

Ana-Chek® CALCIUM ARS III

METHOD – ARSENAZO III
PRODUCT CODE – LC01

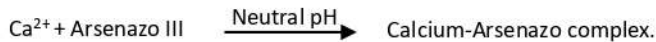


INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of Calcium in serum / plasma using Arsenazo III method.

SUMMARY AND PRINCIPLE

Elevated Calcium levels are associated with primary hyperparathyroidism, breast cancer, bronchial cancer, pancreatic tumour, osteoporosis, Paget's disease and Addison's disease. Ana-Chek® Calcium Ars III is a single ready to use reagent set for determination of Calcium in human serum and plasma. Arsenazo III reacts with calcium ions at neutral pH to form a blue coloured complex.



KIT COMPONENTS

Reagent 1 : Calcium Arsenazo III Reagent
Reagent 2 : Calcium Standard (10 mg/dL)

REAGENT PREPARATION, STORAGE & STABILITY

Ana-Chek® Calcium Ars III is a ready to use single reagent. The reagent kit should be stored at RT ($\leq 30^\circ\text{C}$) and is stable till the expiry date indicated on the label. Protect the reagent from direct light.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Patients receiving EDTA treatment cannot be assayed for calcium correctly. A thorough rinsing of glass wares by 0.1N HCl followed by distilled water is recommended for calcium assay. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.800 O.D. against D/W at 600 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Cal Ars III	Reagent Volume	1000 μL
Reaction Type	End Point	Sample Volume	20 μL
Wavelength	650 nm	Incubation Temperature	R.T.
Flow Cell Temp.	37 $^\circ\text{C}$	Incubation Time	2 min.
Blank setting	Reagent	Standard Conc.	10 mg/dL
Blank abs. limit	< 0.800	Linearity	16 mg/dL

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Serum or heparinized plasma can be used. **Do not use citrate, oxalate or EDTA as anticoagulant.** Avoid venous stasis. Calcium in the serum/plasma is stable for 5 days when stored at 2 - 8 $^\circ\text{C}$ and 20 days when stored at - 20 $^\circ\text{C}$.

COMPONENTS OF REAGENT

Component	Concentration
Imidazole Buffer, pH 7.0	100 mmol/l
Arsenazo III	90 mol/l
8 - Hydroxyquinoline	5 mmol/l

ASSAY PROCEDURE

	Blank	Standard	Test
Reagent	1000 μL	1000 μL	1000 μL
Standard	NA	20 μL	NA
Sample	NA	NA	20 μL
Mix the reagent and sample/standard in the above-mentioned ratio.			
Incubate the assay mixture for 2 minutes at room temperature.			
Aspirate reaction mixture into flow cell and measure the absorbance.			
The final colour is stable for 1 hour if not directly exposed to light.			
Stabilizers and inactive ingredients.			

CALCULATION

$$\text{Calcium (mg/dL)} = \frac{\text{Abs. of sample} \times 10}{\text{Abs. of standard}}$$

REFERENCE VALUES FOR NORMAL PEOPLE

8.5 - 10.5 mg/dL

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 0.6-16 mg/dL. If the Calcium value exceeds linearity limit (above 16 mg/dL), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct calcium value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL, Ascorbic Acid upto 8 mg/dL and Haemoglobin upto 500 mg/dL.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (mg/dL)	SD (mg/dL)	CV %	Mean (mg/dL)	SD (mg/dL)	CV %
Low Value Serum	9.51	0.07	0.8	8.78	0.08	0.9
High Value Serum	11.65	0.60	5.1	11.3	0.56	4.9

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides

between run precision and accuracy data for Calcium. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

BIBLIOGRAPHY

1. Thomas L., Clinical Laboratory Diagnostics, 1st ed. Frankfurt : TH – Books Verlagsgesellschaft., 1998 : 192 - 202.
2. Endres D.B., Rude RK. Mineral and Bone Metabolism. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia : WB Saunders Company., 1999 : 1395 - 1457.
3. Michaylova V, Ilkova P. Photometric determination of microamounts of calcium with arsenazo III. Anal. Chem. Acta 1971; 53 : 194-8.
4. Bauler PJ, Affinity and Stoichiometry of calcium binding by arsenazo III. Anal. Biochem. 1981., 110 : 61-72.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485: 2016
GMP
CE