

**GENESIS**

Instructions For Use

Calcium Single Reagent (Arsenazo III Method)

Cat no.	size
1308 101	2*25
1308 102	4*25
1308 103	3*25

INTENDED USE

Quantitative determination of total calcium in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS

Calcium is the most prevalent cation found in the body, distributed in bone (99%), soft tissues and extracellular fluid. Its concentration in plasma is regulated by parathyroid hormone, vitamin D and calcitonin. Calcium ion is important in the transmission of nerve impulses, in the maintenance of normal muscle contractility, as a cofactor in certain enzyme reactions, and in the coagulation of the blood. Hypercalcemia can be due to vitamin D intoxication, enhanced renal retention, osteoporosis, sarcosidosis, thyrotoxicosis, hyperparathyroidism, multiple myeloma, idiopathic hypercalcemia of infancy, and carcinoma metastatic to bone. Elevated calcium concentration in urine is found in nephrolithiasis and metabolic acidosis. Hypocalcemia may be caused by primary and secondary hypoparathyroidism, pseudo hypo parathyroidism, vitamin D deficiency, malnutrition and intestinal malabsorption.

PRINCIPLE OF THE METHOD**Arsenazo III colorimetric Method**

At a neutral pH, the Ca_{+2} form with Arsenazo III a complex, the color intensity of which is directly proportional to the concentration of calcium in the sample.

COMPOSITION

Colour reagent	Arsenazo III MES, pH 6.40	200 $\mu\text{mol/L}$ 100 mmol/L
Standard(St)		10.0 mg/dL

STORAGE.

Store at 2-8°C.

Reagents and Standard are stable until the expiry date shown on the Vial label when stored tightly closed and if contaminations are prevented during their use.

ADDITIONAL EQUIPMENT

- Analyzer, spectrophotometer able to read at 620 nm.

PRECAUTIONS AND WARNINGS

Do not ingest or inhale. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

SPECIMEN

1. Serum, heparinized plasma or urine collected by standard procedures.
2. Calcium in serum or plasma is stable for 10 days at 2-8°C.
3. Anticoagulants other than heparin should not be used.
4. Collect a 24-hour urine specimen in a bottle containing 10 mL of 50 % (v/v) nitric acid. Stable for 10 days at 2-8°C.

Centrifuge or filter and dilute $\frac{1}{2}$ with distilled water before testing.**PROCEDURE**

1. Pipette into labeled test tubes:

	Blank	Standard	Sample
Working Reagent	1.0 mL	1.0 mL	1.0 mL
Standard (S)	-	10 μL	-
Sample	-	-	10 μL

		Symbols in Product Labeling	
EC	REP	Authorized Representative	Expiration date
IVD		For in-vitro diagnostic use	CAUTION, consult instructions for use
REF		Catalogue number	Manufactured by
LOT		Lot number	Temperature Limit
		Consult instructions for use	

2. Mix thoroughly and incubate the tubes for **5 minutes** at room temperature.

3. Measure the absorbance (A) of the Standard and Sample at 620 nm against the blank.

CALCULATIONS

The concentration in the sample is calculated using the following general formula:

$$\frac{\text{A Sample}}{\text{A Standard}} \times \frac{10}{2.5} = \text{mg/dL}$$

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REFERENCE VALUES

Serum or plasma
Adults 8.5 – 10.5 mg /dL \cong 2.1 – 2.6 mmol/L
Children 10.0 – 12.0 mg/dL \cong 2.5 – 3.0 mmol/L
Newborns 8.0 – 13.0 mg/dL \cong 2.0 – 3.25 mmol/L
Urine:
Adults 50 – 300 mg/24h \cong 1.25 – 7.5 mmol/24h
Children 80 – 160 mg/24h \cong 2.0 – 4.0 mmol/24h

QUALITY CONTROL

It is recommended to use the Control Serum level I and II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control .

METROLOGICAL CHARACTERISTICS

Detection limit 1.8 mg/dL

Linearity limit: 20.0 mg/dL

For higher values dilute sample **1/2** with physiological saline and repeat measurement.**Precision****- Repeatability (within run):**

Mean Concentration	cv	n
9.6 mg/dL	1.68 %	20
13.58 mg/dL	1.43 %	20

- Reproducibility (run to run):

Mean Concentration	cv	n
9.6 mg/dL	2.21 %	25
13.58 mg/dL	1.59 %	25

INTERFERENCES

Interferences: Bilirubin (< 20 mg/dL), hemolysis (hemoglobin < 10 g/L) and lipemia (triglycerides < 30 g/L) do not interfere.Drugs and substances may interfere.

BIBLIOGRAPHY

1. Barnett RN: A scheme for the comparison of quantitative methods. AM J Clin Pathol 43: 562, 1965.
2. Fiereck EA: Appendix. Normal values. in:Fundamentals of clinical chemistry. NW Tietz, editor,Saunders, Philadelphia, p1208,1976.
3. Kessler G, wolfman M: An automated procedure for the simultaneous determination of calcium and phosphorus.Clin Chem 10:686, 1964.
4. Peters JP, Van Slyke, DD: Quantitative clinical chemistry, vol 2,williams and wilkins, Baltimor (MD),1932, p 760

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