

NS Bio-Tec

Calcium- Arsenazo III (Single Reagent)

CAA-MC-02100 (2X100 ml) CAA-MC-0230 (2x30ml)
 CAA-MC-0260 (2x60ml) CAA-MC-0420 (4x20ml)
 CAA-MC-0620 (6x20ml)

INTENDED FOR USE:

for the in-vitro Quantitative, diagnostic determination of calcium in human serum

Principle :

At a neutral pH, the Ca²⁺ form with Arsenazo III a complex, the color intensity of which is directly proportional to the concentration of calcium in the sample.

SPECIMEN :

Serum and plasma

Use nonhemolyzing serum. Heparin is the only acceptable anticoagulant. No other anticoagulant can be used. Fresh serum collected in the fasting state is the preferred specimen. Serum or plasma should be separated from cells as soon as possible, because prolonged contact with the clot may cause lower calcium values. Sera from patients receiving EDTA (treatment of hypercalcemia) are unsuitable for analysis, since EDTA will chelate the calcium and render it unavailable for reaction with O-cresolphthalein complexone. The biological half-life of calcium in blood is few hours.

Urine

Specimens should be collected in acid washed bottles. 24 hour Specimens should be collected in containers containing 5 ml of 6 mol/L HCl. If the specimen is collected without acid, the pH should be adjusted < 3 with 6 mol/L HCl. Dilute urine specimen 2 times with bidistilled water (1 volume urine + 1 volume distilled water) before assay.

Stability (serum): 7 days at 15 – 25 °C; 3 weeks at 4 – 8 °C; 8 months at -20°C

Stability (urine): 2 days at 15 – 25 °C; 4 days at 4 – 8 °C; 3 weeks at -20 °C

Stored serum or urine specimens must be mixed well prior to analysis.

REAGENTS COMPOSITION:

Reagent (R2)	MES, pH 6.40 Arsenazo III	100 mmol/l 200 µmol/L
Standard Calcium (R1)		2.5 mmol/l (10 mg/dL)

PACKAGE : Collection & Storage .

Calcium reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when stored sealed at 2 – 8 °C.

PRECAUTION / DANGER SYMBOLES

Avoid pipette by mouth .

The preparation , according to current regulation . is classified as not dangerous.

The total concentration of non active components (preservatives , detergents , stabilizers) is below the minimum required for citation .

Anyway handle with care , avoid ingestion , avoid contact with eyes , skin and mucous membranes The samples must be handle as potentially infected from HIV or Hepatitis .

REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and instrumentations .

PROCEDURE :

Wavelength 650 nm (600 nm)
 Optical path : 1 cm
 Temperature : +25/30/
 Reading : Against blank reagent
 Assay tipe : End Point
 Sample/Reagent/Ratio : 1/100

Pipetting in cuvette :

	BLANK	STANDARD	SAMPLE
Reagent (A)	1000 µL	1000 µL	1000 µL
Distilled water	10 µL		
Standard		10 µL	
Sample			10 µL

Mix, incubate for 3 min (+15-25°C); Read sample and standard extinction .

Volumes can be proportionally modified.

This methodology describes the manual procedure to use the kit.

For automated procedure, ask for specific application.

Calibration with watery standard may cause a systematic error when using automatic instrumentations.

CALCULATION:

Serum:

$$\text{calcium mg/dl} = \frac{(\text{A}) \text{ Sample}}{(\text{A}) \text{ Standard}} \times 10 (\text{ standard value})$$

Urine 24/h:

$$\text{calcium mg/dl} = \frac{(\text{A}) \text{ Sample}}{(\text{A}) \text{ Standard}} \times 10 \times 10^2 \times \text{V}^{***}$$

* The factor "10" converts mg/dl to mg/litre

** The factor "2" represents the dilution factor

*** "V" represents the 24-hour urine volume in litres

EXPECTED VALUES :

Serum children up to 12 y	8.8-12.0 mg/dL	2.2-3.0 mmol/L
Serum adults	8.8-10.5 mg/dL	2.2-2.6 mmol/L
Urine	100-300 m/24h	25-75 mmol/L

the above mentioned values are to be considered as a reference.

It is strongly recommended that each laboratory establish its own normal range

WASTE DISPOSAL :

This product is made to be used in professional laboratories.

Please consult local regulations for a correct waste disposal.

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.

QUALITY CONTROL :

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

REFERENCES :

1. Connerty H.V. & Briggs A.R., Clin.Chem11(716), 1965.
2. Connerty H.V. & Briggs A.R., Am J Clin Path45(290)1966
3. Moorehead W.R. & Briggs A.R., Clin. Chem 20(1458)1977
4. Young D.S. et al., Clin Chem 21(272), 1975.
5. Friedman R.B. et al., Clin Chem 26(61), 1980

PERFORMANCE :

MEASURE INTERVAL / LINEARITY :	0.61-20 mg/dL
DETECTION LIMIT (2DS)	0.61 mg/dL
SENSITIVITY :	0.1 mg/dL = 0.00198A-578 nm

INTRA-ASSAY PRECISION : n=20

LOW LEVEL	M = 4.35 mg/dL	C.V = 4.35%
MEDIUM LEVEL	M = 9.18 g/dL	C.V = 2.75%
HIGH LEVEL	M = 20.41 mg/dL	C.V = 1.52%

INTER-ASSAY PRECISION : n=20

LOW LEVEL	M = 4.51 mg/dL	C.V = 3.61%
MEDIUM LEVEL	M = 8.98 mg/dL	C.V = 2.20%
HIGH LEVEL	M = 19.66 mg/dL	C.V = 3.74%
CORRELATION	r = 0.996	n=40
LIN. REGRESSION	y = 0.95 × +0.47	n = 40

INTERFERENCE:

Interferences are negligible up to :	
Hemoglobin	10 g/L
Triglycerides	1250 mg/dL
Biliru bin	20 mg/dL

METHOD LIMITATIONS:

For concentration higher than 20 mg/dl, repeat the measure on a sample diluted 1:2 with saline solution and multiply the result x 2 .

Highly hemolyzed serums may cause falsely high calcium level .

Prepare a blank sample with distilled water.

Care must be taken to avoid calcium contamination of glassware .The use of disposable plastic tubes is strongly recommended. If glassware is used it should be soak in diluted HCl and thoroughly rinsed with deionized water.

for a thorough evaluation of the interfering substances , consult: Young , D . S , et al , Clin , Chem , 21:1D (1975) .



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