TRUEchemie Calcium Test Kit (Arsenazo III)

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

INTENDED USE

The TRUEchemie Calcium Test Kit (Arsenazo III) is used 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 intensi ty 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	50 T
Cat. No.	ADX291	ADX294
Kit contents		
1) Calcium Reagent	2 x 50 ml	50 x 1 ml
2) Calcium Standard (10 mg/dL)	1 x 2 ml	1 x 2 ml

REAGENT COMPOSITION

1) **Calcium Reagent**
   Buffer (50 mmo/L) : 50 mmol/L
   8-Hydroxy quinoline 5-sulphonic acid : 5.0 mmol/L
   Arsenazo III : 120 µmol/L
   Surfactants and anti-oxidants

2) **Calcium Standard** : 10 mg/dL

REAGENT PREPARATION

Ready to use reagents.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Specimens should be considered infectious and handled appropriately.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. As calcium is a ubiquitous ion, essential precautions must be taken against accidental contamination. Use only disposable material (test tubes, micro tips etc.).
5. Traces of chelating agent such as E.D.T.A. can prevent the formation of coloured complex.
6. Contamination of glassware will adversely affect the calcium test results.
7. 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.
8. Contamination free disposable plastic tubes are only recommended to perform the Calcium assay.
9. The disposal of the residues has to be done as per local legal regulations.

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.

REAGENT STORAGE & STABILITY

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 15-30°C. Do not use reagents over the expiration date.

SPECIMEN COLLECTION AND STORAGE

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

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Disposable test tubes.
3. Timer
4. Photometer capable of accurately measuring absorbance at 630 nm.

TEST PROCEDURE

Wavelength : 630 nm

	Blank (µL)	Standard (µL)	Sample (µL)
Calcium Reagent	1000	1000	1000
Calcium Standard	--	10	--
Sample	--	--	10

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.

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

QUALITY CONTROL

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

EXPECTED VALUE

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.

PERFORMANCE CHARACTERISTICS

Sensitivity: 0.85 mg/dL.
Linearity: upto 25 mg/dL under the described assay conditions. If the concentration is greater than linearity (25 mg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor. The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

PRECISION:

Intra-assay precision within run (n=10)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Control Level - 1	10.2	0.1	1.0
Control Level - 2	12.6	0.1	1.1

Inter-assay precision run to run (n=12)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Control Level - 1	10.4	0.2	2.2
Control Level - 2	12.5	0.2	1.9

The reagent was tested for 12 days, using two different Calcium concentrations. The coefficient of variation was <5%.

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using TRUEchemie Calcium reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.983 and the regression equation is y=1.010x-0.131.The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

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

WASTE MANAGEMENT

Please refer to local regulation requirements.

SYSTEM PARAMETERS

Mode	:	End point
Std. Conc.	:	10
Wave length	:	630 nm
Units	:	mg/dL
Flow cell Temp.	:	37 °C
Blank	:	Reagent
Reagent volume	:	1000 µL
Sample volume	:	10 µL
Incubation	:	3 min. at R.T.
Low Normal	:	8.4
High Normal	:	11.0
Sensitivity	:	0.85
Linearity	:	25.00
Reaction Slope	:	Increasing

REFERENCES

1. Gitelman, H.J. (1967) Annal. Biochem 18, 521
2. Berthelot, E.S. (1973) Clin.Chem Acta 46, 46.
3. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of Symbols

Consult instructions for use	REF Catalogue number	Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
15°C 30°C Temperature limit 15-30°C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry
		Keep away from sunlight

Do not use if package is damaged — Contains sufficient for <n> tests

Athenese-Dx Pvt. Ltd.
Module No. 407 & 408, 4th Floor,
TICEL Bio Park II, No. 5, CSIR Road.
Taramani, Chennai-600113, India
Tel: +91-44-22541131
E-mail: info@athenesedx.com
Website: www.athenesedx.com

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