

Calcium Arsenazo III (Single Reagent)

REF: 227 001 (2 x 30 ml) 60 test
 REF: 227 002 (2 x 100 ml) 200 test
 REF: 227 003 (4 x 30 ml) 120 test
 REF: 227 004 (4 x 100 ml) 400 test

Intended Use

Spectrum Diagnostics calcium reagent is intended for the in-vitro quantitative, diagnostic determination of calcium in human serum, plasma and urine on both automated and manual systems.

Background

Calcium is the fifth most common element in the body, most of which (98 %) is present in the skeleton. One half of the remaining calcium is found in extracellular fluid and the rest in tissues. Calcium has a crucial role in bone mineralization and is also vital for basic physiological processes such as blood coagulation, neuromuscular conduction, and normal muscle tone. Calcium is constantly lost from the body through excretion in faeces, urine and to a small extent in sweat. The determination of serum calcium is useful for monitoring myeloma, renal failure, acid base balance, and cirrhosis. Both serum and tissue calcium in the body are controlled by parathyroid hormone, calcitonin and vitamin D. Hypocalcemia may be observed in hypoparathyroidism, steatorrhea, pancreatitis and nephrosis. Increased levels may be associated with multiple myeloma and other neoplastic diseases.

Method

Colorimetric Arsenazo III.

Assay Principle

At a neutral pH, the Ca^{+2} form with Arsenazo III a complex, the color intensity of which is directly proportional to the concentration of calcium in the sample.

Reagents

Standard Calcium (ST)		
10 mg/dL	2.5	mmol/L
Reagent (R)		
MES, pH 6.40	100	mmol/L
Arsenazo III	200	μ mol/L

Precautions and Warnings

Do not ingest or inhale. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.











Reagent Preparation, Storage and Stability

Spectrum Calcium reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when stored sealed at 2 – 8 °C. Once opened, the reagent and standard are stable for 3 months at the specified temperature.

Deterioration

Do not use the Spectrum Calcium reagents if turbid. Failure to recover control values within the assigned range may be an indication of reagent deterioration.

SYMBOLS IN PRODUCT LABELLING

 EC REP	Authorised Representative	 Use by/Expiration Date
 IVD	For in-vitro diagnostic use	 CAUTION. Consult instructions for use
 LOT	Batch Code/Lot number	 Manufactured by
 REF	Catalogue Number	 (Xi) - Irritant
 T_c	Consult instructions for use	 Temperature Limitation

Specimen Collection and Preservation Serum and plasma

Use nonhemolyzed serum. Heparin is the only acceptable anti-coagulant. No other anticoagulant can be used. Fresh serum collected in the fasting state is the preferred specimen. Serum or plasma should be separated from cells as soon as possible, because prolonged contact with the clot may cause lower calcium values. Sera from patients receiving EDTA (treatment of hypercalcemia) are unsuitable for analysis, since EDTA will chelate the calcium and render it unavailable for reaction with Arsenazo III. The biological half-life of calcium in blood is few hours.

Urine

Specimens should be collected in acid washed bottles. 24 hour Specimens should be collected in containers containing 5 ml of 6 mol/L HCl. If the specimen is collected without acid, the pH should be adjusted < 3 with 6 mol/L HCl. Dilute urine specimen 2 times with bidistilled water (1 volume urine + 1 volume distilled water) before assay.

Stability (serum): 7 days at 15 – 25 °C; 3 weeks at 4 – 8 °C;
8 months at -20 °C

Stability (urine): 2 days at 15 – 25 °C; 4 days at 4 – 8 °C;
3 weeks at -20 °C

Stored serum or urine specimens must be mixed well prior to analysis.

