay Procedure

Wavelength	600 - 630 nm
Optical path	1 cm
Temperature	20 – 25°C
Measurement	against reagent blank

	Blank	**Sample or standard**
Sample or standard	-	4 µL
Dist. water	4 µL	-
Reagent	200 µL	200 µL

Mix, incubate for 2 min. and read absorbance against reagent blank.

Calculation
With standard or calibrator

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

Conversion factor
Calcium [mg/dL] x 0.2495 = Calcium [mmol/L]
Calcium/U [mg/24 h] x 0.025 = Calcium/U [mmol/24 h]

Calibrators and Controls
For calibration of automated photometric systems the DiaSys TruCal U calibrator is recommended. This method has been standardized against the reference method Atomic Absorption Spectrometry (AAS). For internal quality control DiaSys TruLab N and P or TruLab Urine controls should be assayed. Each laboratory should establish corrective actions in case of deviations in control recovery.

Performance Characteristics

Measuring range
The test has been developed to determine calcium concentrations within a measuring range from 0.2 – 20 mg/dL. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Specificity/Interferences
No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 500 mg/dL, lipemia up to 2000 mg/dL triglycerides and magnesium up to 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].

Sensitivity/Limit of Detection
The lower limit of detection is 0.2 mg/dL.

Reference Range
Serum/Plasma:

		8.6 – 10.3 mg/dL	(2.15 – 2.57 mmol/L)
Urine [1]:	Women	< 250 mg/24 h	(6.24 mmol/24 h)
	Men	< 300 mg/24 h	(7.49 mmol/24 h)

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

Precision (at 20 – 25°C)

Inter-assay precision n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	8.62	0.09	1.01
Sample 2	9.46	0.21	2.24
Sample 3	12.8	0.14	1.1

Method Comparison
A comparison of DiaSys Calcium (y) with a commercially available test (x) using 70 samples gave following results:
y = 1.02 x - 0.20; r = 0.999

Limitations

1. It is recommended that disposable plastic labware be used for this test.
2. If glassware is used, it must be acid washed.
3. It is recommended that if gloves are worn when performing this procedure powderless gloves be used.

Warnings and Precautions

1. As calcium is a 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 colored complex.
3. The reagent contains 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. For diagnostic purposes, the results should always be ed with the patient's medical history, clinical examinations and other findings.
6. For professional use only !

Clinical Interpretation

Sustained low calcium levels in blood may confirm a diagnosis of calcium deficiency disease. Normal calcium levels for adults can range from 8.6 to 10.3 milligrams per deciliter (mg/dL), according to the Merck Manual. If calcium level is below 8.6 mg/dL, it may indicate risk of calcium deficiency disease.

Literature

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt:
2. TH-Books Verlagsgesellschaft; 1998. p. 231–241.
3. 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.
4. Michaylova V, Ilkova P. Photometric determination of micro amounts of calcium with arsenazo III. Anal Chim Acta 1971;53:194-8.
5. Bauer PJ. Affinity and stoichiometry of calcium binding by arsenazo III. Anal Biochem 1981;110:61-72.
6. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 20-1 and p. 50-1.
7. 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.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Notes on Symbols and Marks

	Consult instructions for use
	Use-by date
LOT	Batch code
REF	Catalouge number
	Caution
	Manufacturer
IVD	*In vitro diagnostic* medical device
	Temperature limit
	Do not re-use
CONT.	The pack contains
	Recycle
	Date of manufactures

ISO 9001, ISO 13485 and ICMED 13485 Certified Company

DiaSys Diagnostics India Private Limited
Plot No. A – 821, T.T.C. Industrial Area, MIDC,
Mahape, Navi Mumbai – 400710.
Maharashtra, India.

Customer Care
For feedback/queries contact customer care at :
Toll Free number : 1800 120 1447
Email ID : helpdesk.service@diasys.in
Website : www.diasys.in

Revision No. :01
May. : 2022

IN/0077 v01