Calcium AIII – Instructions for use (IFU)

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CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

IVD CE

6 x 50 mL • REF A-R0100000301
3 x 18,5 mL • REF R3330000012

INTENDED USE
Product for use in the quantitative determination in vitro of the Calcium concentration in human serum, plasma or urine. The results of the test must always be interpreted in conjunction with the clinical context. For professional use only.

INTRODUCTION
Calcium is one of the mineral elements present in the blood, and one of the chief constituents of bone tissue. It is present in small amounts in soft tissues and in extracellular fluids. About 50% of the calcium present in the blood is free, 40% is bound to proteins and 10% is present in compounds. About 80% of calcium bound to proteins is associated with albumin and the remaining 20% with globulins. Extracellular calcium has the role of maintaining intracellular calcium, mineralizing bone, blood coagulation and maintenance of the cell membrane. Calcium is of particular importance in muscular contraction, in addition to being a second messenger which influences enzymatic activity and hormonal secretion. High serum calcium levels (hypercalcemia) are essentially due to an increased flow of extracellular calcium produced by bone, intestinal and renal tissue. Low serum calcium levels (hypocalcemia) may be due to a reduction in the calcium bound to albumin or to the free fraction.

PRINCIPLE
Calcium ions form a highly coloured complex with Arsenazo III at neutral pH. The colour which has formed will correspond to the amount of calcium present in the sample.

Calcium + 2 Arsenazo III → Ca-Arsenazo Complex

REAGENTS
A-R0100000301 – 6 x 50 mL
Reagent: no. 6 vials x 50.0 mL ready to use
R3330000012 – 3 x 18.5 mL
Reagent: no. 3 vials x 14.0 mL ready to use

Concentrations

Reagent:			
	Conc.	**U.M.**	
Imidazol buffer (pH 6.75)	100	mM	 GHS08*
Arsenazo III	0.20	mM	
Stabilizing agents	-	-	

* Warning **DANGER** Contains: imidazole (CAS 288-32-4)
H360D- May damage the unborn child.
P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves/protective clothing/eye protection/ face protection/hearing protection.
P308+P313 - IF exposed or concerned: Get medical advice/attention.
P501 - Dispose of contents/container in accordance with local/ Regional /national /international regulations.

Precautions
Kit for professional laboratory use, used only by qualified and properly trained technical personnel, under the supervision of a doctor in charge of the laboratory. In addition to risk indications related to the active components, reagents may contain inactive components such as preservatives and detergents. The total concentration of these components is lower than the limits reported in the EC 1272/2008 Regulation and subsequent amendments and additions. However, it is recommended to handle reagents according to the standards of good laboratory practice

Reports of serious incidents
In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

Storage and stability
Store at 2 - 8°C and protect from direct light. When correctly stored, the reagents are stable up to the expiry date reported on the label. A slight variation in the composition of the reagents may occur between batches, but this has no effect on the test results.
After opening, the vial R1 and R2 are stable 30 days if recapped immediately and protected from contamination, evaporation, direct light and stored at correct temperature.

Reagent Preparation
The reagent is liquid ready for use. After opening, the reagent is stable for 30 days if closed and stored at 2 - 8°C. Do not mix different batches.

SAMPLE COLLECTION
Type of sample and storage
Heparinized plasma or serum samples should be used. Do not use anticoagulants containing citrates, oxalates or EDTA as these tend to remove the calcium through formation of complexes. The samples can be stored for 7 days at 20 - 25°C, 3 weeks at 4 - 8°C, 8 months at – 20°C.

Precautions
All human samples must be handled and disposed of as potentially infectious materials.

PROCEDURE
Quality control
Control sera with known Calcium content are commercially available for quality control, including certificates of analysis showing the values and limits of confidence. Normal and pathological control sera are available as "Normal control serum" cod. R0400000006 and "Pathological control serum" code R0400000106. The values obtained must be contained within the acceptability range. In case of incorrect results check the following points:
- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation
Although this device has been developed and manufactured to be used by manual method and instrumental systems, it can also be used in combination with other instrumental devices that are able to meet the requirements indicated in the paragraph "Reaction conditions / Technique".
All applications that are not explicitly approved cannot be guaranteed in terms of performance and will therefore have to be evaluated by the user.

