CALCIUM ARSENAZO III CE

REF 1113000	REF 1113025
2 x 50 mL	1 x 250 mL
CONTENTS	**CONTENTS**
R1. 2 x 50 mL CAL. Standard 1 x 3 mL	R1. 1 x 250 mL CAL. Standard 1 x 3 mL
For *in vitro* diagnostic use only	

CALCIUM ARSENAZO

TOTAL

Colorimetric method

ENDPOINT

PRINCIPLE

The method[1] is based on the specific binding of arsenazo III and calcium at acid pH with the resulting shift in the absorbtion wavelength of the complex. The intensity of the cromophore formed is proportional to the concentration of total calcium in the sample.

$$\text{Arsenazo III + Calcium} \xrightarrow{\text{pH 6.5}} \text{Arsenazo III-Calcium complex}$$

REAGENT COMPOSITION

R1 **Arsenazo indicator.** Arsenazo III 120 mmol/L, imidazol 75 mmol/L pH 6.5.

CAL **Calcium / Magnesium standard**. Calcium 10 mg/dL / Magnesium 2 mg/dL. Organic matrix based primary standard. Concentration value is traceable to Standard Reference Material 909b (NIST).

STORAGE AND STABILITY

Store at 2-30ºC.
All the kit compounds are stable until the expiry date stated on the label. Do not use reagents over the expiration date.
Store the vials tightly closed, protected from light and prevented contaminations during the use.
Discard If appear signs of deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 650 nm > 0.500 in 1cm cuvette.

REAGENT PREPARATION

The Reagents are ready-to-use.

SAMPLES

Serum or heparinized plasma and urine (see notes). Other anticoagulants (EDTA, oxalate and citrate) must not be used.
Calcium in serum or plasma is stable for 10 days at 2-8ºC. Freeze for longer storage.
Calcium in acidified samples of urine (see Notes) is stable for 10 days at 2-8ºC.

INTERFERENCES

- Lipemia (intralipid >1 g/L) may affect the results.
- Bilirubin (40 mg/dL), hemoglobin (12 g/L) do not interfere.
- Other drugs and substances may interfere[3].
- Many detergents and water supplies (see Notes).

MATERIALS REQUIRED

- Photometer or colorimeter capable of measuring absorbance at 650 ± 20 nm.
- Pipettes with disposable plastic tips to measure reagents and samples.
- Disposable plastic tubes for the tests.

PROCEDURE

1. Bring reagents and samples to room temperature.
2. Pipette into labelled test tubes:

TUBES	Blank	Sample	CAL. Standard
R1.Reagent	1.0 mL	1.0 mL	1.0 mL
Sample	–	10 µL	–
CAL.Standard	–	–	10 µL

3. Mix and let the tubes stand 2 minutes at room temperature.
4. Read the absorbance (A) of the samples and the standard at 650 nm against the reagent blank.

The color is stable for at least 8 hours at room temperature.

CALCULATIONS

Serum, plasma

$$\frac{A_{Sample}}{A_{Standard}} \times C_{Standard} = \text{mg/dL total calcium}$$

Samples with concentrations higher than 22 mg/dL should be diluted 1:2 with saline and assayed again. Multiply the results by 2.

Urine

$$\frac{A_{Sample}}{A_{Standard}} \times C_{Standard} \times F = \text{mg/24-hours total calcium}$$

F = Dilution factor = 2

If results are to be expressed as SI units apply:
mg/dL x 0.25 = mmol/L

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

LINEAR CHEMICALS, S.L.U. Joaquim Costa 18 2ª planta. 08390 Montgat (Barcelona) SPAIN
Telf. (+34) 934 694 990; E-mail: info@linear.es ; website: www.linear.es NIF-VAT:B60485687

REFERENCE VALUES[4]

Serum, plasma

Newborns (< 10 days)	7.6 - 10.4 mg/dL (1.9 - 2.6 mmol/L)
Children (2-12 years)	8.8 - 10.4 mg/dL (2.2 - 2.6 mmol/L)
Adults (12-60 years)	8.4 - 10.2 mg/dL (2.1 - 2.5 mmol/L)

Urine

Adults (normal diet)	100-300 mg/24-h (25 - 75 mmol/24-h)

It is recommended that each laboratory establishes its own reference range.

QUALITY CONTROL

The use of a standard to calculate results allows to obtain an accuracy independent of the system or instrument used.
To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

REF **1980005** HUMAN MULTISERA NORMAL
Borderline level of calcium. Assayed.

REF **1985005** HUMAN MULTISERA ABNORMAL
Elevated level of calcium. Assayed.

If the values are found outside of the defined range, check the instrument, reagents and procedure.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

CLINICAL SIGNIFICANCE

Calcium exists in the blood in three forms: ionized (13%), complexed (47%) and bound to protein, mainly albumin (40%). When calcium determinations are performed, the total calcium concentration is determined regardless of the amount of calcium present in each form. A depressed concentration of total calcium can be due to hypoproteinemia, but the concentration of physiologically active (ionized) calcium in such case may be normal. For this reason, a protein determination should accompany each calcium analysis so that the calcium value can be interpreted properly.

Depressed serum calcium levels usually accompany hypoparathyroidism, some bone diseases, certain kidney diseases, and low protein levels.
Elevated serum calcium levels occur in hyperparathyroidism, vitamin-D poisoning, and sarcoidosis.

The plasma level in calcium is greatly affected by the plasma level of inorganic phosphate. In most cases, there is an inverse relationship between calcium and inorganic phosphate.

Conditions associated with *hypercalcemia*, such as primary hyperparathyroidism are usually associated with *hypophosphatemia*; the opposite is true as well.

Urine calcium excretion parallels the serum calcium level. Large amounts of calcium are excreted in the urine in hyperparathyroidism, metabolic acidosis, renal tubular insufficiency, and multiple myeloma and bone malignancies.

NOTES

- Most of the detergents and water softening products used in the labs contain chelating agents. A defective rinsing will invalidate the procedure. Keep the glassware acid washed and thoroughly rinsed at all times.
- Collect a 24-hour urine specimen into a plastic bottle containing 10 mL of 50% (v/v) HCl. Centrifuge or filter, and dilute 1:2 with distilled water before testing.
- This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

ANALYTICAL PERFORMANCE

- ***Detection Limit :*** 0.07 mg/dL
- ***Linearity :*** Up to 22 mg/dL
- ***Precision:***

mg/dL	**Within-run**		**Between-run**	
Mean	9.5	12.6	9.5	12.6
SD	0.05	0.07	0.14	0.17
CV%	0.53	0.57	1.52	1.37
N	10	10	10	10

- ***Sensitivity:*** 0.038 A / mg/dL calcium.
- ***Correlation:*** This assay (y) was compared with a similar commercial method (x). The results were:

  N = 62 r = 0.98 y = 0.97x + 0.41

The analytical performances have been generated using on automatic instrument. Results may vary depending on the instrument.

REFERENCES

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2. Friedman and Young. Effects of disease on clinical laboratory tests, 3th ed. AACC Press, 1997.
3. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
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LINEAR CHEMICALS, S.L.U. Joaquim Costa 18 2ª planta. 08390 Montgat (Barcelona) SPAIN
Telf. (+34) 934 694 990; E-mail: info@linear.es ; website: www.linear.es NIF-VAT:B60485687