



CALCIUM ARSENAZO LR liquid reagent

REF **C1850650** 1309 Test

CE **C1850650A** 1309 Test

IVD For in vitro medical device

"Inter-Assay" precision (between-Run)

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (mg/dl)	N = 8.69	H = 13.93
S.D.	N = 0.20	H = 0.29
C.V.%	N = 2.33	H = 2.06

Analytical sensitivity

The test sensitivity in terms of detection limit is: 1.2 mg/dl.

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor **r = 0.95**

$$y = 0.9986 x - 0.277$$

Interferences

No interference was observed by the presence of:

Bilirubin	≤ 20 mg/dl
Triglycerides	≤ 800 mg/dl
Hemoglobin	≤ 500 mg/dl
Magnesium	≤ 10 mg/dl

Lipemic specimens should not be used for analysis.

For a comprehensive review of interfering substances, refer to the publication by Young.

Quality controls

It's necessary, each time the kit is used, to perform quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Kaplan, L.A., Pesce, A.J.: "Clinical Chemistry", Mosby Ed. (1996).

Young D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, DC 5th ed.2000.

Symbols

	CE Mark (98/79 CE regulation)
	in vitro medical device
	Batch Code
	Use by
	Storage temperature limits
	Read instruction for use
	Gesano Production srl

Use

Kit for measurement of calcium in serum, plasma and urine. Colorimetric arsenazo method.

Summary

Calcium measurements are used in the diagnosis and treatment of certain disorders of calcium metabolism.

Principle

End point analysis. Arsenazo III, in presence of calcium ions in neutral pH environment, gives a coloured complex whose colour intensity is directly proportional to the calcium concentration in the tested sample.

Reagents

R1	Goods buffer	pH 6.8	100.0 mmol/l
	Arsenazo III		0.40 mmol/l

Reagent Preparation

Reagent is liquid and ready for use.

Storage and stability

- Store the kit at 15-25°C.
- After opening, the vial R1 is stable 90 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.

Precaution in Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). However the reagent should be handled with care, according to good laboratory practice.

Waste Management

Please refer to the local legal requirements.

Specimen Collection and Preparation

- Serum or plasma.
- Diluted urine: 1:3.
- Do not use samples with haemolysis. Do not use anticoagulants as EDTA, oxalate, citrate or fluoride.
- Avoid venous standstill. The use of tourniquet can rise the calcium level in the withdrawal in 0.5 mg/dl (0.12 mmol/l) as well.
- After picked up, serum and plasma must be separated, as soon as possible, from red cells to avoid calcium absorption by red cells.
- The calcium is stable in the serum or plasma 1 day at 2-8°C or 8 months at -20°C.
- Serum strongly jaundiced or lipoemic must be tested using a blank sample.

Note

- The kit, according to this method, must be used in manual procedures. About automatic use follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the single vials.

Procedure

Wavelength	λ: 650 (600-670) nm
Working Temperature	37 °C
Optical path	1 cm
Reaction	"end point"

Monoreagent Procedure "sample starter"

	BLANK	STD	SAMPLE
Working Reagent	1000 µl	1000 µl	1000 µl
Distilled Water	25 µl	--	--
Sample	--	--	25 µl
Standard	--	25 µl	--

Mix, then incubate for 5' at 37°C (15-25°C). Measure the absorbance of the sample (EC) and standard (ESTD) against the reagent blank.

Calculation

$$\text{Calcium [mg/dl] o [mmol/l]} = \text{EC/ESTD} \times \text{Conc. STD}$$

Diluted urines: multiply the result for diluting factor.

The reagent performances are related to 37°C, 1 cm and 650 nm.

Conversion Factor

Calcium [mg/dl] x 0.2495 = Calcium [mmol/l]
Calcium [mg/dl] x 0.4990 = Calcium [mEq/l]

Reference Values

Serum-plasma	8.8-10.2 mg/dl (2.19-2.54 mmol/l)
Urine	50-400 mg/dl (12-98 mmol/24h)

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history

ANALYTICAL PERFORMANCE

Linearity

Reaction is linear up to a concentration of 16 mg/dl Samples with values exceeding 16 mg/dl must be diluted with saline solution. Then multiply the result for diluting factor.

"Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (mg/dl)	N = 8.89	H = 13.91
S.D.	N = 0.19	H = 0.26
C.V.%	N = 2.17	H = 1.89