System Parameters

Wavelength	650 nm (600 nm)
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample : Reagent Ratio	1 : 100
e.g.: Reagent volume	1 ml
Sample volume	10 μ l
Temperature	15 - 25 °C
Zero adjustment	Reagent Blank
Sensitivity	2 mg/dL (0.25 mmol/L)
Linearity	20 mg/dL (5 mmol/L)

Procedure

	Blank	Standard	Specimen
Standard	10 μ l
Specimen	10 μ l
Reagent	1 ml	1 ml	1 ml

Mix and incubate for 3 minutes at 20 - 25 °C. Measure absorbance of specimen (A_{specimen}) and standard (A_{standard}) against reagent blank.

Calculation

$$\text{Serum calcium concentration (mg/dL)} = \frac{A_{\text{specimen}}}{A_{\text{standard}}} \times 10$$

$$\text{Urine calcium (mg/24 hrs)} = \frac{A_{\text{specimen}}}{A_{\text{standard}}} \times 10 \times 10^4 \times 2^{**} \times V^{***}$$

* The factor "10" converts mg/dl to mg/litre

** The factor "2" represents the dilution factor

*** "V" represents the 24-hour urine volume in litres

Quality Control

Normal & abnormal control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	9.58	13.97
SD	0.12	0.207
CV%	1.33	1.48

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	9.62	14.15
SD	0.23	0.221
CV%	1.42	1.53

Methods Comparison

A comparison between Spectrum Diagnostics Calcium reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.979 was obtained.

Sensitivity

When run as recommended, the minimum detection limit of this assay is 2.0 mg/dL.

Linearity

The reaction is linear up to calcium concentration of 20 mg/dL. Specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result x 2).

Interfering Substances:

Haemolysis

Avoid haemolysis.

Icterus

No significant interference.

Lipemia

No significant interference.

Anticoagulants

Complexing anticoagulants such as citrate, oxalate and EDTA must be avoided.

Expected values Serum, plasma

Adults

20 - 50 years	8.8-10.2 mg/dl	(2.20-2.55 mmol/L)
>50 years	8.4- 9.7 mg/dl	(2.09-2.42 mmol/L)

Children

4 -18years	9.2-11.0 mg/dl	(2.30-2.75 mmol/L)
>4 weeks	7.2-11.2 mg/dl	(1.80-2.8 mmol/L)

Urine (24 h)

Females	<250 mg/day	(<6.25 mmol/day)
Males	<300 mg/day	(<7.5 mmol/day)
Children	<6 mg/kg/day	(<0.15 mmol/day)

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Analytical Range

2 – 20 mg/dl (0.5-5 mmol/L).

Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. refer to special instructions/safety data sheets.

References

- Barnett RN: A scheme for the comparison of quantitative methods. AM J Clin Pathol 43: 562, 1965.
- Fiereck EA: Appendix. Normal values. in: Fundamentals of clinical chemistry. NW Tietz, editor, Saunders, Philadelphia, p1208, 1976.
- Kessler G, Wolfman M: An automated procedure for the simultaneous determination of calcium and phosphorus. Clin Chem 10:686, 1964.
- Peters JP, Van Slyke, DD: Quantitative clinical chemistry, vol 2, Williams and Wilkins, Baltimore (MD), 1932, p 760.
- Tietz NW: Blood gases and electrolytes. In: Fundamentals of clinical chemistry, NW Tietz, editor, Saunders, Philadelphia, 176, pp 903, 908.
- Young DS, Effects of drugs on clinical laboratory tests. AACC press, Washington, D.C. 1990.

ORDERING INFORMATION

CATALOG NO.	QUANTITY
227 001	2 x 30 ml
227 002	2 x 100 ml
227 003	4 x 30 ml
227 004	4 x 100 ml



Spectrum For Diagnostic Industries - Free Zone

Ismailia Free Zone Industrial Area, Block 5 .

Cairo- Port said Avenue.

Ismailia, Egypt

Tel: +2 064 3488 013 - +2 064 3488 014 Fax: +2 064 3488 015

www.sdi-fz.com



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany



IFUFCC70

Rev.(2), 11/3/2020