

PRODUCT CODE
CE007

INTENDED USE:

Reagent for the measurement of calcium concentration in human serum, plasma or urine. The obtained values are useful as an aid in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

CLINICAL SIGNIFICANCE:

Calcium is the most abundant and one of the most important minerals in the human body. Approximately 99% of body calcium is found in bones. A decrease in albumin level causes a decrease in serum calcium. Among causes of hypercalcemia are cancers, large intake of vitamin D, enhanced renal retention, osteoporosis, sarcoidosis, thyrotoxicosis, hyperparathyroidism. Low levels of calcium are found in hypoparathyroidism, pseudohypoparathyroidism, vitamin D deficiency, malnutrition and intestinal malabsorption. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE:

Calcium with Arsenazo III (1,8-Dihydroxy-3,6-disulpho-2,7-naphthalene-bis (azo)-dibenzeneearsonic acid), at neutral pH, yields a blue colored complex. The intensity of the colour formed is proportional to the calcium concentration in the sample.

REAGENT COMPOSITION:

Calcium Reagent	Arsenazo III	0.2 mmol/L
	Imidazole	75 mmol/L
Calcium Standard:	Calcium aqueous primary standard 10 mg/dl	

REAGENT PREPARATION:

Reagent is provided ready to use.

STORAGE AND STABILITY:

Store at 2-8°C.

Components are stable once opened until the expiry date marked in the label if they are stored well closed and care is taken to prevent contamination during their use.

Indications of deterioration: Absorbance of the blank over the limit indicated in "Test Parameters".

SPECIMEN:

Serum, heparinized plasma or urine collected by standard procedures Calcium in serum or plasma is stable for 10 days at 2-8°C. Anticoagulants other than heparin should not be used. 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 before testing.

ASSAY:

Wavelength: 650 nm
Cuvette: 1 cm light path
Temperature: 37°C/ 15-25°C.
Adjust the instrument to zero with distilled water.

PROCEDURE:

	Blank	Standard	Sample
Reagent (ml)	1 ml	1 ml	1 ml
Standard (µl)	-----	10 µl	-----
Sample (µl)	-----	-----	10 µl

Mix and incubate for 2 min at 37°C / 15-25°C.

Read the absorbance (A) of the samples and standard, against the blank. The color is stable for at least 1 hour.

CALCULATIONS:

-Serum and Plasma:

$$\text{Calcium mg/dl} = \frac{(A)\text{Sample} - (A)\text{Blank}}{(A)\text{Standard} - (A)\text{Blank}} \times 10 \text{ (STD Conc.)}$$

-Urine 24h:

$$\text{Calcium mg/24 h} = \frac{(A)\text{Sample} - (A)\text{Blank}}{(A)\text{Standard} - (A)\text{Blank}} \times 10 \text{ (STD Conc.)} \times \text{vol. (dl) urine/24h}$$

PRECAUTION:

R: H360-May damage fertility or the unborn child. STD: H290-May be corrosive to metals. Follow the precautionary statements given in MSDS and label of the product.

LINEARITY:

The test is linear up to a calcium value of 32 mg/dL .If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L and multiply the result by 2.

NORMAL RANGE:

-Serum or plasma:
Adults: 8,5 - 10,5 mg/dL = 2,1 - 2,6 mmol/L

Children :10 - 12 mg/dL = 2,5 - 3,0 mmol/L
Newborns: 8 - 13 mg/dL = 2,00 - 3,25 mmol/L

- Urine:

Adults: 50 - 300 mg/24 h = 1,25 - 7,50 mmol/24
Children 80 - 160 mg/24 h = 2 - 4 mmol/24

These values are for orientation purpose; each laboratory should establish its own reference range.

QUALITY CONTROL:

All control sera with Calcium determined by this method may be used. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

CALIBRATION:

A reagent blank should be done every day and a calibration at least every 2 months, after reagent lot change or as required by quality control procedures.















INTERFERENCES:

No interferences were observed with triglycerides up to 1,25 g/L1,2,3. A list of drugs and other interfering substances with calcium determination has been reported by young et.

NOTES:

- Contaminated glassware is the commonest source of error. Disposable plastic is recommended for this test.
- It is recommended to use disposable material. If glassware is used the material should be scrupulously cleaned with diluted (1/2) HNO3 in water and then thoroughly rinsed it with distilled water.
- Most of the detergents and water softening products used in the laboratories contains chelating agents. A defective rinsing will invalidate the procedure.
- Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
- Use clean disposable pipette tips for its dispensation

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
	Catalogue Number		Pack Size
	Expiry Date		Volume
	Storage Condition		Lot Number
	Instruction for Use		In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests		For Single Use Only
	EC Representative		European conformity

BIBLIOGRAPHY

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