CALCIUM

ARSENAZO III

Diagnostic reagent for determination of Calcium concentration.

Liquid. Mono Reagents. Store at 15°C - 25°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2060	5 x 100 mL	R2061	962 Tests	BY2060	6364 Tests	M2060	2273 Tests
A2061	5 x 50 mL	S2060	1920 Tests	BY2061	4545 Tests	M2061	909 Tests
A2062	5 x 25 mL	S2061	1440 Tests	BY2062	3182 Tests	L2060	5000 Tests
T2060	5294 Tests	K2060	3500 Tests	N2060	758 Tests	L2061	2667 Tests
T2061	2353 Tests	K2061	2500 Tests	N2061	424 Tests	DM2060	990 Tests
R2060	2885 Tests						

INTENDED USE

The test is applied for the quantitative determination of calcium in serum, plasma and urine.

TEST PRINCIPLE

Arsenazo (III) combines with calcium at slight acidic pH to form a blue complex, the absorbance of which is measured at 660 nm. The reaction has high specificity and interference from magnesium is avoided, due to pH.

For bichromatic analyzers, the reference wavelenght must be set at 700 nm.

TEST PARAMETERS

Method	: Colorimetric, Endpoint, Increasing Reaction
Wavelength	: 660 nm (650 - 660 nm)
Temperature	: Room temperature, 37°C
Sample	: Serum or heparinized Plasma, acidified Urine
Linearity	: 1.5 mg/dL - 20 mg/dL (3.75 mmol/L)

REAGENT COMPOSITION

Arsenazo (III)	≤ 0.2 mM,
Good's buffer pH 6.8, Stabilizers.	≤ 50 mM

REAGENT PREPARATION

Reagents are ready to use.

REAGENT STABILITY AND STORAGE

Reagents are stable up to expiration date on labels at 15-25°C.

Once opened vials (reagent 1) are stable minimum 60 days at 15°C - 25°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum (preferred), plasma heparinate are collected by standard procedure. Do not use citrate, oxalate and EDTA as anticoagulant. Total calcium is stable 7 days at 2-8°C and for several months when frozen at -20°C.

Urine specimens should be collected in 20 to 30 ml of HCl 6M per 24/h specimen (1-2 ml for random urine) in order to prevent calcium salt precipitation.

Dilute sample urine 1:2 with redistilled water and multiply results by two.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

$$\frac{\text{Absorbance Sample}}{\text{Absorbance Standard}} \times \text{Conc. of Standard}$$

= mg/dL (mmol/L) Calcium in sample

Unit Conversion

mg/dL x 0.2495 = mmol/L

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Serum/Plasma : 8.5 - 10.5 mg/dL
(2.02 - 2.60 mmol/L)

Urine : 100-250 mg/24 Hour

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

All control sera with calcium values determined by this method can be used. We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The assay requires the use of a Calcium Standard or a Calcium Calibrator. We recommend:
ARCHEM Standard
Cat.No. ASX2060S conc. 10 mg/dL

Any commercially available Standard or Calibrator suitable for this method may be used.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 15 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 1.5 mg/dL.

High Linearity: The assay is linear up to 20 mg/dL.

Above this concentration, dilute the sample with redistilled water or %0,9 NaCl and reassay multiplying the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (Intra-assay)

Mean conc.	SD	CV	n
8.89 mg/dL	0.10	1.1%	10
13.74 mg/dL	0.16	1.2%	10

Reproducibility (run to run) (Inter-assay)

Mean conc.	SD	CV	n
9.22 mg/dL	0.19	2.1%	10
14.04 mg/dL	0.23	1.7%	10

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 0.1 mg/dL.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Interferences: No interference was observed by the presence of:
Hemoglobin ≤ 300 mg/dL
Bilirubin ≤ 40 mg/dL
Lipids interferences are possible performing readings at single wavelenght of 660 nm. To avoid interferences, perform a bichromatic reading at 660/700 nm.

Methods comparison: A comparison between Archem and a commercially available product gave the following results:
Calcium Archem = x
Calcium competitor = y
n = 97
y = 0.98x + 0.17 mg/dl $r^2 = 0.94$

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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