

A-400 CALCIUM

DIAGNOSTIC KIT FOR DETERMINATION OF CALCIUM CONCENTRATION

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-cresolphthalein 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	4 x 21 ml
2-Reagent	2 x 11 ml

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

Concentrations in the test

o-cresolphthalein 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 meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008.

Warning.



H335 May cause respiratory irritation.
P261 Avoid breathing spray.
P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P312 Call a POISON CENTER or doctor if you feel unwell.

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 15-25°C or up to 1 day at 2-8°C. Samples frozen at -20°C can be stored up to 1 year. 24-hours urine samples should be kept at 2-8°C.

Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used in automatic analyser BS-400.

1-Reagent and 2-Reagent are ready to use.

For reagent blank deionised water is recommended.

APPLICATION

BASIC

Test information		Reagent volume	
No.	13	R1	160
Test	CALC	R2	40
Full Name	Calcium	R3	
Std. No.	13	R4	

Sample volume

Standard	4	15	10
Increased	8	15	10
Decreased	2	15	10

Reaction Parameters

Reac. Type	Endpoint	Direction	Increase
Pri. Wave	570	Rgt. Blank	41 42
Sec. Wave	800	Reac. Time	50 51

Result Setup

Decimal	0.01	Slope	1
Unit	mg/dl	Inter	0

Judgment Criteria

Absorbance	0	0	Lin. Range	0.25	15
Incre. Test	0		Lin. Limit		
Decre. Test	0		Subs. Limit		

Prozone Rate Antigen

Q1	0	Q2	0	Q3	0	Q4	0
PC	0			ABS	0		

CALIBRATION

Calibration

Rule	Two-Point Linear
Replicate	3
K	

Judgment Criteria

Sensitivity	Blank Abs.
Factor Diff.	Error Limit
SD	Corr. Coeff.

REFERENCE VALUES ⁸

serum, plasma	mg/dl	mmol/l
premature	6.2 – 11.0	1.55 – 2.75
adults	8.6 – 10.0	2.15 – 2.50
18 – 60 yr	8.8 – 10.2	2.20 – 2.55
60 – 90 yr	8.2 – 9.6	2.05 – 2.40
> 90 yr		
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) are recommended.

The calibration curve should be prepared every 5 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 automatic analyser BS-400. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 0.25 mg/dl (0.06 mmol/l).
- **Linearity:** up to 15 mg/dl (3.75 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	9.09	0.11	1.19
level 2	14.21	0.37	2.59

Reproducibility (day to day) n = 56	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	8.50	0.29	3.45
level 2	12.61	0.33	2.63

- **Method comparison**

A comparison between calcium values determined at BS-400 (y) and at Cobas Integra 400 (x) using 31 samples gave following results:

$$y = 0.9263 x + 0.5532 \text{ mg/dl};$$

$$R = 0.9506 \quad (R - \text{correlation coefficient})$$

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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