February 7, 2020

Abbott Point of Care Inc.
Susan Tibedo
Director, Regulatory Affairs
400 College Road East
Princeton, NJ 08540

Re: K183688
Trade/Device Name: i-STAT CHEM8+ cartridge with the i-STAT 1 System
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium Test System
Regulatory Class: Class II
Product Code: JGS, CDS, CEM, CGZ
Dated: January 9, 2020
Received: January 10, 2020

Dear Susan Tibedo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie Kelm, Ph.D.
Acting Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K183688

Device Name
i-STAT CHEM8+ cartridge with the i-STAT 1 System

Indications for Use *(Describe)*
The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the in vitro quantification of sodium, potassium, chloride and blood urea nitrogen in arterial or venous whole blood in point of care or clinical laboratory settings.

Sodium measurements are used for monitoring electrolyte imbalances.

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

Chloride measurements are primarily used in the diagnosis, monitoring, and treatment of electrolyte and metabolic disorders including, but not limited to, cystic fibrosis, diabetic acidosis, and hydration disorders.

Blood urea nitrogen measurements are used for the diagnosis, monitoring, and treatment of certain renal and metabolic diseases.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# 510(k) Summary

The information in this 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

## 1. Submitter Information


Owner

Abbott Point of Care Inc.
400 College Road East
Princeton, NJ 08540

Contact

Primary: Susan Tibedo
Director Regulatory Affairs
susan.tibedo@abbott.com
Phone: 609-454-9360

Secondary: Maria Figueroa
Manager Regulatory Affairs
maria.l.figueroa@abbott.com
Phone: 609-454-9271


Date Prepared: February 5, 2020

510(k) Number: k183688

## 2. Device Information

Proprietary Name: i-STAT CHEM8+ cartridge with i-STAT 1 System

Common Name: Chemistry test, analyzer, handheld

| Product code | Device Classification name | Regulation Number | Class | Panel |
|---|---|---|---|---|
| JGS | Electrode, Ion Specific, Sodium | 862.1665 | II | Clinical Chemistry |
| CEM | Electrode, Ion Specific, Potassium | 862.1600 | II | Clinical Chemistry |
| CGZ | Electrode, Ion Specific Chloride | 862.1170 | II | Clinical Chemistry |
| CDS | Electrode, Ion Specific, Urea Nitrogen | 862.1770 | II | Clinical Chemistry |

## 3. Predicate Device

| | |
|---|---|
| Proprietary Name | SYNCHRON Systems Sodium Reagent on UniCel DxC 600/800 SYNCHRON Clinical System<br><br>SYNCHRON Systems Potassium Reagent on UniCel DxC 600/800 SYNCHRON Clinical System<br><br>SYNCHRON Systems Chloride Reagent on UniCel DxC 600/800 SYNCHRON Clinical System<br><br>SYNCHRON Systems BUN Reagent on UniCel DxC 600/800 SYNCHRON Clinical System |
| 510(k) Number | K042291 |

| Product code | Device Classification name | Regulation Number | Class | Panel |
|---|---|---|---|---|
| JGS | Electrode, Ion Specific, Sodium | 862.1665 | II | Clinical Chemistry |
| CEM | Electrode, Ion Specific, Potassium | 862.1600 | II | Clinical Chemistry |
| CGZ | Electrode, Ion Specific Chloride | 862.1170 | II | Clinical Chemistry |
| LFP | Conductivity Rate, Urea Nitrogen | 862.1770 | II | Clinical Chemistry |

## 4. Device Description

The i-STAT CHEM8+ test cartridge contains test reagents to analyze whole blood at the point of care or in the clinical laboratory for sodium, potassium, chloride and blood urea nitrogen. The test is contained in a single-use, disposable cartridge. Cartridges require two to three drops of whole blood which are typically applied to the cartridge using a transfer device.

The i-STAT 1 Analyzer is a handheld, *in vitro* diagnostic analytical device designed to run only i-STAT test cartridges. The instrument interacts with the cartridge to move fluid across the sensors and generate a quantitative result (within approximately 2 minutes).

The i-STAT 1 System is comprised of the i-STAT 1 analyzer, the i-STAT test cartridges and accessories (i-STAT 1 Downloader/Recharger, electronic simulator and portable printer). The system is designed for use by trained medical professionals at the patient point of care or in the clinical laboratory and is for prescription use only.

