Calcium Assay Kit (Ca)

Method: Arsenazo III

Cat .No.	Size	Instrument
GB400E	R1: 6×50 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS401E	R1: 6×50 ml	For Hitachi917 & OlympusAU640/400/600
GH401E	R1: 6×50 ml	For Hitachi902
GX401E	R1: 1×100 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GT401E	R1: 6×50 ml	For TOSHIBA
GD401E	R1: 36×4.3 ml	For DATE DIMENSION

INTENDED USE

For the *in vitro* quantitative determination of Calcium in serum.

CLINICAL SIGNIFICANCE[1]

Calcium is the fifth most common element. Calcium exists in three physical chemical states: (1) free or ionized calcium;
(2) calcium complexed to anions, including bicarbonate, lactate, phosphate, and citrate;
(3) calcium bound to plasma proteins.
Calcium has key roles in muscle contraction, hormone secretion, glycogen metabolism, and cell division. Increased calcium levels in serum are reported in hyperparathyroidism, cancer, metastatic bone lesions and hypervitaminosis, while decreased levels are observed in hypoparathyroidism, nephrosis, rickets, nephritis and calcium-losing syndromes.

ASSAY PRINCIPLE[2]

Arsenazo III reacts with calcium in solution to form a blue-purple complex. The color developed has a maximum absorbance at 650 nm and is proportional to the calcium concentration in the sample.

Arsenazo III + Ca^{2+} ⟶ blue-purple

SAMPLE COLLECTION AND PREPARATION

Serum samples.
Use fresh patient serum samples. Serum samples are stable for 8 hours at room temperature, for 24 hours at 2-8°C.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Arsenazo III	348 μmol/L
Sodium acetate	90 mmol/L, pH7.0
Stabilizer	

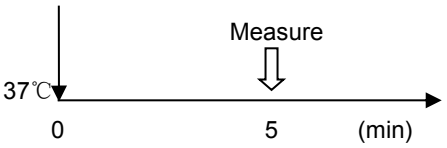
STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Unopened kit: Up to the expiry date at 2-8℃.
The reagents are stable for 1 month after opening and kept at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 917)
Assay Mode: 1 Point End
Wave Length (main): 660 nm

Sample:3 μl
R1: 200 μl



1. Mix 3 μl sample with 200 μl R1 and incubate at 37℃ for 5 minutes.
2. Measure the absorbance of the sample (A_{sample}) and calibrator ($A_{calibrator}$) against reagent blank.

CALCULATION

$$\text{Concentration} = \frac{A_{sample} - A_{blank}}{A_{calibrator} - A_{blank}} \times \text{Calibrator value}$$

CALIBRATION

Recommend that this assay should be calibrated using Randox Calibration Serum Level 3 or Level 2.

QUALITY CONTROL

For quality control, use Ca Control as daily quality control sera and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE[3]

Serum: 2.02 – 2.60 mmol/L (8.10-10.4 mg/dl)

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 7.03 mmol/L. Sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor.

PRECISION

The CV of the test should be less than 5%.

Inter assay precision		
N=5	Level1	Level 2
Mean (mmol/L)	2.24	3.59
SD	0.02	0.03
CV	0.94%	0.84%

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Intra assay precision		
N=20	Level1	Level 2
Mean (mmol/L)	2.28	3.37
SD	0.03	0.03
CV	1.12%	0.94%

SENSITIVITY
The minimum detectable level that can be distinguished from zero has been determined as 0.191 mmol/L.

INTERFERENCE
The following analytes were tested up to the levels indicated and found not to interfere:
Hemoglobin: 500 mg/dl
Intralipid: 140 mg/dl
Total bilirubin: 80 mg/dl
Ascorbic Acid: 60 mg/dl

CORRELATION
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
Y=1.0450X-0.1147 and correlation coefficient of 0.9994. And 60 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS
1. For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES
1. Tietz, N.W., Fundamentals of Clinical Chemistry 2nd. Edition W.B. Saunders Co., Philadelphia (1976)
2. V. Michaylova and P. Ilkova, Photometric determination of micro amounts of calcium with arsenazo III, (1971)Anal. Chim. Acta. 53:194-198
3. Barnett, R.N., et al. Performance of "kits" used for clinical chemical analysis of calcium in serum. (1973) Amer. J. Clin. Path. 59: 836-845.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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