SODIUM/NA

Sodium is measured by ion-selective electrode potentiometry. In the calculation of results for sodium, concentration is related to potential through the Nernst equation.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2]

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

Intended Use

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

Sodium measurements are used for monitoring electrolyte imbalances.

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 sodium, a list of reactive ingredients is indicated below:

Reactive Ingredient	Minimum Quantity
Sodium (Na^+)	121 mmol/L

Metrological Traceability

The i-STAT System test for sodium measures sodium amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Sodium 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 of Care Inc.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Sodium/Na	mmol/L (mEq/L)	100–180	138 – 146

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

Rev. Date: 15-Jul-16

Art: 714173-00P

Abbott Point of Care

The i-STAT reference range for whole blood listed above is similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

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

Tests for sodium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for sodium include dehydration, diabetes insipidus, salt poisoning, skin losses, hyperaldosteronism and CNS disorders. Some causes for decreased values for sodium include dilutional hyponatremia (cirrhosis), depletional hyponatremia and syndrome of inappropriate ADH.

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[4]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] 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.

*The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data are collected over a narrow range, the estimate of the regression parameters is relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid." [4] 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 for r >0.975.

Precision Data (mmol/L or mEq/L)

Aqueous Control	Mean	SD	%CV
Level 1	120.0	0.46	0.4
Level 3	160.0	0.53	0.3

Method Comparison (mmol/L or mEq/L)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	0.74	0.52	0.54
Syy	0.53	0.58	0.53

Slope	1.00	0.98	0.95
Int't	-0.11	3.57	5.26
Sy.x	1.17	1.04	1.53
Xmin	126	120	124
Xmax	148	148	148
r	0.865	0.937	0.838

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC4+ cartridges. In the 130–150 mmol/L range the average difference was 0.750.

Factors Affecting Results*

Sodium heparin may increase sodium results up to 1 mmol/L[6].

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 minimize these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g., gluconate).

Interference studies were based on CLSI guideline EP7-A2[7]. Test concentrations used were as per the CLSI guideline unless otherwise indicated.

When added to a plasma pool the following substances (at the concentrations indicated) were found to interfere with the i-STAT sodium assay:

Substance	Test Concentration (mmol/L)	Interference
Bromide	37.5	Use another method. See Note 1 below.
Nithiodote (sodium thiosulfate)	16.7[12]	Increased i-STAT Sodium results. See Note 2 below.

The following substances are known not to significantly interfere with the i-STAT sodium assay at the stated test concentrations:

Substance	Test Concentration (mmol/L)
Acetaminophen	1.32
Acetylcysteine	10.2
Ascorbate	0.34
Bromide *(therapeutic)*	2.5 [8,9,10]
β-Hydroxybutyrate	6.0 [11]
Lactate	6.6
Magnesium Chloride	1.0
Salicylate	4.34

Note:

1) Bromide has been tested at two levels: the CLSI recommended level and a therapeutic plasma concentration level of 2.5 mmol/L. The latter is the peak plasma concentration associated with halothane anesthesia, in which bromide is released. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level. Bromide at a concentration of 37.5 mmol/L increased i-STAT sodium results, while a therapeutic range of bromide (2.5 mmol/L) did not significantly interfere with i-STAT sodium results.

2) Nithiodote (sodium thiosulfate) is indicated for the treatment of acute cyanide poisoning. The journal article titled "Falsely increased chloride and missed anion gap elevation during treatment with sodium thiosulfate" indicated that sodium thiosulfate could be used in the treatment of calciphylaxis indicating that "the highest concentration likely to be seen in plasma [is] after infusion of a 12.5 g dose of sodium thiosulfate pentahydrate. Assuming that the 12.5 g dose of sodium thiosulfate pentahydrate is distributed in a typical blood volume of 5 L with a hematocrit of 40%, the peak sodium thiosulfate plasma concentration expected is 16.7 mmol/L."[12]

*It is possible that other interfering substances may be encountered. The degree of interference at concentrations other than those listed might not be predictable.

References

1. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, “Electrolytes “ in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

2. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

3. B.E. Statland, Clinical Decision Levels for Lab Tests (Oradell, NJ: Medical Economic Books, 1987).

4. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* NCCLS document EP9-A [ISBN 1-56238-283-7]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

5. P.J. Cornbleet and N. Gochman, “Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis,” Clinical Chemistry 25:3, 432 (1979).

6. *Tips on Specimen Collection*. Vol 1. Monograph of Medical Laboratory Observer's "Tips from the Clinical Experts", published by Medical Economics in collaboration with Becton, Dickinson and Company. Mark Zacharia, ed. Montvale NJ; 1997:26.

7. Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition.* CLSI document EP7-A2 (ISBN 1-56238-584-4). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2005.

8. Kharasch E.D., Hankins D., Mautz D., Thummel K.E.. Identification of the enzyme responsible for oxidative halothane metabolism: implications for prevention of halothane hepatitis. Lancet 1996; 347:1367-71.

9. Morrison J.E., Friesen R.H., Elevated serum bromide concentrations following repeated halothane anaesthesia in a child. Can J Asaesth 1990; 37 (7): 801-803.

10. Hankins D.C, Kharasch E.D., Determination of the halothane metabolites trifluoroacetic acid and bromide in plasma and urine by ion chromatography. J of Chromatography B. 692 (1997) 413-418.

11. Charles R.A, Bee Y.M, Eng P.H.K., Goh S.Y. Point of care blood ketone testing: screening for diabetic ketoacidosis at the emergency department. Singapore Med J 2007; 48 (11): 986.

12. Wendroth Scott M., Tiffany N. Heady, Doris M. Haverstick, Lorin M. Bachmann, Mitchell G. Scott, James C. Boyd, and David E. Bruns. Falsely increased chloride and missed anion gap elevation during treatment with sodium thiosulfate. Clinica Chimica Acta 2014; 431: 77–79.

Abbott Point of Care Inc.
100 and 200 Abbott Park Road
Abbott Park, IL 60064 • USA

EC REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

CE IVD