# LiquiMAX CALCIUM - SLR

**(ARSENAZO III METHOD)**

## ORDERING INFORMATION

| Ref. No. | Pack Size | Presentation |
|---|---|---|
| AVCAL1 - 25 | 25 x 1 ml | Single Liquid Reagent |
| AVCAL1 - 50 | 50 x 1 ml | |
| AVCAL1 - 100 | 2 x 50 ml | |

## INTENDED USE :

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

## PRODUCT FEATURES:

1. Single Liquid Reagent. Available in mono test packs
2. One step End Point assay
3. Heating and centrifugation of specimen not required.
4. Addition of 8-Hydroxy Quinolene overcomes Magnesium interference.
5. Results correlate with (O-CPC) and Methyl Thymol Blue Methods.
6. Linearity 25 mg/dl.
7. 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 calcium hydroxyapatite 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 calcitonin. The test is used for the diagnosis and monitoring of regulated by the parathyroid hormone (PTH), calcitriol (CT) and 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.

## PRINCIPLE

Calcium with Arsenazo III at neutral pH yields a Blue Coloured Complex, whose intensity is proportional to the Calcium concentration in the sample. Interference by Magnesium is eliminated by addition of 8-hydroxy quinoline-5-sulphonic acid.

## STORAGE AND STABILITY

All the reagents are stable up to the expiry date mentioned on the labels when the proper storage conditions are maintained.

## KIT COMPONENTS

1. Calcium Reagent
2. Calcium Standard : Concentration as stated on the label

## COMPOSITION

| | |
|---|---|
| Buffer (50 mmo/l) pH7.2 | |
| 8-hydroxy quinoline-5-sulphonic acid | 10 mmol/L |
| Arsenazo III | 110 µmol/L |
| Surfactants and anti oxidants | |

## REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at RT & 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 micro pipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

## REAGENT DETERIORATION

Discard any turbid reagent if blank reagent absorbance exceeds 1.2 at 630 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 COLLECTION AND STORAGE

1. Fresh Unhemolysed Serum is the preferred specimen.
2. Heparinsed plasma may also be used.
3. Don't use E.D.T.A. plasma.

## SYSTEM PARAMETERS:

| | | |
|---|---|---|
| Reaction type (mode) | : | End Point |
| Wavelength | : | 630nm (600-650) |
| Flow cell temperature | : | 37ºC |
| Sample volume | : | 10 µl |
| Reagent volume | : | 1000 µl |
| Standard concentration | : | 10.0 |
| Units | : | mg / dl |
| Blank | : | Reagent |
| Low normal | : | 8.4 |
| High normal | : | 11.5 |
| Linearity | : | 25 |

## TEST PROCEDURE

Pipette in to well washed tubes labeled Blank (B), Standard (S) and Test (T) as follows.

| Reagent | B | S | T |
|---|---|---|---|
| Arsenazo III Reagent | 1.0 ml | 1.0 ml | 1.0 ml |
| Calcium Standard (Conc. 10 mg/dl) | ---- | 10 µl | ---- |
| Specimen | ---- | ---- | 10 µl |

After adding the specimen/standard close the lid of the vial and mix well. Incubate for 3 minutes at R.T. Read absorbance of Standard (S) and Test (T) against Blank (B) at 630 nm 630 nm(600-650).

## CALCULATIONS

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

## EXPECTED VALUES

| | | |
|---|---|---|
| Serum | adults | 8.4 to 11.5 mg/dl |
| Urine | women | <250 mg/24 hours |
| | men | <300 mg/24 hours |

## 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:
a) When using a new reagent or lot.
b) 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-SLR (y) with a commercial obtainable assay (x) gave the following result : $y = 1.113x - 0.278$; $r = 0.990$

## LIMITATIONS

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 (e.g. 2).

## WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

## NOTES

1. All glassware and cuvettes should be rinsed with 30% Hydrochloric acid and again rinse with high quality distilled water thoroughly and repeatedly before use.
2. If a larger volume of working reagent is required for the absorbance-reading, requisite volumes can be taken in multiples keeping the same ratio of reagent to specimen or standard.
3. Dilute lipemic samples with normal saline (made in deionised water) and multiply with dilution factor.
4. Protect the kit from direct sunlight.
5. For accuracy of results, procedure has to be followed meticulously.
6. As with all diagnostic procedures the physician should evaluate data obtained by way of this kit in light of other clinical information.

## REFERENCE


1. Gitelmen, H.J. (1967) Annal. Biochem 18, 521.
2. Berthelot, E.S. (1973) Clin. Chem Acta 46, 46.


## Symbols Used on Pack

| | | | |
|---|---|---|---|
| REF | Catalogue Number | | Warning/Caution |
| LOT | Batch No. | IVD | 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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Ver. : 05/01-26