## 5. Intended Use Statement

The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of sodium, potassium, chloride and blood urea nitrogen in arterial or venous whole blood in point of care or clinical laboratory settings.

Sodium measurements are used for monitoring electrolyte imbalances.

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

Chloride measurements are primarily used in the diagnosis, monitoring, and treatment of electrolyte and metabolic disorders including, but not limited to, cystic fibrosis, diabetic acidosis, and hydration disorders.

Blood urea nitrogen measurements are used for the diagnosis, monitoring, and treatment of certain renal and metabolic diseases.

## 6. Summary Comparison of Technological Characteristics

| Similarities and Differences: System (Test and Instrument) for Sodium | | |
|---|---|---|
| **Feature or Characteristic** | **Predicate SYNCHRON Systems Sodium Reagent on UniCel DxC 600/800 SYNCHRON Clinical System (K042291)** | **Candidate Sodium Test with i-STAT 1 System** |
| **Intended Use** | The sodium test systems are intended for the quantitative determination of sodium concentration in human serum, plasma or urine.<br><br>Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of hormone aldosterone), diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. | The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of sodium, potassium, chloride and blood urea nitrogen in arterial or venous whole blood in point of care or clinical laboratory settings.<br><br>Sodium measurements are used for monitoring electrolyte imbalances. |
| **Reportable Range** | 100-200 mmol/L (Serum or Plasma)<br>10-300 mmol/L (Urine) | Sodium: 100-180 mmol/L (mEq/L) |
| **Sample Type** | Serum, plasma, urine | Arterial or venous whole blood |
| **Sample Volume** | 0.5 mL (500 µL) | 95 µL |
| **Preparation** | Sample tubes prepared and then processed within analyzer | Ready to Use |
| **Traceability** | NIST SRM 919 | NIST SRM 956 |
| **Calibration** | Must be conducted every 24 hours and with each new reagent | 1-point on-board contained within the cartridge |
| **Time to Test (Sample Stability)** | Serum or plasma: Within 8 hours at room temperature, or up to 48 hours if stored at +2°C to +8°C<br><br>Urine: Within 2 hours of collection | Heparinized samples: within 30 minutes of collection |
| **Principle of Measurement** | Ion selective electrode | Ion selective electrode |
| **Reagent Format** | Reagent handling system, stored within analyzer | Cartridge |
| **Reagent Storage and Stability** | Room temperature | 2°C to 8°C (35-46°F) |
| **Analyzer Type** | Floor Model | Handheld |

| Similarities and Differences: System (Test and Instrument) for Potassium | | |
|---|---|---|
| **Feature or Characteristic** | **Predicate SYNCHRON Systems Potassium Reagent on UniCel DxC 600/800 SYNCHRON Clinical System (K042291)** | **Candidate Potassium Test with i-STAT 1 System** |
| **Intended Use** | The potassium test systems are intended the quantitative determination of potassium concentration in human serum, plasma or urine.<br><br>Potassium measurements are used in the diagnosis and treatment of hypokalemia (metabolic alkalosis, metabolic acidosis or the absence of acid-base disturbances), hyperkalemia (over administration of potassium, acidosis, or crush injuries), renal failure, Addison's disease or other diseases involving electrolyte imbalance. | The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of sodium, potassium, chloride and blood urea nitrogen in arterial or venous whole blood in point of care or clinical laboratory settings<br><br>Potassium measurements are used in the diagnosis and monitoring of diseases and clinical conditions that manifest high and low potassium levels. |
| **Reportable Range** | 1-15.0 mmol/L (Serum or Plasma) | 2.0 – 9.0 mmol/L (mEq/L) |
| **Sample Type** | Serum, plasma, urine | Arterial or venous whole blood |
| **Sample Volume** | 0.5 mL (500 µL) | 95 µL |
| **Sample Preparation** | Sample tubes prepared and then processed within analyzer | Ready to Use |
| **Traceability** | NIST SRM 918 | NIST SRM 956 |
| **Calibration** | Must be conducted every 24 hours and with each new reagent | 1-point on-board contained within the cartridge |
| **Time to Test (Sample Stability)** | Serum or plasma: Within 8 hours at room temperature, or up to 48 hours if stored at +2°C to +8°C<br><br>Urine: Within 2 hours of collection | Non-anticoagulated samples: within 3 minutes of collection<br><br>Heparinized samples: within 30 minutes of collection |
| **Principle of Measurement** | Ion selective electrode | Ion selective electrode |
| **Reagent Format** | Reagent handling system, stored within analyzer | Cartridge |
| **Reagent Storage and Stability** | Room temperature | 2°C to 8°C (35-46°F) |
| **Analyzer Type** | Floor Model | Handheld |

