

COD 12570 10 x 50 mL
Only for <i>in vitro</i> use in the clinical laboratory



INTENDED USE

Reagent for the measurement of calcium concentration in human serum, plasma or urine. The obtained values are useful as an aid in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

This reagent is for use in the BioSystems A25 and A15 analyzers or in other analyzer with similar performance characteristics.

CLINICAL SIGNIFICANCE

Calcium is the most prevalent cation found in the body, distributed in bone (99%), soft tissues and extracellular fluid. Its concentration in plasma is regulated by parathyroid hormone, vitamin D and calcitonin.

Calcium ion is important in the transmission of nerve impulses, in the maintenance of normal muscle contractility, as a cofactor in certain enzyme reactions, and in the coagulation of the blood.

Hypercalcemia can be due to vitamin D intoxication, enhanced renal retention, osteoporosis, sarcoidosis, thyrotoxicosis, hyperparathyroidism, multiple mieloma, idiopathic hypercalcemia of infancy, and carcinoma metastatic to bone^{1,2}.

Elevated calcium concentration in urine is found in nephrolithiasis and metabolic acidosis^{1,2}.

Hypocalcemia may be caused by primary and secondary hypoparathyroidism, pseudohypoparathyroidism, vitamin D deficiency, malnutrition and intestinal malabsorption^{1,2}.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Calcium in the sample reacts with arsenazo III forming a coloured complex that can be measured by spectrophotometry³.

CONTENTS AND COMPOSITION

A. Reagent. 10 x 50 mL. Arsenazo III 0.2 mmol/L, imidazole 75 mmol/L.

DANGER: H360: May damage fertility or the unborn child. P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P280: Wear protective gloves/protective clothing/eye protection/face protection. P308+P313: IF exposed or concerned: Get medical advice/attention. P405: Store locked up.

For further warnings and precautions, see the product safety data sheet (SDS).

STORAGE AND STABILITY

Store at 2-8°C.

Components are stable once opened until the expiry date marked in the label if they are stored well closed and care is taken to prevent contamination during their use.

On board stability: Reagents open and kept in the refrigerated compartment of the analyzer are stable 2 months.

Indications of deterioration: Absorbance of the blank over the limit indicated in "Test Parameters".

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

Biochemistry Calibrator (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).

REAGENT PREPARATION

Reagent is provided ready to use.

SAMPLES

Serum, heparinized plasma or urine collected by standard procedures (Note 1).

Calcium in serum or plasma is stable for 10 days at 2-8°C. Anticoagulants other than heparin should not be used.

Collect a 24-hour urine specimen in a bottle containing 10 mL of 50 % (v/v) nitric acid. Stable for 10 days at 2-8°C. Centrifuge or filter before testing.

CALIBRATION

A reagent blank should be done every day and a calibration at least every 2 months, after reagent lot change or as required by quality control procedures.

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, 18009 and 18042) and II (cod. 18007, 18010 and 18043) to verify the accuracy of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if control results are not within the acceptable limits.

REFERENCE VALUES

Serum and plasma¹: 8.6-10.3 mg/dL = 2.15-2.58 mmol/L.

Urine¹: 100-300 mg/24-h = 2.5-7.5 mmol/24-h.

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

METROLOGICAL CHARACTERISTICS

The metrological characteristics described below have been obtained using an A25 analyzer. Results are similar with A15.

- Detection limit: 0.26 mg/dL = 0.06 mmol/L.
- Linearity limit: 18 mg/dL = 4.5 mmol/L.
- Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
8.90 mg/dL = 2.22 mmol/L	0.9 %	2.2 %
13.29 mg/dL = 3.32 mmol/L	1.1 %	2.2 %

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

LIMITATIONS OF THE PROCEDURE

- Interferences: bilirubin (up to 20 mg/dL), hemolysis (hemoglobin up to 250 mg/dL) and lipemia (triglycerides up to 1000 mg/dL) do not interfere. Other drugs and substances may interfere⁴.

NOTES

1. Some plasma sample recoveries may be higher than that expected with serum.

BIBLIOGRAPHY

1. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. Burtis CA, Ashwood ER, Bruns DE. WB Saunders Co, 2005.
2. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.
3. Michaylova V, Illkova P. Photometric determination of micro amounts of calcium with Arsenazo III. Anal Chim Acta 1971; 53:194-198.
4. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000..

TEST PARAMETERS

These reagents may be used in several automatic analyzers. Specific instructions for application in many of them are available on request.

R1: use Reagent A.

	A25	A15
GENERAL		
Name	CALCIUM ARSENAZO	CALCIUM ARSENAZO
Sample type	SER / URI	SER / URI
Analysis mode	endpoint mon.	endpoint mon.
Units	mg/dL	mg/dL
Turbidimetry test	no	No
Decimals	2	2
Type of reaction	increasing	increasing
PROCEDURE		
Reading mode	monoch.	monoch.
Main filter	635	635
Reference filter	-	-
Sample	5	5
Vol. R1	300	300
Vol. R2	-	-
Washing	1.2	1.2
Reading 1 (cycle)	21	14
Reading 2 (cycle)	-	-
Reagent 2 (cycle)	-	-
Predilution factor	- / 2	- / 2
CALIBRATION AND BLANK		
Calibration type	multiple	multiple
Number of calibrators	-	-
Calibration curve	-	-
OPTIONS		
Blank absorbance limit	0.750	0.750
Kinetic blank limit	-	-
Linearity limit	18 / 36	18 / 36
Substrate depletion	-	-