Calcium- Arsenazo III (Single Reagent)

REF: **CAL154060** (2 x 30 ml) 60 test
REF: **CAL1540120** (4 x30 ml) 120 test
REF: **CAL1540200** (2 x 100 ml) 200 test

SYMBOLS IN PRODUCT LABELLING

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

Intended Use

BioMed Diagnostics calcium reagent is intended for the in-vitro Quantitative, diagnostic determination of calcium in human serum 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 physio-logical processes such as blood coagulation, neuromuscular conduction, and normal muscle tone. Calcium is constantly lost from the body through excretion in feces, 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 serums and tissue calcium in the body are controlled by parathyroid hormone, calcitonin and vitamin D. Hypocalcemia may be observed in hypoparathyrodism, 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 Ca2+ 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 (R1)	
10 mg/dL	2.5 mmol/L
Reagent (R2)	
MES, pH 6.40	100 mmol/L
Arsenazo III	200 µmol/L

Precautions and Warnings

Do not ingest or inhalate. 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

BioMed Calcium reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when stored sealed at 15 – 25 °C.

Deterioration

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

Specimen Collection and Preservation
Serum and plasma

Use nonhemolyzed serum.Heparin is the only acceptable antico-agulant. No other anticoagulant can be used. Fresh serum collected in the fasting state is the perferred 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 O-cresolphthalein complexone. 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 (1volume urine + 1volume distilled water) before assay.

Stability (serum): 7 daysat 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 µl
Temperature	15 - 25 °C
Zero adjustment	Reagent Blank
Sensitivity	1 mg/dL (0.25 mmol/L)
Linearity	20 mg/dL (5 mmol/L)

Procedure

	Blank	Standard	Specimen
Standard	……	10 µl	……
Specimen	……	……	10 µl
Reagent 2	1 ml	1 ml	1 ml

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

Calculation

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

Urine calcium (mg/24 hrs) = $\frac{A\text{specimen}}{A\text{standard}}$ x10 x10*x 2**x 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 Characterstics

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 BioMed 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 • 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)

BioMed 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

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3. Kessler G, wolfman M: An automated procedure for the simultaneous determination of calcium and phosphorus.Clin Chem 10:686, 1964.
4. Peters JP, Van Slyke, DD: Quantitative clinical chemistry, vol 2,williams and wilkins, Baltimor (MD),1932, p 760.
5. Tietz NW: Blood gases and electrolytes. In:Fundamentals of clinical chemistry, NW tietz, editor,Saunders, Philadelphia, 176,pp 903, 908.
6. Young DS, Effects of drugs on clinical laboratory tests. AACC press, Washington, D.C. 1990.

ORDERING INFORMATION	
CATALOG NO.	QUANTITY
CAL154060	**2 x 30 ml**
CAL1540120	**4 x 30 ml**
CAL1540200	**2 x 100 ml**

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