| Similarities and Differences: System (Test and Instrument) for Chloride | | |
|---|---|---|
| **Feature or Characteristic** | **Predicate SYNCHRON Systems Chloride Reagent on UniCel DxC 600/800 SYNCHRON Clinical System (K042291)** | **Candidate Chloride Test with i-STAT 1 System** |
| **Intended Use** | The chloride test systems are intended for the quantitative determination of chloride concentration in human serum, plasma, urine or cerebrospinal fluid (CSF).<br><br>Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis. | The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of sodium, potassium, chloride and blood urea nitrogen in arterial or venous whole blood in point of care or clinical laboratory settings.<br><br>Chloride measurements are primarily used in the diagnosis, monitoring, and treatment of electrolyte and metabolic disorders including, but not limited to, cystic fibrosis, diabetic acidosis, and hydration disorders. |
| **Reportable Range** | 50-200 mmol/L (Serum or Plasma) | 65-140 mmol/L (mEq/L) |
| **Sample Type** | Serum, plasma, urine | Arterial or, venous whole blood |
| **Sample Volume** | 0.5 mL (500 µL) | 95 µL |
| **Sample Preparation** | Sample tubes prepared and then processed within analyzer | Ready to Use |
| **Traceability** | NIST SRM 918/919 | NIST SRM 956 |
| **Calibration** | Must be conducted every 24 hours and with each new reagent | 1-point on-board contained within the cartridge |
| **Time to Test (Sample Stability)** | Serum or plasma: Within 8 hours at room temperature, or up to 48 hours if stored at +2°C to +8°C<br>Urine: Within 2 hours of collection | Non-anticoagulated samples: within 3 minutes of collection<br>Heparinized samples: within 30 minutes of collection |
| **Principle of Measurement** | Ion selective electrode | Ion selective electrode |
| **Reagent Format** | Reagent handling system, stored within analyzer | Cartridge |
| **Reagent Storage and Stability** | Room temperature | 2°C to 8°C (35-46°F) |
| **Analyzer Type** | Floor Model | Handheld |

| Similarities and Differences: System (Test and Instrument) for Blood Urea Nitrogen (BUN) | | |
|---|---|---|
| **Feature or Characteristic** | **Predicate SYNCHRON Systems BUN Reagent on UniCel DxC 600/800 SYNCHRON Clinical System (K042291)** | **Candidate BUN Test with i-STAT 1 System** |
| **Intended Use** | The blood urea nitrogen (BUN) test systems are intended for the quantitative determination of urea nitrogen or urea concentration in human serum, plasma or urine.<br><br>Urea nitrogen or urea measurements are used in the diagnosis and treatment of certain renal and metabolic diseases. | The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of sodium, potassium, chloride and blood urea nitrogen in arterial or venous whole blood in point of care or clinical laboratory settings<br><br>Blood urea nitrogen measurements are used for the diagnosis, monitoring, and treatment of certain renal and metabolic diseases. |
| **Reportable Range** | 1-150 mg/dL (Serum or Plasma)<br>10-1500 mg/dL (Urine) | 3-140 mg/dL |
| **Sample Type** | Serum, plasma, urine | Arterial or venous whole blood |
| **Sample Volume** | 0.5 mL (500 µL) | 95 µL |
| **Sample Preparation** | Sample tubes prepared and then processed within analyzer | Ready to Use |
| **Traceability** | NIST SRM 912 | NIST SRM 909 |
| **Calibration** | Must be conducted every 24 hours and with each new reagent | 1-point on-board contained within the cartridge |
| **Time to Test (Sample Stability)** | Serum or plasma: Within 8 hours at room temperature, or up to 48 hours at +2°C to +8°C<br>Urine: Within 2 hours of collection | Non-anticoagulated samples: within 3 minutes of collection<br>Heparinized samples: within 30 minutes of collection |
| **Principle of Measurement** | Conductivity | Ion selective electrode |
| **Reagent Format** | Reagent handling system, stored within analyzer | Cartridge |
| **Reagent Storage and Stability** | 2°C to 8°C (35-46°F) | 2°C to 8°C (35-46°F) |
| **Analyzer Type** | Floor Model | Handheld |

