POTASSIUM/K

Potassium is measured by ion-selective electrode potentiometry. In the calculation of results for potassium, 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 potassium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of potassium in arterial, venous, or capillary whole blood.

Potassium measurements are used in the diagnosis and monitoring of diseases and clinical conditions that manifest high and low potassium levels.

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 potassium, a list of reactive ingredients is indicated below:

Reactive Ingredient	Minimum Quantity
Potassium (K^+)	3.6 mmol/L

Metrological Traceability

The i-STAT System test for potassium measures potassium amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Potassium 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]
Potassium/K	mmol/L (mEq/L)	2 – 9	3.5 – 4.9**

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

**The reference range for potassium listed above has been reduced by 0.2 mmol/L from the range cited in Reference 3 to account for the difference between serum and plasma results.

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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 potassium 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 potassium include renal glomerular disease, adrenocortical insufficiency, diabetic ketacidosis (DKA), sepsis and *in vitro* hemolysis. Some causes of decreased values for potassium include renal tubular disease, hyperaldosteronism, treatment of DKA, hyperinsulinism, metabolic alkalosis and diuretic therapy.

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	2.85	0.038	1.3
Level 3	6.30	0.039	0.6

Method Comparison (mmol/L or mEq/L)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	0.060	0.031	0.065
Syy	0.055	0.059	0.055
Slope	0.97	1.06	0.99
Int't	0.02	-0.15	-0.01
Sy.x	0.076	0.060	0.112
Xmin	2.8	3.0	2.8
Xmax	5.7	9.2	5.8
r	0.978	0.993	0.948

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 3.0–5.0 mmol/L range the average difference was 0.049.

Factors Affecting Results*

If heparinized whole blood is allowed to stand before testing, potassium values will first decrease slightly, then increase over time. Potassium values will increase in iced specimens.

Potassium values from anticoagulated samples are preferred to serum values because 0.1 to 0.7 mmol/L potassium can be released from platelets[1] and red blood cells during the clotting process. Potassium values obtained from skin puncture samples may vary due to hemolysis or an increase in tissue fluid from improper technique during the collection procedure.

Interference studies were based on CLSI guideline EP7-A2.[6] 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 potassium assay:

Substance	Test Concentration (mmol/L)	Interference
Bromide	37.5	Use another method. See Note 1 below.
Nithiodote (sodium thiosulfate)	16.7[8]	Decreased i-STAT Potassium results. See Note 2 below.

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

Substance	Test Concentration (mmol/L)
Acetaminophen	1.32
Acetylcysteine	10.2
Ascorbate	0.34
Bromide	2.5
ß-Hydroxybutyrate	6.0 [7]
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 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 potassium results and the rate of potassium star (***) outs, while a therapeutic range of bromide (2.5 mmol/L) did not significantly interfere with i-STAT potassium results.

Note 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."[8]

*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

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4. 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.

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