

CALCIUM

Cat. No.	Pack Name	Packaging (Content)
BLT00015	CA 100	R1: 2 x 50 ml, R2 standard: 1 x 5 ml
BLT00016	CA 250	R1: 1 x 250 ml, R2 standard: 1 x 5 ml

EN



INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Calcium in human serum, plasma or urine.

CLINICAL SIGNIFICANCE

Calcium has numerous function within the body, not only as a structural factor in bones and teeth, but also in normal neuromuscular function and the clotting of blood.

Hypercalcaemia may develop in patients with Paget's disease of bone and hyperparathyroidism. The cause of hypercalcaemia in malignancy is an increased bone resorption either caused by metastasis or by humoral factors produced by the tumor cell.

In Rickets, Coeliac diseases, idiopathic steatorrhea, osteomalacia, tropical sprue and following surgical resection of the small intestine, serum calcium is often moderately reduced, usually in association with low plasma protein concentration.

PRINCIPLE

Arsenazo III combines with calcium ions at pH 6.5 to form a coloured chromophore, the absorbance of which is measured at 650 nm (650-660 nm) and is proportional to calcium concentration.

Arsenazo III has a high affinity ($K^{\circ} = 1 \times 10^{-7}$) for calcium ions and shows no interference from other cations normally present in serum, plasma or urine.

REAGENT COMPOSITION

R1	
Arsenazo III	0.10 mmol/l
Phosphate buffer (pH 7.8 ± 0.1)	50 mmol/l
R2 standard	See bottle label

REAGENT PREPARATION

Reagents are liquid, ready to use.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8 °C.

SPECIMEN COLLECTION AND HANDLING

Use unheamolytic serum or plasma (heparin) or urine.

It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability in serum/plasma:

7 days at 20–25°C
3 weeks at 4–8°C
8 months at -20°C

Stability in urine:

2 days at 20–25°C
4 days at 4–8°C
3 weeks at -20°C

FREEZE ONLY ONCE!

For the determination in urine dilute the sample using redistilled water in 1 + 2 ration and after adding several drops of HCl 0.1 mol/l adjust the sample pH to 3 – 4 (result x 3).

Discard contaminated specimens.

CALIBRATION

Calibration with the standard included in the kit or the calibrator XL MULTICAL, Cat. No. XSYS0034 is recommended.

QUALITY CONTROL

For quality control ERBA NORM, Cat. No. BLT00080 and ERBA PATH, Cat. No. BLT00081 are recommended.

UNIT CONVERSION

mg/dl x 0.25 = mmol/l

EXPECTED VALUES ⁴

Serum: Adult	8.6 - 10.2 mg/dl
Child	
2 - 12 y	8.8 - 10.8 mg/dl
10 d - 24 mo	9.0 - 11.0 mg/dl
0 - 10 d	7.6 - 10.4 mg/dl
Urine: Female	< 250 mg/24 h
Male	< 300 mg/24 h

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on ERBA XL systems. Data obtained in your laboratory may differ from these values.

Limit of quantification: 0.6 mg/dl

Linearity: 16 mg/dl

Measuring range: 0.6 – 16 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	7.836	0.068	0.89
Sample 2	11.956	0.052	0.43

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	9.096	0.184	2.05
Sample 2	11.748	0.264	2.26

COMPARISON

A comparison between XL-Systems Calcium (y) and a commercially available test (x) using 40 samples gave following results:

$y = 0.979x - 0.076$ mg/dl

$r = 0.999$

INTERFERENCES

Following substances do not interfere:

haemoglobin up to 10 g/l, bilirubin up to 40 mg/dl, triglycerides up to 500 mg/dl.

Note: Care must be taken to avoid calcium contamination. The use of the plastic tubes or cuvettes is strongly recommended. The user should ensure that such disposables are free for calcium contamination. If glassware is used, it should be soaked in dilute HCl deionized water and dried.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.

Reagents of the kit are not classified like dangerous but Reagent R 1 contains in low concentration Arsenazo III, toxic and dangerous substance for the environment.

WASTE MANAGEMENT

Please refer to local legal requirements.

ASSAY PROCEDURE

Wavelength: 650 (630 – 670) nm

Cuvette: 1 cm

	Reagent blank	Standard (Cal.)	Sample
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	-	-	10 µl
Standard (Cal.)	-	10 µl	-
Distilled water	10 µl	-	-

Mix, incubate 1 min. at 37°C. Measure absorbance of the sample A_{sam} and standard A_{st} against reagent blank.

CALCULATION

$$\text{Calcium (mg/dl)} = \frac{\Delta A_{sam}}{\Delta A_{st}} \times C_{st} \quad C_{st} = \text{standard (calibrator) concentration}$$

Applications for automatic analysers are available on request.


ASSAY PARAMETERS FOR PHOTOMETERS


Mode	End Point
Wavelength 1 (nm)	630 (670)
Sample Volume (µl)	10
Reagent Volume (µl)	1000
Incubation time (min.)	1
Incubation temp. (°C)	37
Normal Low (mg/dl)	8.6
Normal High (mg/dl)	10.2
Linearity Low (mg/dl)	0.6
Linearity High (mg/dl)	16
Concentration of Standard	See bottle label
Blank with	Reagent
Absorbance limit (max.)	1.2
Units	mg/dl


REFERENCES


1. Beeler, M.F. and Catrou, P.G. "Disorders of Calcium Metabolism" in Interpretations in Clinical Chemistry A.C.S.P. Press Chicago 1983; 34-44.
2. Farrell C.E. "Electrolytes" in Clinical Chemistry Theory, Analysis and Correlation. The C.V. Mosby Company. Kaplan L. A., Pesce A. J. (Ed). 1984; Chap 55; 1054.
3. Baurer P.J. Anal. Biochem 1981: 110:61-72.
4. Tietz Textbook of Clinical Chemistry. Burtis CA and Ashwood ER, Fifth Edition, 2012.

SYMBOLS USED ON LABELS


 REF Catalogue Number


 Manufacturer

 See Instruction for Use

 LOT Lot Number

 CE Mark -
Device comply with
the Directive 98/79/EC


 Storage Temperature

 Expiry Date

 IVD In Vitro Diagnostics

 CONT Content

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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