Spectrum For Diagnostic Industries

Calcium Arsenazo III

IVD

Cat. No.	Pack size
197 01 050	(1 x 50 ml) 50 tests
197 02 030	(2 x 30 ml) 60 tests
197 05 030	(5 x 30 ml) 150 tests

Intended Use

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

Introduction

Calcium is the fifth most common element in the body. All the calcium in human adult is extracellular, 99 % is present in 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.

Method

Colorimetric. Arsenazo III.

Principle

At a neutral pH, the Ca2+ forms a complex with Arsenazo III, of which the color intensity is directly proportional to the concentration of calcium in the sample.

Reagents

Reagent (R)

MES	100	mmol/L
Arsenazo III	200	µmol/L

Standard (ST)

10 mg/dL	2.5	mmol/L

Reagent preparation, storage and stability

Calcium reagents are supplied ready-to-use and stable till the expiration date labeled on the bottles when stored sealed at 2 – 8 ^{o}C.Once opened, the reagent and standard are stable for 3 months at the specified temperature.

Deterioration

Failure to recover control values within assigned range may indicate reagent deterioration

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.

Specimen collection and preservation

Serum and plasma
Use non-hemolyzed serum. Heparin is the only acceptable anticoagulant. 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 are unsuitable for analysis.

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 to be < 3 with 6 mol/L HCl. Dilute urine specimen 2 times with bidistilled water (1volume urine + 1volume distilled water) before assay.

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

Stability (urine): 2 days at 15 – 25 ^{o}C; 4 days at 4 – 8 ^{o}C; 3 weeks at -20 ^{o}C

Procedure

Wavelength	650 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 ^{o}C
Zero adjustment	Reagent Blank
Sensitivity	2 mg/dL (0.25 mmol/L)
Linearity	20 mg/dL (5 mmol/L)

	Reagent blank	Standard	Specimen
Reagent (R)	1.0 ml	1.0 ml	1.0 ml
Standard	____	10 µl	____
Specimen	____	____	10 µl

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

Calculation

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

Urine calcium (mg/24 hrs)= $\frac{A_{specimen}}{A_{standard}}$ 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

Interference

Hemolysis
No significant interference .

Icterus
No significant interference .

Lipemia
No significant interference

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

Quality control

Normal and abnormal control serum of known concentration should be analyzed with each run.

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 -18 years	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)

Performance Characteristics

A study using 20 human specimens between this Calcium reagent and a reference method yielded a correlation coefficient of 0.983 and a linear regression equation of y = 1.016x + 0.05.

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	8.82	14.1
SD	0.01	0.12
CV%	0.12	0.87

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	8.82	14.1
SD	0.01	0.11
CV%	0.118	0.83

Sensitivity

2.0 mg/dL.

Linearity

20 mg/dL.

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

1. Fiereck EA: Appendix. Normal values. in:Fundamentals of clinical chemistry. NW Tietz, editor,Saunders, Philadelphia
2. Peters JP, Van Slyke, DD: Quantitative clinical chemistry, vol 2,williams and wilkins, Baltimor (MD)
3. Tietz NW: Blood gases and electrolytes. In:Fundamentals of clinical chemistry, NW tietz, editor,Saunders, Philadelphia

SYMBOLS IN PRODUCT LABELLING

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

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