

# TRUEchemie CALCIUM (ARS III) TEST KIT

## ( ARSENAZO III )



for the quantitative determination of Calcium in serum or plasma or urine

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### INTENDED USE

The TRUEchemie Calcium reagent test for the quantitative determination of Calcium in serum or plasma or urine.

### INTRODUCTION

Calcium plays an essential role in many cell functions intracellular in muscle contraction and glycogen metabolism, extracellular, in bone mineralization, in blood coagulation and in transmission of nerve impulses. Calcium is present in plasma in three forms free, bound to proteins or complex with anions as phosphates, citrate and bicarbonate. Decreased total calcium levels can be associated with diseases of bone apparatus (especially osteoporosis), kidney diseases (especially under dialysis), Defective intestinal absorption and hypoparathyroidism. Increased total calcium can be measured in hyperparathyroidism, malignant diseases with metastasis and sarcoidosis. Calcium measurements also help in monitoring of calcium supplementation mainly in the prevention of Osteoporosis.

### 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.

### PACK SIZE

Kit Size	2 x 50 ml	25 T	50 T
Cat. No.	ADX291	ADX293	ADX294
Kit contents			
1) Calcium Reagent	2 x 50 ml	25 x 1 ml	50 x 1 ml
2) Calcium Standard (10 mg/dl)	1 x 2 ml	1 x 2 ml	1 x 2 ml

### REAGENTS COMPOSITION

- Calcium reagent**
  - Buffer (50 mmol/L) : 50 mmol/L
  - 8-Hydroxy quinoline 5-sulphonic acid : 5.0 mmol/L
  - Arsenazo III : 120 µmol/L
  - Surfactants and anti-oxidants
- Calcium standard** : 10 mg/dl

### STORAGE AND STABILITY

The components of the kit, stored at +15 - +30 °C or Room Temperature, will remain stable until the expiry date stated on the label.

### REAGENT PREPARATION

Ready to use reagents.

### SAMPLE / SPECIMEN AND STORAGE

- Fresh unhemolysed serum is the preferred specimen
- Heparinized Plasma may also be used. Don't use E.D.T.A. plasma.
- Urine sample

### MATERIALS REQUIRED BUT NOT PROVIDED

- Pipettes to accurately measure required volumes.
- Disposable test tubes.
- Timer
- Photometer capable of accurately measuring absorbance at 630 nm.

### WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Specimens should be considered infectious and handled appropriately.
- Avoid ingestion. DO NOT PIPETTE BY MOUTH.
- As calcium is a ubiquitous ion, essential precautions must be taken against accidental contamination. Use only disposable material (test tubes, micro tips etc.).
- Traces of chelating agent such as E.D.T.A. can prevent the formation of coloured complex.
- Contamination of glassware will adversely affect the calcium test results.
- While dispensing the reagent into the tubes if blue coloured complex is formed which is having more colour than the blank before the addition of the sample means that the tubes are contaminated.
- Contamination free disposable plastic tubes are only recommended to perform the Calcium assay
- The disposal of the residues has to be done as per local legal regulations.

### TEST PROCEDURE

Wavelength : 630 nm

	Blank (ml)	Standard (ml)	Sample (ml)
Calcium Reagent	1.000	1.000	1.000
Calcium Standard	--	0.010	--
Sample	--	--	0.010

Incubate all tubes at Room Temperature for 3 minutes. After incubation, zero the photometer with the reagent blank at 630 nm. Read and record the incubated standards and samples.

Calculation =  $\frac{\text{Sample OD}}{\text{Standard OD}} \times 10 \text{ mg Calcium/dl}$

### QUALITY CONTROLS

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

### NORMAL VALUES

Serum or Plasma	: 8.4 - 11.0 mg/dl
Urine	: Women <250 mg/24 hrs. Men <300 mg/24 hrs.

It is strongly recommended that each laboratory establish its own normal range.

### AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

### CALIBRATION

The procedures are calibrated with the standard solution which is included with each series of tests. Its absorbance is used to calculate the results.

### LIMITATIONS OF TEST

- Linearity : upto 25 mg/dl.
  - Sensitivity : upto 0.85 mg/dl.
- Samples that have calcium values greater than 25 mg/dl should be diluted with saline water (NaCl 0.9 %) 1:1, re-assayed and the results multiplied by 2.

### INTERFERENCES

- Bilirubin can result in falsely depressed Calcium levels.
- Hemoglobin samples may cause falsely elevated Calcium levels.

### SYSTEM PARAMETERS

Mode	: End point
Std. Conc.	: 10
Wave length	: 630 nm
Units	: mg/dl
Flow cell Temp.	: 37 °C
Blank	: Reagent
Reagent volume	: 1.000 ml
Sample volume	: 0.010 ml
Incubation	: 3 min. at R.T.
Low Normal	: 8.4
High Normal	: 11.0
Linearity	: 25.00

### REFERENCES

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

### Index of symbols

Consult instructions for use	Catalogue number	Use-by date
For <i>in vitro</i> diagnostic use only	Batch code	Do not use if package is damaged
Temperature limit 15-30 °C	Keep away from sunlight	Keep dry
Manufacturer	Date of manufacture	European Conformity
If device is non-sterile	Warnings / Precautions	Authorized Representative