

Calcium (Arsenazo) Instructions For Use

For in-vitro diagnostic use only.
Store at room temperature to 25°C.

KIT CONTENTS

R1 Arsenazo Reagent 2 x 125 ml
R4 Standard 1 x 5 ml

INTENDED USE

For quantitative determination of Calcium in Serum / Plasma or Urine.

TEST PRINCIPLE

Arsenazo III reacts with calcium ions to form a blue colored complex.
The amount of complex formed is directly proportional to the calcium concentration in the sample.

CLINICAL SIGNIFICANCE

Serum calcium levels are influenced by changes in protein concentrations. Increased calcium levels can be present in numerous disease states from dehydration to malignancies, e.g. of lung or kidney.
Low levels can also be clinically significant.

REAGENT CONCENTRATION

Arsenazo Reagent	Arsenazo Dye	> 0.2 g/l
	Sodium Acetate	90 mmol/l
Standard	Calcium	2.50 mmol/l (10mg/dl)

REAGENT HANDLING AND PREPARATION

The reagent is supplied ready to use and is stable until the expiry date quoted when stored at the recommended temperature.

SAMPLE

Serum is the recommended sample, Heparinised Plasma or Urine.
Dilute Urine 1 + 1 prior to assay with 0.9% NaCl.

STABILITY

8 hours at room temperature
24 hours at 2-8°C

MANUAL PROCEDURE

Wavelength	Temperature	Cuvette	Measurement
650 nm (640-660nm)	25,30,37°C	1 cm light path	Against Reagent Blank

Pipette into test tubes as follows:			
	Reagent Blank	Standard	Sample
DDH ₂ O	15 µl	-	-
Sample	-	-	15 µl
Standard	-	15 µl	-
Arsenazo Reagent	1000 µl	1000 µl	1000 µl

Mix, incubate at assay temperature for 5 minutes, then read absorbance of the sample and standard against reagent blank.

CALCULATION

$$\text{Calcium Concentration} = \frac{\text{Abs sample}}{\text{Abs standard}} \times \text{std. conc}$$

LINEARITY

The method is linear up to a calcium concentration of 4.8 mmol/l (19 mg/dl).

SENSITIVITY

The method will accurately measure calcium levels at a level of 0.05mmol/l (0.2 mg/dl).

PRECISION

Intra Assay – Within run		
Calcium conc (mmol/l)	n	CV%
2.14	20	1.33 %
3.10	20	1.31 %

Inter Assay – Between Run		
Calcium conc (mmol/l)	n	CV%

2.14	10	1.94 %
3.40	10	1.71 %

These characteristics were established using an AU600 analyser. Results will vary depending on the system in use.

NORMAL VALUES

	mmol/l	mg/dl
Infant (up to 1 month)	1.75-2.87	7-11.5
1 Month to 1 Year	2.15-2.79	8.6-11.2
Adults up to 30 years	2.05-2.54	8.2-10.2

These values are supplied as a guideline only. It is recommended that a laboratory establishes its' own reference Range.

USE ON AUTOMATED ANALYSERS

This reagent is suitable for use on a range of automated analysers. Specific instructions for these applications are available on request from our technical department.
For automated use we recommend a serum based calibrator to eliminate any matrix bias which may be observed with the aqueous standard.

QUALITY CONTROL

It is recommended that a laboratory uses normal and elevated reference control sera to verify the performance of the procedure, both reagent and any instrumentation employed for the determination. Results obtained should fall within specified ranges quoted.

QC materials of human source have been tested at donor level for HbsAg Antigen, HIV1&2 antibodies and HCV antibody and found to be negative. However no test can offer complete assurance to the absence of infectious diseases so all material should be handled and disposed of as if it is potentially infectious. Some common reasons for incorrect results can be:

1. Wavelength used for the determination
2. Light source
3. Temperature
4. Cleanliness, e.g of cuvettes used in measurements
5. Bacterial contamination of reagent
6. Reagent expiry
7. Calibration frequency





HEALTH & SAFETY





This kit is designed for use by suitably qualified laboratory personnel only. Exercise the normal precautions required for the handling of laboratory reagents. Do not ingest the material. Dispose of material according to local guidelines.

REFERENCES

1. Tietz NW. *Clinical Guide to Laboratory Tests* 3rd Edition
2. Jacobs DS. *Laboratory Test Handbook* 2nd Edition 1990
3. Thomas L. *Clinical Laboratory Diagnostics* 1st Edition

SYMBOL INDEX

	For In Vitro Diagnostics Use Only
	Lot Number
	Catalogue Number
	Storage Temperature

	Expiry Date (Year/Month)
	Warning, Read Enclosed Documents
	Instructions For Use
	Manufactured By

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