Cat. No 9-456

DIAGNOSTIC KIT FOR DETERMINATION OF CALCIUM CONCENTRATION

OS – CALCIUM ARSENAZO

INTRODUCTION

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 PRINCIPLE

Photometric test using arsenazo III.
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.

REAGENTS

Package

1-Reagent	6 x 53 ml

The reagent when stored at 2-8°C is stable up to expiry date printed on the package. The reagents are stable for 12 weeks on board the analyser at 2-10°C. Do not freeze the reagent. Protect from light and contamination!

Concentrations in the test

phosphate buffer (pH 7.5)	67 mmol/l
8-hydroxyquinoline-5-sulfonic acid	5 mmol/l
arsenazo III	100 µmol/l
detergents	

Warnings and notes

- Product for in vitro diagnostic use only.
- Contaminated glassware is the greatest source of error. The use of disposable plastic ware is recommended. Glassware should be soaked for a few hours in 2M HCl solution and then thoroughly rinsed with distilled water.

SPECIMEN

Serum. Random or 24-hours urine.
Serum can be stored up to 7 days at 20-25ºC or up to 3 weeks at 4-8ºC. Samples frozen at -20ºC can be stored up to 8 months. Discard contaminated specimens.
24-hours urine preparation: To prevent calcium salt precipitation specimens should be collected in 10 ml of 6M HCl. In case of presence of precipitants they can be solved by lowering pH of the urine to below 2.0. Prior to determination dilute the sample with 0.9% NaCl in the ratio of 1 to 1. Multiply the result by the dilution factor.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

This reagent may be used in automatic analysers Olympus AU400/AU640.
1-Reagent is ready to use.
For reagent blank 0.9% NaCl is recommended.

APPLICATION

Reagent ID: **076**

Specific Test Parameters

General | LIH | ISE | Range

Test name: **Ca Ars** Type: **Serum/Urine** Operation: **Yes**

Sample:	Volume	4	µL	Dilution	0	µL	Pre-Dilution Rate:	1
Reagents:	R1 Volume	300	µL	Dilution	0	µL	Min OD	Max OD
	R2 Volume	0	µL	Dilution	0	µL	L -2.0000	H 2.5000
							Reagent OD Limit:	
Wavelength:	Pri.	660		Sec.	700		First L -2.0000	First H 2.5000
Method:		END					Last L -2.0000	Last H 2.5000
Reaction Slope:		+					Dynamic Range:	
Measuring Point 1:	First	0		Last	27		L 0.3	H 21
Measuring Point 2:	First			Last			Correlation Factor:	
Linearity:			%				A 1.000	B 0.000
No-Lag-Time:							On-board Stability Period:	84

Specific Test Parameters

General | LIH | ISE | Range

Test name: **Ca Ars** Type: **Serum/Urine**

Value/Flag: # Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7.	None Selected					#	#
8	Out of Range					#	#

	L	H		
Panic Value:	#	#	Unit: **mg/dl**	Decimal Places: **2**

Calibration Specific

General | ISE

Test name: **Ca Ars** Type: **Serum/Urine**

Calibration Type: **2AB** Formula: **POLYGONAL** Counts: **3** Process: **CONC**

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		*	-2.0000	2.5000
Point 2:	#		*	-2.0000	2.5000
Point 3:					
Point 4:					
Point 5:					
Point 6:					
Point 7:					

1-Point Cal.Point: with CONC-0 Slope Check: **None** Advanced Calibration: #

MB Type Factor: Calibration Stability Period: **84**

\# User defined
* Calibrator value

REFERENCE VALUES [4]

serum	mg/dl	mmol/l
adult	8.6 – 10.3	2.15 – 2.57
random urine	mg/dl	mmol/l
male	0.9 – 37.9	0.225 – 9.47
female	0.5 – 35.7	0.125 – 8.92
24-hours urine	mg/24h	mmol/24h
adult	100 – 300	2.5 – 7.5

It is recommended for each laboratory to establish its own reference ranges for local population.

Calcium concentration 24-hours urine - calculation

calcium concentration in 24-hours urine [mg/24h]	=	calcium concentration in sample of 24-hours urine [mg/dl]	×	urine volume of 24-hours urine [dl/24h]

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) for determination in serum or CORMAY URINE CONTROL LEVEL 1 (Cat. No 5-161) and LEVEL 2 (Cat. No 5-162) for determination in urine with each batch of samples.

For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) is recommended.

The calibration curve should be prepared every 12 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analyser Olympus AU400. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 0.3 mg/dl (0.075 mmol/l).

- **Linearity:** up to 21 mg/dl (5.25 mmol/l).
  For higher calcium concentrations dilute the sample with 0.9% NaCl in the ratio of 1 to 1 and reassay. Multiply the result by 2.

- **Specificity / Interferences**
  Haemoglobin up to 1.88 g/dl, ascorbate up to 62 mg/l, bilirubin up to 40 mg/dl, triglycerides up to 1000 mg/dl and magnesium up to 20 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	9.13	0.04	0.43
level 2	11.62	0.05	0.47

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	8.98	0.16	1.80
level 2	11.51	0.21	1.86

- **Method comparison**

A comparison between calcium values determined at Olympus AU400 (y) and at ADVIA 1650 (x) using 29 samples gave following results:

y = 0.9855 x - 0.0193 mmol/l;

R = 0.979 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Endres DB, Rude RK. Mineral and bone metabolism. In: . Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, PA: Moss D.W., Henderson A. R. (1999) p. 1395-1457.
2. Michaylova V, Ilkova P. Photometric determination of micro amounts of calcium with arsenazo III. Anal Chim Acta 1971;53: 194-8.Bauer PJ. Affinity and stochiometry of calcium binding by arsenazo III. Anal Biochem 1981; 110:61-72.
3. Bauer PJ. Affinity and stochiometry of calcium binding by arsenazo III. Anal Biochem 1981; 110:61-72.
4. Alan H.B. Wu. editor. Tietz Clinical Guide to Laboratory Tests, 4th ed. St. Louis: W.B Saunders Company; 2006, p. 202-204.

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