GENESIS

Instructions For Use

Calcium (OCPC Method)

Cat no.	size
1301 101	2*25
1301 102	4*25
1301 103	2*50

INTENDED USE

Calcium Reagent is intended for the in vitro Quantitative diagnostic 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, hyperparathyroidsm, multiple mieloma, idiopathic hypercalcemia of infancy, and carcinoma metastasic 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

This Calcium OCPC procedure is based on calcium ions (Ca^{2+}) reacting with o-cresolphthalein complexone in an alkaline solution to form an intense violet colored complex which maximally absorbs at 546 nm. 8-Hydroxyquinoline is added to remove interference by magnesium and iron. In this method the absorbance of the Ca-OCPC complex is measured spectrophotometrically at 546 nm. The resulting increase in absorbance of the reaction mixture is directly proportional to the calcium concentration in the sample.

$$Ca^{2+} + OCPC \xrightarrow{\text{8-Hydroxyquinoline}} Ca - OCPC\ Complex$$

COMPOSITION

Reagent (R1)	Diethanol amine buffer pH 10	100 mmol/L
Reagent (R2)	8-Hydroxyquinoline OCPC Hydrochloric acid	1 mmol/L 0.3 mmol/L 0.5 N
Standard (S)		10.0 mg/dL

STORAGE.

Store at 15-30ºC.

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.

REAGENT PREPARATION

Working Reagent:-Mix (1) volume of buffer (R1) with (1) volume of colour reagent (R2).

ADDITIONAL EQUIPMENT

− Analyzer, spectrophotometer able to read at 546 nm

SPECIMEN

1.Serum, heparinized plasma or urine collected by standard procedures.

2.Calcium in serum or plasma is stable for 10 days at 2-8ºC.

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 2-8ºC.

-Centrifuge or filter and dilute ½ with distilled water before testing.

PRECAUTIONS AND WARNINGS

Do not ingest or inhalate. 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.

Symbols in Product Labeling

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

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

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

3. Measure the absorbance (A) of the Standard and Sample at 546 nm against the blank.

CALCULATIONS

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

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

REFERENCE VALUES

Serum or plasma				
Adults	8.5 – 10.5	mg /dL	≅ 2.1 – 2.6	mmol/L
Children	10.0 – 12.0	mg/dL	≅ 2.5 – 3.0	mmol/L
Newborns	8.0 – 13.0	mg/dL	≅ 2.0 – 3.25	mmol/L
Urine:				
Adults	50 – 300	mg/24h	≅ 1.25 – 7.5	mmol/24h
Children	80 – 160	mg/24h	≅ 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 0.6 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
9.58 mg/dL	1.7 %	20
13.6 mg/dL	1.4 %	20

− Reproducibility (run to run):

Mean Concentration	cv	n
9.58 mg/dL	2.2 %	25
13.6 mg/dL	1.6 %	25

INTERFERENCES

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

BIBLIOGRAPHY

1. K. Lorentz. Improved determination of serum calcium with 2-cresolphthalein comlpexone. Clin Chim Acta 1982; 126:327-334.

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