

CALCIUM CPC Multi-Purpose (MPR) Liquid Reagent

KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GL102C	3 x 125 ml	CALCIUM CPC - 1	15 - 25°C
	1 x 125 ml	CALCIUM CPC - 2	
	1 x 10 ml	CALCIUM - Standard	
GL112C	10 x 15 ml	CALCIUM CPC - 1	15 - 25°C
	1 x 50 ml	CALCIUM CPC - 2	
	1 x 10 ml	CALCIUM - Standard	
GL122C	3 x 250 ml	CALCIUM CPC - 1	15 - 25°C
	1 x 250 ml	CALCIUM CPC - 2	
	1 x 10 ml	CALCIUM - Standard	

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:

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 extra cellular fluid. The skeleton contains 99% of the body's calcium predominantly as extra cellular 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, hyperparathyroidism, osteomalacia and rickets. Increased levels of serum Calcium are evident in primary hyperparathyroidism, malignancy with skeletal involvement, haematological malignancy, renal disease and Vitamin D & A overdose.

PRINCIPLE OF THE TEST:

In alkaline solution, o-cresolphthalein complexone (CPC) forms a purple complex with calcium. Interference with magnesium ions is reduced by the addition of 8-hydroxyquinoline. The colour intensity of the complex formed is measured and is directly proportional to the calcium concentration in the sample.

Calcium + CPC $\xrightarrow{\text{Alkaline Solution}}$ calcium-o-cresolphthalein 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: Clear colourless liquid.

Reagent 2: Clear yellow 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:

CAUTION: Take all necessary precautions required when handling laboratory reagents. Material Safety Data Sheet is available upon request.

Label Elements:



DANGER

H302 – Harmful if swallowed.

H312 – Harmful in contact with skin.

H314 – Causes severe skin burns and eye damage.

H332 – Harmful if inhaled.

H335 – May cause respiratory irritation.

Precautionary Statements:

P260 – Do not breathe dust/fume/gas/mist/vapours/spray.

P280 – Wear protective gloves/protective clothing/eye protection/face protection.

P301 + P330 + P331 – IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303 + P361 + P353 – IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304 + P340 – IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 – Immediately call a POISON CENTER or doctor/physician.

Handling Precautions:

- 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 1	Ethanolamine Buffer	927 mmol/l
Reagent 2	CPC	0.32 mmol/l
Standard	8-hydroxyquinoline	13.6 mmol/l
	Calcium	2.5 mmol/l

REAGENT PREPARATION AND STABILITY:

Before use, mix reagent by gently inverting each bottle.

If stored and handled properly, unopened components are stable until the expiry date stated on the label

Monoreagent procedure: Add 1 volume of Reagent 2 to 3 Volumes of Reagent 1.

Working reagent is stable 1 day at 15-25°C.

Bireagent procedure: Liquid reagent 1 and 2 are ready for use.

Once open, components are stable until expiry date on label if store and handle properly.

TYPE OF SPECIMEN: 1

Serum is the preferred specimen. Heparinised plasma can also be used. *Do not use* Citrate, Oxalate and EDTA plasma.

It is recommended to follow CLSI 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: up to 7 days at 4°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 : 546 nm

Temperature: 37°C

Optical path: 1 cm light path.

MONOREAGENT PROCEDURE:			
	Blank	Calibrator	Sample
Working reagent	1000 μ l	1000 μ l	1000 μ l
Sample	----	----	20 μ l
Calibrator	----	20 μ l	----
Gently mix and incubate at 37°C for 5 minutes or at 15 - 25°C for 15 minutes. Measure the Optical Density (OD).			
BIREAGENT PROCEDURE:			
	Blank	Calibrator	Sample
Reagent 1	1000 μ l	1000 μ l	1000 μ l
Sample	----	----	40 μ l
Calibrator	----	20 μ l	----
Reagent 2	330 μ l	330 μ l	330 μ l
Gently mix and incubate at 37°C for 5 minutes or at 15 - 25°C for 15 minutes. Measure the Optical Density (OD).			

Calibration:

Using recommended Calibrator or standard included, calibrate the assay:

- Daily.
- 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 Program.

CALCULATION:

$$\text{Concentration of Calcium} = \frac{\text{OD}_{\text{Sample}}}{\text{OD}_{\text{Calibrator}}} \times \text{Concentration of Calibrator}$$

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

EXPECTED VALUES: 1

Total Calcium in Serum	mmol/l		Mg/dl	
	Baby (< 24 months)	2.25 to 2.75	9.02 – 11.0	
Child (<12 years)	2.20 to 2.70	8.82 – 10.8		
Adult	2.15 to 2.50	8.62 – 10.0		

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:

Linear up to 4mmol/L.

For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Interfering substances:

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

Sensitivity:

The Lowest Detectable Level was estimated at 0.03mmol/l.

Precision:

Within Run N = 20	Mean (mmol/l)	SD	% CV	Between Run N = 20	Mean (mmol/l)	SD	% CV
Level 1	2.12	0.03	1.41	Level 1	2.25	0.05	2.38
Level 2	3.32	0.02	0.70	Level 2	3.54	0.08	2.20

Method Comparison:

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















$y = 0.985x + 0.012$	$r = 0.988$	Sample range: 1.10 to 4.20 mmol/l
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BIBLIOGRAPHY:

- Burtis CA., Ashwood ER., Tietz Fund. Of Clin. Chem. 5th ed; 30-54, 797-802 and 968.
- Connerty HV. Bridges AR. Am J Clin Path 45. 1996; 290-296.

SYMBOLS:

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

	In Vitro Diagnostics		Catalogue No
	Batch Code		Content
	Reagent		Aqueous Standard
	CE Mark - Device complies with the Directives 98/79/EC		Storage temperature
	Expiry Date (Last day of the month)		Reconstitute with
	Biological risk		Manufactured By
	Consult Instruction for Use		CE

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