Calibration
For calibration use the kit "Multicalibrator" code R0300000006. For ISE srl instruments, calibration is recommended every 10 days.

Traceability
Calcium traceability is visible in the insert of the calibration serum packaging.

MANUAL METHOD
The kit, in Open format, can be used manually through the use of spectrophotometer or photometer with the following parameters:

Reaction conditions
Wavelength (primary): 660 nm
Temperature: 37°C

Technical – procedure with Serum as starter
Bring the reagents to reaction temperature and operate away from direct light.

	U.M.	**Blank**	**Calibr. Serum**	**Sample**
Reagent	µL	1000	1000	1000
Calibr. serum	µL	-	20	-
Sample	µL	-	-	20
Blank	µL	20	-	-

Mix well and incubate for 5 minutes at 37°C.
Measure absorbance of the sample and standard against reagent blank.
The reaction volumes may be varied proportionally without alteration of results.

Results:
Manual Method
Calculatin of Calcium:

$$\frac{\text{O.D. Sample}}{\text{O.D. Calibrator serum}} \times \text{Calibrator serum Concentration} = \text{Calcium mg/dL}$$

NORMAL VALUES
Serum or plasma: 8.6 – 10.3 mg/dL (2.15 – 2.57 mmol/L)
Urine: 100 – 400 mg/24 h (2.5 – 10 mmol/24 h)
Each laboratory must establish its own normal values on the basis of its local catchment area.

Sclavo Diagnostics International
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Reagents included in the kit
The reagents are described above.

Materials required but not supplied in the kit
Calibrators and controls.

ANALYTICAL CHARACTERISTICS/PERFORMANCE
Linearity
The method is linear up to 17.90 mg/dL .

Specificity
The method is specific for the determination of Calcium in the analytical conditions described.

Accuracy – Recovery
The recovery of Calcium added to normal samples at known concentrations showed an accuracy of 94.4%.

Interferences
The high dilution of the sample with the reagent reduces to a minimum the interference by lipids. Bilirubin below 58 mg/dL does not interfere in the reaction, hemoglobin interferes at concentrations above 10 g/L. Copper may cause interference. It is therefore advisable to avoid contamination with reagents containing high concentrations of copper such as Biuret for the reading of total proteins. For other interfering substances, make reference to the bibliography reported below (4) .

Precision of the method

Within-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	5.46	0.166	3.03%	20
High	mg/dL	11.65	0.133	1.14%	20
Between-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	5.46	0.081	1.49%	20
High	mg/dL	11.65	0.754	6.47%	20

Sensitivity
At λ 630 nm, a concentration of about 0.1 mg/dL of Calcium in the conditions established for this test.

Comparative method
The Calcium Arsenazo III reagent was compared with a similar commercial method. Samples tested No. = 71; Y = 0.9069x + 0.97; r = 0.989.

Disposal of reagents
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

Manufacturer:
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Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

Reference

1. Butris CA and Ashwood ER (Ed.), Tietz Fundamentals of Clinical Chemistry, 5th Edition, W.B. Saunders Company, Philadelphia, 2001, p.797-799, 968.
2. Janssen JW and Helbing AR. Arsenazo III. An improvement of the routine calcium determination in serum. Eur. J. Clin. Chem. Clin. Biochem. 29 (3) pp. 197-201,1991.
3. Guder WG, Narayanan S., Wisser H., Zavata B. List of analyses; preanalitycal variables. Brochure in: Samples: from patient t o the laboratory. Git Verlag GmbH, Darmstadt, 1996.
4. Young D, Effects of drugs on clinical laboratory tests. 5th Edition, AACC Press, Washington, DC, 3-149 – 3-158, 2000.

REVISION	DATE	CHANGE
Rev.A	12/2022	New Issue for IVDR Regulation (UE) 2017/746 compliance