SyRe

TBA-120FR

AGAPPE

CALCIUM (ARSENAZO)

4 x 72 mL
12011007

Intended Use
This reagent is intended for *in vitro* quantitative determination of Calcium in serum, plasma & urine.

-Modified Arsenazo III method

-Linear up to 16 mg/dL

Clinical Significance
Calcium is an important ion present in the body. It is mainly found in bones. In serum calcium exists equally in a free ionized form & also in a bound form with albumin. Calcium helps in enzyme activation, muscle contraction, coagulation of blood, regulation of some hormonal secretions & cell membrane permeability.

Increased levels are found in hyperthyroidism, malignant tumors, acute & osteoporosis, adrenal insufficiency.

Decreased levels are found in hypoparathyrodism, osteomalacia, rickets, renal failure & tetanus.

Principle
At a neutral pH the Ca^{2+} form with Arsenazo III a complex, the color intensity of which is directly proportional to the concentration of calcium in the sample.

Kit Components

Reagent/ Component	Product Code 12011007	Description	
Calcium Arsenazo Reagent	4 x 72 mL	MES, pH 6.5 Arsenazo III	1000 mmol/L 200 mmol/L

Risk & Safety
Material Safety data sheets (MSDS) will be provided on request

Reagent Preparation
Calcium Arsenazo Reagent is ready to use.

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at 2-8^{O}C.

Open Vial Stability
Once opened the reagents are stable up to 90 days if contamination is avoided.

On-board Calibration Stability
Calibration is stable for 7 days.

Reagent Deterioration
Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Qualicheck Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
To avoid contamination, use clean laboratory wares. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Fresh serum / plasma (Do not use lipemic or hemolysed sample)

Urine diluted 1/3 with distilled water; adjust to pH 3-4 with HCI (N/10).

Take dilution factor into account for the calculation of the concentration in urine.

Interferences
No interference for

Bilirubin up to	10 mg/dL
Haemoglobin up to	1000 mg/dL
Ascorbic acid up to	50 mg/dL

Materials provided
Calcium Arsenazo Reagent

Reagents required but not provided
Multicalibrator (Product Code: 11610002), Qualicheck Norm (Product Code: 11601003), Qualicheck Path (Product Code: 11601002)

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
mg/dL	mmol/L	x 0.25

Calibration
Agappe Multicalibrator (Product Code: 11610002) is recommended for calibration of the assay.

Quality control
It is recommended to use Qualicheck Norm (Product Code: 11601003) or Qualicheck Path (Product Code: 11601002) to verify the performance of the measurement procedure.

Each Laboratory has to establish its own internal quality control scheme and procedures for corrective action if controls do not recover within the acceptable tolerance.

Reference Range
It is recommended that each laboratory should establish its own reference values.

The following value may be used as guide line.

Serum / plasma : 8.8 – 10.2 mg/dL

Urine : 100-400 mg/24 hrs

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance
1. Linearity

The reagent is linear up to 16 mg/dL. If the concentration is greater than linearity (16 mg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Comparison

A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.970 and a regression equation of y = 0.9967x.

3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dL)	9.5	12.2	9.37	11.94
SD	0.30	0.46	0.30	0.44
CV(%)	3.16	3.77	3.15	3.72

Accuracy (mg/dL)		
Control	Expected Value	Measured Value
Control Level 1	9.47 ± 0.93	9.7
Control Level 2	12.5 ± 1.3	12.2
Qualicheck Norm	8.9 ± 0.80	8.5
Qualicheck Path	13.50 ± 2.2	12.9

4. Sensitivity

Lower detection Limit is 0.5 mg/dL

Bibliography

1. Baver, P.J. Anal. Biochem., 110, (1981), 61

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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CE ISO 9001:2015
EN ISO 13485:2016