ROBONIK®

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prietest™ ...Clinical Chemistry Reagents

CALCIUM (ARSENAZO III)

In vitro diagnostic test kit, for professional use only

INTENDED USE : Quantitative in vitro determination of concentration of calcium in serum, plasma or urine on photometric systems.

ORDERING INFORMATION	**Pack Size**	**Cat No.**
	25 Tests	CAL AR 01 25
	50 Tests	CAL AR 01 50
	2 X 50 ml	CAL AR 02 50

CLINICAL SIGNIFICANCE : Calcium plays an essential role in many cell functions: intracellular 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 hyperparathyroidism. 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 : Photometric test using Arsenazo III, End Point

PRINCIPLE :

Calcium with Arsenazo III [2,7-(bis(2-arsonophenyfazo))-1,8-dihydroxynaphtaiene-3,6-disulphoric acid], 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 :

COMPONENTS AND CONCENTRATIONS :

Imidazole Buffer	:	100 mmol/l	
8 - Hydroxy Quinoline	:	5 mmol /l	
Arsenazo III	:	120 µmol/l	
Preservative & Stabilizer			
Standard :	:	10.0 mg/dl	(2.50 mmol/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY :

The reagent and the standard are stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C, protected from light and contamination is avoided. Do not freeze the reagent!

The standard is stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C.

WARNINGS AND PRECAUTIONS :

1. As calcium is an ubiquitous ion, essential precaution must be taken against accidental contamination. Only use disposable materials.
2. Traces of chelating agent, such as EDTA can prevent the formation of the colored complex.
3. The reagent contains sodium azide (0.95 g/l) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
4. Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT :

Please refer to local regulation requirements.

REAGENT PREPARATION :

The reagent and the standard are ready-to-use.

MATERIALS REQUIRED BUT NOT PROVIDED :

NaCl Solution 9 g/l, General laboratory equipment, Analyser / Photometer, Pipettes etc.

SPECIMEN :

Serum, Heparinized Plasma or Urine collected on 24 hours without preservative.

Do not use EDTA plasma.

Stability in serum / plasma:

7 days at 20 to 25°C, 3 weeks at 4 to 8°C, 8 months at –20°C

Stability in urine:

2 days at 20 to 25°C, 4 days at 4 to 8°C, 3 weeks at –20°C

Add 10 ml of concentrated HCl to 24 h urine and heat the specimen to dissolve calcium oxalate. Discard contaminated specimens.

ASSAY PROCEDURE :

Application sheets for automated systems are available on request.

Wavelength	:	Hg 630 nm, 650 nm
Optical Path	:	1 cm
Temperature	:	37°C
Mode	:	End Point

Bring all the contents of the kit to Room Temperature prior to use.

Read absorbance of sample against reagent blank.

Label the test tube as blank, standard, sample, control and pipette into respective test tube the reagent, standard, sample, control sample as per the table given below :

	Blank	Standard	Sample / Control
Reagent	1000 µl	1000 µl	1000 µl
Deionised Water	10 µl	—	—
Standard	—	10 µl	—
Sample / Control	—	—	10 µl

Mix and read the absorbance (A) after a 2 minutes incubation.

CALCULATION :

With standard or calibrator.

$$\text{Conc. of unknown Sample} = \frac{\text{Concentration of Standard}}{\text{Abs. Standard} - \text{Abs. of Reagent Blank}} \times \text{Abs. of unknown Sample} - \text{Abs. of Reagent Blank}$$

CONVERSION FACTOR :

Calcium [mg/dl] x 0.2495 = Calcium [mmol/l]

CALIBRATION :

For the calibration of automated photometric systems use of the commercially available calibrator is recommended.

QUALITY CONTROL :

To ensure adequate quality, use of the commercially available control sera is recommended.

PERFORMANCE CHARACTERISTICS :

MEASURING RANGE :

The test has been developed to determine Calcium concentrations within a measuring range from 0.4 to 15 mg/dl (0.10 to 3.74 mmol/L). When values exceed higher limit of the range, such samples should be diluted 1 + 1 with NaCl solution (9 g/l) and the result multiplied by 2.

SPECIFICITY / INTERFERENCES :

No interference was observed by Ascorbic Acid up to 30 mg/dl (1703.4 µmol/L), Bilirubin up to 40 mg/dl (684.00 µmol/L), Hemoglobin up to 0.5 g/dl (5 g/L), Lipemia up to 700 mg/dl (7.98 mmol/L) Triglycerides and Magnesium up to 15 mg/dl (6.17 mmol/L). A list of drugs and other interfering substances with Calcium determination has been reported by Young et al.

SENSITIVITY / LIMIT OF DETECTION :

The lower limit of detection is 0.4 mg/dl (0.10 mmol/L).

PRECISION :

Intra-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	9.1	0.09	0.99
Sample 2	11.93	0.07	0.59
Sample 3	12.05	0.09	0.75

Inter-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	11.7	0.1	0.85
Sample 2	12.27	0.11	0.90
Sample 3	12.24	0.16	1.30

METHOD COMPARISON :

A comparison between Robonik Prietest Calcium Arsenazo III (y) and a commercially available test (x) using 20 samples gave following results :

Linear Regression	:	y = 1.0091x - 0.5049 mg/dl
Correlation Coefficient	:	r = 0.8497

REFERENCE RANGE :

Serum / Plasma	:	8.6 to 10.3 mg/dl		(2.15 to 2.57 mmol/L)
Urine	:	Women	< 250 mg/24 h	(< 6.25 mmol/24h)
		Men	< 300 mg/24 h	(< 7.5 mmol/24h)

It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Endres, D.B., Rude, R.K., *Mineral and bone metabolism*, Tietz Fundamentals of Clinical Chemistry, 5th Ed., Burtis, C.A. & Ashwood, E.R. W.B. Saunders eds. Philadelphia USA, (2001), 795.
2. Tietz, N.W., Clinical guide to laboratory tests, 3 rd Ed., W.B. Saunders eds. Philadelphia USA, (1995), 100.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed. AACC Press, 1995.

INSTRUMENT APPLICATION ***prietest TOUCH***
Name : CALCIUM, Mod : END-P Pri.: 630 , Sec.: 0 Temp: 37C , KF : 1.000 Vol : 500ul , Unit : mg/dl Lag : 5 , Read : NA Blk : Y, QC : Y, Norm : Y Std : 1 , Concen : Std.: 1 = 10.0 Normal HI = 10.3 Normal LO = 8.6 QCNH : * QCNL : * QCABH = * QCABL = * Rgnt. Linearity : 15 NOTE : * Indicates user definable parameter. NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING	
TEST NAME	CALCIUM ARS. III
Reaction	End Point
Wavelength 1	630 or 623 nm
Temperature	37°C
Zero Setting	Reagent Blank
Standard Conc.	10
Units	mg/dl
Sample Volume	10 µl
Reagent Volume	1000 µl
Incubation Time	2 minutes
Reference Range	8.6 to 10.3
Reagent Linearity	15

ROBONIK®

An ISO 9001 : 2008 Certified Company
An ISO 13485 : 2012 Certified Company

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