Cat. No 9-413

DIAGNOSTIC KIT FOR DETERMINATION OF CALCIUM CONCENTRATION

OS – CALCIUM

INTRODUCTION

Calcium and phosphorus as a hydroxyapatite constitute mineral portion of bone. Calcium occurs also as divalent cations (free or bound with negatively charged proteins) which participate in blood coagulation, neuromuscular excitability, skeletal and cardiac muscle contractility and in multiple cellular functions. Calcium flux in organism is controlled by action of parathyroid hormone (PTH), vitamin D and calcitonin. Calcium serum level abnormalities are caused usually by parathyroid or thyroid disease, disorders of vitamin D metabolism or acute pancreatitis.

METHOD PRINCIPLE

Calcium ions form a violet complex with o-cresolophthalein complexone in alkaline solution. The intensity of violet colour of this complex measured at 570-580 nm is proportional to the calcium concentration in the sample.

REAGENTS

Package

1-Reagent	2 x 56 ml
2-Reagent	2 x 18.5 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 8 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

o-cresolophtalein complexone	0.06 mmol/l
8-quinolinol	8.6 mmol/l
hydrochloric acid	30 mmol/l
ethanolamine	377 mmol/l

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.
- 2-Reagent is classified as a corrosive!

Ingredients: ethanolamine;
C – Corrosive.
R 20/21/22-34: Harmful by inhalation, in contact with skin and if swallowed. Causes burns.

S 26-28-36/37/39-45: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of water. Wear suitable protective clothing, gloves and eye/face protection. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

SPECIMEN

Serum, heparinized plasma free from hemolysis, 24-hours urine.
Recommended anticoagulants: heparine lithium, sodium or ammonium salt.
Urine preparation: To prevent calcium salt precipitation in urine, specimens should be collected in HCl, 20-30 ml of 6M for 24-h specimen. Any specimens collected without acid should be acidified using 20-30 ml of 6M HCl, well mixed and allowed to stand for 1 h before aliquotting. Prior to determination dilute the sample with 0.9% NaCl in the ratio of 1 to 1. Multiply the result by the dilution factor.

Serum and plasma can be stored up to 8 hours at 15-25ºC or up to 1 day at 2-8ºC. Samples frozen at -20ºC can be stored up to1 year.
24-hours urine samples should be kept at 2-8ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used in automatic analysers Olympus AU400/AU640.
1-Reagent and 2-Reagent are ready to use.
For reagent blank 0.9% NaCl is recommended.

APPLICATION

Reagent ID: **013**

Specific Test Parameters
General | LIH | ISE | Range

Test name: **CA** Type: **Serum** Operation: **Yes**

Sample: Volume	**2** µL	Dilution **0** µL	Pre-Dilution Rate: **1**		
Reagents: R1 Volume	**100** µL	Dilution **0** µL	Min OD		Max OD
R2 Volume	**25** µL	Dilution **0** µL	L **-2.0000**		H **2.5000**
			Reagent OD Limit:		
Wavelength: Pri.	**570**	Sec. **None**	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 **1.2**		H **20**
Measuring Point 2: First	**0**	Last **9**	Correlation Factor:		
Linearity:	%		A **1.000**		B **0.000**
No-Lag-Time:			On-board Stability Period: **56**		

Specific Test Parameters
General | LIH | ISE | Range

Test name: **CA** Type: **Serum**

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						#	#

Panic Value: L # H # Unit: **mg/dl** Decimal Places: **1**

Calibration Specific
General | ISE

Test name: **CA** Type: **Serum**

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: **3**

\# User defined
* Calibrator value

REFERENCE VALUES [8]

serum, plasma		mg/dl	mmol/l
premature		6.2 – 11.0	1.55 – 2.75
adults	18 – 60 yr	8.6 – 10.0	2.15 – 2.50
	60 – 90 yr	8.8 – 10.2	2.20 – 2.55
	> 90 yr	8.2 – 9.6	2.05 – 2.40
24-hours urine		mg/24h	mmol/24h
		100 – 300	2.5 – 7.5

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

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) or 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) and LEVEL 2 (Cat. No 5-175; 5-177) is recommended.
The calibration curve should be prepared every 3 days, 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:** 1.2 mg/dl (0.3 mmol/l).

- **Linearity:** up to 20 mg/dl (5 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 2.5 g/dl, bilirubin up to 20 mg/dl, ascorbate up to 62 mg/l and triglycerides up to 1000 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	7.66	0.14	1.78
level 2	10.73	0.32	2.96

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	8.52	0.47	5.51
level 2	11.96	0.56	4.69

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 86 samples gave following results:
y = 1.0673 x - 0.2546 mmol/l;
R = 0.9900 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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