

LiquiMAX CALCIUM

(O - CPC METHOD)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVCAL2 -50	2 x 25 ml	(R1 : 25ml, R2 : 25ml)
AVCAL2 -100	2 x 50 ml	(R1 : 50ml, R2 : 50ml)
AVCAL2 -500	2 x 250 ml	(R1 : 250ml, R2 : 250ml)

INTENDED USE:

LiquiMAX CALCIUM is an in-vitro diagnostic kit for the quantitative determination of calcium in human serum urine.

PRODUCT FEATURES:

- Two Liquid Reagents.
- Heating and centrifugation of specimen not required.
- Addition of 8-Hydroxy Quinolene overcomes Magnesium interference
- Results correlate with Arsenazo-III and Methyl Thymol Blue Methods.
- Linearity 25 mg/dl.
- Disposable calcium free test tubes provided for testing.
- Can be used on any colorimeter, spectrophotometer, discrete semi automated and automated analyzers.

CLINICAL SIGNIFICANCE

The calcium content of an adult is somewhat over 1 kg (25000 mmol), i.e. about 2% of the body weight of this, 99% is present as calciumhydroxylapatite in bones and less than 1 % is present in the extraosseous ICS (intracellular space) or ECS (extracellular space). The calcium level in the ECS (approx. 100 mmol) is in dynamic equilibrium with the rapidly exchangeable fraction of bone calcium. Calcium ions affect the contractility of the heart and the skeletal musculature and are essential for the function of the nervous system. In addition, calcium ions play an important role in blood clotting and bone mineralization. In plasma, calcium is bound to a considerable extent to proteins (approx. 40%), 10% is in the form of inorganic complexes and 50% is present as free (ionized) calcium. The body's calcium balance is regulated by the parathyroid hormone (PTH), calcitriol (CT) and calcitonin. The test is used for the diagnosis and monitoring of hypocalcemia (calcium deficiency) and hypercalcemia (excess calcium) in serum. The characteristic symptom of hypocalcemia is latent or manifest tetany and osteomalacia. Hypocalcemia is due to the absence or impaired function of the parathyroid or impaired vitamin D-synthesis. Hypercalcemia is brought about by increased mobilization of calcium from the skeletal system (osteoporosis) or increased intestinal absorption. The majority of cases are due to primary hyperparathyroidism (pHPT) or bone metastasis of carcinoma of the breast, prostate or thyroid and bronchial carcinoma. The main significance of determining urinary calcium lies in the differentiation between hypercalciuria and hypocalciuria and the differential diagnosis of nephrolithiasis. Complexometric methods are used in addition to atomic absorption spectrometry (AAS) for determining calcium. The following calcium determination is based on the reaction of calcium with o-cresolphthalein complexone in alkaline solution. Magnesium is masked with 8-hydroxyquinoline.

PRINCIPLE:

In an alkaline medium, serum Calcium reacts with O-Cresolphthalein complexone to form a purple colored complex. The absorbance of which is proportional to the Calcium concentration. Interference from magnesium and iron is eliminated by complexing with 8-hydroxyquinolene.

the expiry date mentioned on the labels when the proper storage conditions are maintained.

STORAGE & STABILITY

All the reagents are to be stored at 2-8°C and are stable till the expiry date mentioned on the label.

KIT COMPONENTS

- Calcium Reagent R1
- Calcium Reagent R2
- Calcium Standard : Concentration as stated on the label

COMPOSITION

Buffer (50 mmol/l) pH7.2
8-hydroxy quinoline-5-sulphonic acid 10 mmol/L
Surfactants and anti oxidants

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent if blank reagent absorbance exceeds 0.2 at 578 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN:

Serum is the only preferred specimen.
EDTA should not be used as an anti coagulant.

SYSTEM PARAMETERS:

Reaction Type (Mode)	:	End Point
Wave Length	:	578 (546-600)
Flow Cell Temp	:	37°C
Sample Volume	:	10 µl
Reagent Volume	:	500 µl R1 + 500 µl R2
Standard Conc.	:	10
Units	:	mg/dl
Blank	:	Reagent
Low Normal	:	8.4
High Normal	:	10.8
Linearity	:	25

TEST PROCEDURE:

Reagent	B	S	T
1. Alkaline Reagent	0.5ml	0.5ml	0.5ml
2. Colour Reagent	0.5 ml	0.5ml	0.5ml
3. Calcium Standard (Conc. 10 mg/dl)	--	10µl	--
Specimen	--	--	10µl

Mix well and keep for 5 minutes at R.T. Read absorbance of Standard (S) and Test (T) against Blank (B) at 578 nm (546-600 nm).

CALCULATIONS:

$$\text{Serum Calcium in mg/dl} = \frac{\text{Abs. of Test}}{\text{Abs. of Standard}} \times 10$$

EXPECTED VALUES

Serum Calcium : 8.4 -10.8 mg/dl

It is recommended that laboratories establish their own normal range.

QUALITY CONTROL & CALIBRATION

It is recommend to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended calibrator (Avecon) or the standard included, calibrate the assay:

- When using a new reagent or lot.
- When QC values are out of range.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 25 mg/dl

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 0.2 mg/dl

3. Interferences

No significant interference was observed from Bilirubin up to 20 mg/dl (Both conjugated and unconjugated Bilirubin) Hemoglobin up to 50 mg/dl, Lipemia as Triglycerides up to 2000 mg/dl, Ascorbic acid up to 50 mg/dl.

4. Precision:

Intra-Assay

Sample (N=20)	Mean (mg/dl)	SD (mg/dl)	CV%
Control serum 1	8.17	0.13	1.59
Control serum 2	14.88	0.32	2.15
Control serum 3	22.77	0.58	1.95

Inter-Assay

Sample (N=20)	Mean (mg/dl)	SD (mg/dl)	CV%
Control serum 1	8.21	0.14	1.7
Control serum 2	14.92	0.35	2.35
Control serum 3	22.82	0.65	2.84

5. Method comparison:

A comparison of the LiquiMAX Calcium (y) with a commercial obtainable assay (x) gave the following result:

$$y = 1.113x - 0.278; r = 0.990$$

LIMITATIONS:

Serum/plasma/urine

Measuring range: 0.2-25 mg/dl. Determine samples having higher concentrations manually dilute with 0.9% NaCl or distilled/deionized water (e.g. 1 + 1). Multiply the result by the appropriate dilution factor 2.

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

NOTE:














- LiquiMAX Calcium (O-CPC Method) kit is supplied with disposable Calcium free tubes. For Better results the assay should be performed in the tubes provided only.
- In case the end user does not have disposable tubes he can use glass tubes that are acid washed and calcium free.

- All glassware and cuvettes should be washed with 30% Hydrochloric acid and rinsed with high quality distilled water before use. Glassware preferably to be soaked overnight in acid.
- Microtips should be properly acid washed before pipetting the reagents.
- Programmes for specific autoanalyzers are available on request.
- Dilute lipemic samples with normal saline and multiply with dilution factor.
- Protect the kit from direct sunlight.
- For accuracy of results the procedure has to be followed meticulously.
- As with all diagnostics procedures, the physician should evaluate data obtained by this kit in light of other clinical information.

REFERENCE:

- Gitelman, H. J. (1967) Annal. Biochem 18, 521.
- Berthelot, E. S. (1973) Clin. Chem Acta 46, 46.

Symbols Used on Pack

 REF	Catalogue Number		Warning/Caution
 LOT	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		



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