



# IONIZED CALCIUM/ICA

Ionized calcium is measured by ion-selective electrode potentiometry. In the calculation of results for ionized calcium concentration is related to potential through the Nernst equation. Results are measured at 37°C.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.<sup>1</sup>

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

## Intended Use

The test for ionized calcium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of ionized calcium in arterial, venous, or capillary whole blood.

## Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of ionized calcium, a list of reactive ingredients is indicated below:

Reactive Ingredient
Calcium (Ca <sup>2+</sup> )

## Metrological Traceability

The i-STAT System test for ionized calcium measures ionized calcium (*i.e.* free calcium ion) amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L<sup>-1</sup>) for *in vitro* diagnostic use. Ionized calcium values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point Care Inc..

## Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range <sup>2</sup>
Ionized Calcium/iCa	mmol/L	0.25 – 2.50	1.12 – 1.32
	mg/dL	1.0 – 10.0	4.5 – 5.3

\*The i-STAT System can be configured with the preferred units.

To convert a result from mmol/L to mg/dL, multiply the mmol/L value by 4. To convert mmol/L to mEq/L multiply the mmol/L value by 2.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

### Clinical Significance

Although most of the calcium in blood is bound to protein or complexed to smaller anionic species, the biologically active fraction of calcium is free ionized calcium. Through its role in a number of enzymatic reactions and in membrane transport mechanisms, ionized calcium is vitally important in blood coagulation, nerve conduction, neuromuscular transmission and in muscle contraction. Increased ionized calcium (hypercalcemia) may result in coma. Other symptoms reflect neuromuscular disturbances, such as hyperreflexia and/or neurologic abnormalities such as neurasthenia, depression or psychosis. Decreased ionized calcium (hypocalcemia) often results in cramps (tetany), reduced cardiac stroke work and depressed left ventricular function. Prolonged hypocalcemia may result in bone demineralization (osteoporosis) which can lead to spontaneous fractures. Measurements of ionized calcium have proven of value under the following clinical conditions: transfusion of citrated blood, liver transplantation, open heart surgery, neonatal hypocalcemia, renal disease, hyperparathyroidism, malignancy, hypertension and pancreatitis.

### Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A<sup>3</sup>. Venous blood samples were collected in lithium heparin Vacutainer<sup>®</sup> tubes and analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other.

Deming regression analysis<sup>4</sup> was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.\*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7-P.<sup>5</sup>

\* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".<sup>3</sup> The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if  $r > 0.975$ .

### Precision Data (mmol/L)

Aqueous Control	Mean	SD	%CV
Level 1	1.60	0.017	1.1
Level 3	0.84	0.012	1.4

## Method Comparison (mmol/L)

	Radiometer ICA1	Nova STAT Profile
n	47	57
Sxx	0.009	0.017
Syy	0.017	0.017
Slope	0.925	0.960
Int't	0.113	0.062
Sy.x	0.035	0.029
Xmin	0.46	0.53
Xmax	2.05	2.05
r	0.982	0.982

## Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 24 patient samples using i-STAT CHEM8+ and i-STAT CG8+ cartridges. In the 0.46 - 1.23 mmol/L range, the average difference was 0.003.

## Factors Affecting Results\*

Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid<sup>6</sup>. Exposing the sample to air will cause an increase in pH due to the loss of CO<sub>2</sub> which will decrease ionized calcium.

Heparin binds calcium. Each unit of heparin added per mL of blood will decrease ionized calcium by 0.01 mmol/L.<sup>6</sup> Therefore, the correct ratio of heparin anticoagulant to blood must be achieved during sample collection. Intravenous injection of 10,000 units of heparin has been shown in adults to cause a significant decrease of ionized calcium of about 0.03 mmol/L.<sup>6</sup> Use only unheparinized sample transfer devices when using i-STAT's aqueous control and calibration verification materials.

Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To avoid these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g. gluconate) such as Normosol<sup>®</sup>-R (Abbott Laboratories), Plasma-Lyte<sup>®</sup>-A (Baxter Healthcare Corporation), and Isolyte<sup>®</sup>-S (B Braun Medical) rather than solutions such as normal saline or Ringer's Lactate.

Interferent	Effect
β-hydroxybutyrate	20 mmol/L β-hydroxybutyrate will decrease ionized calcium results by 0.1 mmol/L.
Lactate	20 mmol/L lactate will decrease ionized calcium results by 0.05 mmol/L.
Magnesium	1.0 mmol/L magnesium above normal will increase ionized calcium results by 0.04 mmol/L.
Salicylate	4.34 mmol/L salicylate will decrease ionized calcium results by 0.1 mmol/L.

\*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

## References

1. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests*, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).
2. P.C. Painter, J.Y. Cope, J.L. Smith, "Reference Ranges, Table 41–20" in *Tietz Textbook of Clinical Chemistry—Second Edition*, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).
3. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*. CLSI document EP9-A [ISBN 1-56238-283-7]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.
4. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," *Clinical Chemistry* 25:3, 432 (1979).
5. CLSI. *Interference Testing in Clinical Chemistry; Proposed Guideline*. CLSI document EP7-P [ISBN 1-56238-020-6]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1986.
6. D. Fraser, G. Jones, S.W. Kooh, and I. Raddle, "Calcium and Phosphate Metabolism" in *Tietz Textbook of Clinical Chemistry—Second Edition*, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

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