CALCIUM ARSENAZO III
Multi-Purpose (MPR)
Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
GL162C	4x 250 ml	CALCIUM ARSENAZO III	2-8°C
GL172C	6 x 60 ml	CALCIUM ARSENAZO III	2-8°C

INTENDED USE:

In Vitro Diagnostic reagent pack for the quantitative determination of Calcium in serum and plasma on automated and semi-automated analysers.

SUMMARY AND EXPLANATION: [1]

Calcium is the fifth most common element in the body. It is found mainly in the skeleton with small amounts in the soft tissues and extracellular fluid. The skeleton contains 99% of the body's calcium predominantly as extracellular crystals similar to hydroxyapatite. In the blood approximately 50% of the plasma calcium is free, 40% is protein bound and 10% is complexed. Calcium ions affect the contractility of the heart and skeletal muscle and are essential for the function of the nervous system. The parathyroid hormone (PTH) and calcitonin (CT) regulate the body's calcium balance. The most common cause of low serum calcium is due to Hypoalbuminaemia. Other causes include chronic renal failure, magnesium deficiency, hypoparathyroidism, osteomalacia and rickets. Increased levels of serum calcium are evident in primary hypoparathyroidism, malignancy with skeletal involvement, haemotological malignancy, renal disease and Vitamin D & A overdose.

PRINCIPLE OF THE TEST: [2]

Arsenazo III specifically binds to calcium, forming a coloured complex with absorbance maxima at 600 nm and 650 nm. The absorbance at these wavelengths is proportional to the calcium concentration in the sample, allowing calcium measurement at either wavelength.

Ca^{2+} + Arsenazo III $\longrightarrow$ Coloured Complex

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Dark purple liquid.
Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety Precautions:
Material Safety Data Sheet is available upon request.

Label Elements:

WARNING

H315 – Causes skin irritation.
H319 – Causes serious eye irritation.
H360 – May damage fertility or the unborn child.

Precautionary Statements:
P201 – Obtain special instructions before use.
P264 – Wash thoroughly after handling.
P280 – Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P302+P352 – IF ON SKIN: Wash with plenty of soap and water.

Handling precautions:
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Instrument applications are available upon request.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration in Tests*
Reagent	Imidazole Buffer pH 6.6	100 mmol/l
	Arsenazo III	0.26 mmol/l
	DETERGENT	---

REAGENT PREPARATION AND STABILITY:

Reagent is ready to use.
Before use, mix reagent by gently inverting each bottle.
If stored and handled properly, components are stable until expiry date stated on the label.

TYPE OF SPECIMEN: [1]

Use serum or heparin plasma (plasma must be assayed fresh[3]) as specimen.
Do Not Use Oxalate, EDTA or citrate plasma.
It is recommended to follow NCCLS procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Serum/Plasma should be separated from cells within 2 hours after collection.
Stability$_4$: Serum, up to 3 weeks at 2-8°C

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
General Chemistry Calibrator	GL983	Photometer	N/A
General Chemistry Control Level 1	GL922	General Laboratory Equipment	N/A
General Chemistry Control Level 2	GL932		

Assay procedure:
Wavelength: λ: 650 nm
Temperature: 30°C or 37°C
Optical path: 1 cm light path.

	Blank	**Standard (STD)**	**Sample**
Working Reagent	1000 µl	1000 µl	1000 µl
Sample	----	----	10 µl
Standard (STD)	----	10 µl	----
Gently mix and Incubate at 37°C for 5 minutes. Read Optical Density (OD).			

Calibration:
Using recommended Calibrator, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the Laboratory QC Programme.

CALCULATION:

$$\text{Concentration of Calcium} = \frac{\text{Abs sample – abs blank}}{\text{Abs Std – abs blank}} \times \text{Concentration of Calibrator}$$

*Photometer must be blanked with the reagent blank. (Conversion Factor: Qty in mg/dl x 0.25 = Qty in mmol/l)

EXPECTED VALUES:

Tietz[1], Total Calcium in Serum

	mmol/l	*mg/dl*
Baby (< 24 months)	2.25 to 2.75	9 – 11
Child (<1 12 years)	2.20 to 2.70	8.8 – 10.8
Adult	2.15 to 2.50	8.6 - 10

Each laboratory should establish its own reference range. Calcium results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
This assay is linear up to 4 mmol/l (16 mg/dl).
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Interfering substances:
Results of study are as follows:

Bilirubin (mixed isomers):	Less than 10% interference up to 600µmol/l Bilirubin.
Haemolysis:	Less than 10% interference up to 5 g/l Haemoglobin.
Lipemia:	Less than 10% interference up to 2.5 g/l Intralipid.

Sensitivity:
The Lowest Detectable Level of Calcium was estimated at 0.03mmol/l (0.12 mg/dl).

Precision:

Within Run N = 20	Mean *(mmol/l)*	*SD*	*% CV*	*Between Run N = 20*	Mean *(mmol/l)*	*SD*	*% CV*
Level 1	2.42	0.07	2.93	Level 1	2.37	0.06	2.44
Level 2	3.94	0.08	2.02	Level 2	3.78	0.07	1.90

Method Comparison:
Using 50 samples, a comparison, between this Calcium test (y) and another commercially available test (x), gave the following results:

y = 0.960x + 0.142	r =0.989	Sample range: 1.17 to 4.32 mmol/l

BIBLIOGRAPHY:

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3. Tietz NW ed. Fundlementals of Clinical Chemistry, 3rd ed. Philadelphia, Pa: WB Saunders Company, 1987:718-719.
4. Guder WG, Narayanan S, Wisser H, Zawta B. List of Analytes;Pre-analytical Variables. Brochure in: Samples: From the patient to the Laboratory. Darmstadt: GIT Verlag, 1996.

SYMBOLS:

The following symbols are used in the labelling of Glenbio Ltd. systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	STD	Aqueous Standard

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

Storage temperature → Reconstitute with

Expiry Date (Last day of the month) — Manufactured By

Biological risk — Consult Instruction for Use

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