CALCIUM

Arsenazo method

4 x 50 ml	CL14-200S
4 x 100 ml	CL14-400S

Other available kits for calcium determination:

CALCIUM o-cresolphtaleine	**CL15-200S**
CALCIUM o-cresolpthaleine	**CL16-125S**
CALCIUM MTB	**CL17-200S**

INTENDED USE

Kit for quantitative determination of Calcium in serum and urine.

CLINICAL MEANING

Circulating calcium in the organism is used for various purposes: skeletal metabolism, neuromuscular functions and haemostasis. An increase in total calcium levels can indicate hyperparathyroidism caused by parathyroid adenoma or secondary hyperplasia; metastatic bone tumors; Paget disease, excessive use of vitamin D; milk and antacids.
Lower levels of calcium may instead indicate: hypoparathyroidism caused by surgical removal of parathyroids or by radial therapy; increase in phosphates due to renal impairment; use of laxatives, phosphates or magnesium; acute pancreatitis; lack of vitamin D; rickets etc.

PRINCIPLE

At a slightly acid pH, arsenazo (III) forms a violet-blue complex with calcium which is measuread at 650 nm. The reaction is highly specific and the magnesium interferences are negligible.

SAMPLE

Serum (preferably); heparinized plasma. Do not use EDTA, oxalate or citrate as anticoagulant.
Stability: 24 hours at room temperature, 7 days at 2-8°C; one month at -20°C.
Urine: 24 hour sample, diluted 1:2 with distilled water and acidified with 2-3 drops of HCl 23%.

REAGENTS

Only for in Vitro diagnostics. Liquid reagents ready to use.

Package content	**CL14-200S**	**CL14-400S**
REAGENT 1 Arsenazo(III) 0.2 mM, Buffer pH 6.8.	4 x 50 ml	4 x 100 ml
STANDARD Calcium solution 10 mg/dl.	4 ml	4 ml

STABILITY: Store at 15-25°C and protect from direct light to keep the reagents stable up to the expiration date on the label. After the opening: use the reagent within 60 days, stored at 15-20°C and protected from the sun.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control.

MANUAL ASSAY PROCEDURE

Wavelength:	650 nm (600 ÷ 660 nm)
Optical path:	1 cm
Temperature:	25-37°C
Reading:	against blank reagent
Method:	End Point
Reaction time:	2 minutes
Linearity	20 mg/dl
Sensitivity	0.2 mg/dl
Sample/reagent Ratio	1:100

Bring the working reagent to the chosen temperature for the analysis.
Pipette in cuvette:

	Blank reagent	Standard	Sample
Reagent	1 ml	1 ml	1 ml
Water	10 µl	-	-
Standard	-	10 µl	-
Sample	-	-	10 µl

Mix. Incubate at 37°C then read the absorbance of the sample (Ac) and of standard (As) against the blank reagent.

CALCULATION

Serum and plasma: calcium mg/dl = Ac/As x 10 (value of standard)

Urine: calcium mg/dl = Ac/As x 10 x 2
(value of standard + dilution factor)

24 hours urine: calcium mg/24h = Ax/As x 10 x 2 x urine volume
(value of standard + dilution factor and diuresis in dl).

REFERENCE VALUES

Newborn (Serum): 8,0 – 13,0 mg/dl (2.0 – 3,25 mmol/l)
Serum up to 12 years old: 8.8 - 12 mg/dl (2.2 – 3,0 mmol/l)

Serum in adults: 8.8 – 10,5 mg/dl (2.2 – 2,6 mmol/l)
Urine: 100-300 mg/24h (25-75 mmol/24h)

Each laboratory should set its own reference values according to its population.

QUALITY CONTROL - CALIBRATION

All Clinical Chemistry laboratories should implement a quality control program. Control serums of human origin are available for this purpose on request:
PRE-NORM serums with normal values
PRE-PATH serums with pathological values
If the method requires it, a multiparameter calibrator of human origin is available.
Contact FAR for any other information.

PERFORMANCE CHARACTERISTICS

Sensitivity: the sensitivity of the method is 0,1 mg/dl at 650 nm.
Linearity: up to 20 mg/dl. For higher values, dilute the samples 1+9 with distilled water and repeat the test, then multiply the result by 10.
Precision

Within run (n=30)	Average (mg/dl)	CV%
Sample 1	3,7	4,5
Sample 2	9,8	3,3
Sample 3	18,3	6,2

Within run (n=20)	Average (mg/dl)	CV%
Sample 1	3,8	5,1
Sample 2	9,7	2,8
Sample 3	18,5	6,9

Interferences: hemoglobin ≤ 500 mg/dl, bilirubin ≤ 25 mg/dl, tryglicerides ≤ 1250 mg/dl, phosphorus ≤ 50 mg/dl do not interfere with the test..
Limits of the method: In case of concentration higher than 20 mg/dl, repeat the analysis on a diluted sample (1:2 with saline solution) and multiply the result by 2. Strongly lipemic serums may cause an increase of calcium values. Prepare a blank sample with distilled water.

Correlation against a reference method: the correlation against another method on the market gives these results on an 80-samples comparison:
FAR calcium: x
Competing calcium: y
n=60
y=1,018x + 0,40 R2 = 0,996

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

Avoid contact with the skin and ingestion. Follow usual rules for chemical substances utilisation.

REFERENCES

1. Zak B., Epstein E., Babinski E.S., Review of Calcium Methodologies, Annals of Clinical and Laboratory Science 5, 195-212 (1975). Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994). Clinical Chemistry, vol. 38 n. 6 – 904-908

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KEY SYMBOLS

IVD	in Vitro diagnostics medical device
LOT	batch number
REF	catalog number
	temperature limits
	use by
	caution
	consult accompanying documents

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