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: 20 - 25°C 7 days 3 weeks $4-8^{\circ}C$ at -20°C 8 months at in Urine: 20 - 25°C 2 days at 4 days $4 - 8^{\circ}C$ at -20°C 3 weeks

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



Calculation

With standard or calibrator

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

Conversion factor

Calcium [mg/dL] \times 0.2495 = Calcium [mmol/L] Calcium/U [mg/24 h] \times 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:

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	Mean	SD	CV [%]
n = 20	[mg/dL]	[mg/dL]	
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

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

Warnings and Precautions

- As calcium is a ubiquitous ion, essential precaution must be taken against accidental contamination. Only use disposable materials.
- Traces of chelating agent, such as EDTA can prevent the formation of the colored complex.
- 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].
- 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!

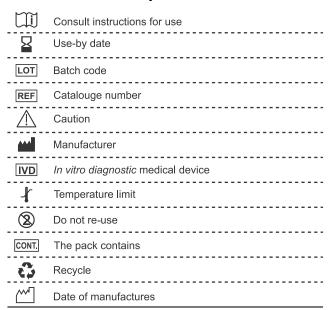
Clinical Interpretation

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

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Notes on Symbols and Marks



ISO 9001, ISO 13485 and ICMED 13485 Certified Company



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Revision No. :01

May.: 2022