## 7. Performance Characteristics

### *Analytical Performance*

### a. Precision

*Precision 20 days (Aqueous Materials)*

The precision of the i-STAT Potassium, Chloride, and BUN Tests on the i-STAT 1 Analyzer were evaluated using 5 levels of aqueous materials. This 20-day multi-day precision testing was based on CLSI document EP05-A3: *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition.* The study

was conducted using multiple instruments and one test cartridge lot over 20 days at one site. Total precision ('within-laboratory', $S_T$), within-run, ($S_r$), between-run, ($S_{rr}$) and between-day, ($S_{dd}$) were estimated for each level. The results of the 20-day precision study are shown in Table 1.

**Table 1: 20-day Precision Study Results (i-STAT 1 Analyzer)**

| i-STAT Test | Fluid Level | N | Mean | Total | | Within-run | | Between-run | | Between-day | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | $S_T$ | $CV_T$ (%) | $S_r$ | $CV_r$ (%) | $S_{rr}$ | $CV_{rr}$ (%) | $S_{dd}$ | $CV_{dd}$ (%) |
| **Sodium (mmol/L)** | CV L1 | 81 | 100.0 | 0.27 | 0.3 | 0.25 | 0.3 | 0.07 | 0.1 | 0.07 | 0.1 |
| | CV L2 | 81 | 121.6 | 0.35 | 0.3 | 0.33 | 0.3 | 0.09 | 0.1 | 0.10 | 0.1 |
| | CV L3 | 81 | 134.8 | 0.31 | 0.2 | 0.28 | 0.2 | 0.09 | 0.1 | 0.10 | 0.1 |
| | CV L4 | 80 | 160.4 | 0.41 | 0.3 | 0.39 | 0.2 | 0.10 | 0.1 | 0.10 | 0.1 |
| | CV L5 | 80 | 178 | 0.42 | 0.2 | 0.40 | 0.2 | 0.10 | 0.1 | 0.11 | 0.1 |
| **Potassium (mmol/L)** | CV L1 | 81 | 2.07 | 0.006 | 0.3 | 0.006 | 0.3 | 0.001 | 0.05 | 0.002 | 0.1 |
| | CV L2 | 81 | 2.83 | 0.011 | 0.4 | 0.011 | 0.4 | 0.003 | 0.1 | 0.002 | 0.1 |
| | CV L3 | 81 | 3.69 | 0.010 | 0.3 | 0.008 | 0.2 | 0.004 | 0.1 | 0.003 | 0.1 |
| | CV L4 | 80 | 6.17 | 0.018 | 0.3 | 0.017 | 0.3 | 0.002 | 0.03 | 0.007 | 0.1 |
| | CV L5 | 80 | 7.75 | 0.033 | 0.4 | 0.027 | 0.3 | 0.017 | 0.2 | 0.009 | 0.1 |
| **Chloride (mmol/L)** | CV L1 | 81 | 70.9 | 0.47 | 0.7 | 0.43 | 0.6 | 0.12 | 0.2 | 0.12 | 0.2 |
| | CV L2 | 81 | 76.2 | 0.53 | 0.7 | 0.50 | 0.7 | 0.13 | 0.2 | 0.13 | 0.2 |
| | CV L3 | 81 | 89.2 | 0.33 | 0.4 | 0.29 | 0.3 | 0.08 | 0.1 | 0.12 | 0.1 |
| | CV L4 | 80 | 107.9 | 0.43 | 0.4 | 0.40 | 0.4 | 0.11 | 0.1 | 0.12 | 0.1 |
| | CV L5 | 80 | 122.3 | 0.48 | 0.4 | 0.44 | 0.4 | 0.15 | 0.1 | 0.12 | 0.1 |
| **BUN (mg/dL)** | CV L1 | 81 | 107.3 | 0.91 | 0.8 | 0.81 | 0.8 | 0.41 | 0.4 | 0.04 | 0.04 |
| | CV L2 | 81 | 59.7 | 0.92 | 1.5 | 0.86 | 1.4 | 0.23 | 0.4 | 0.20 | 0.3 |
| | CV L3 | 81 | 10.5 | 0.12 | 1.1 | 0.11 | 1.0 | 0.05 | 0.5 | 0.03 | 0.3 |
| | CV L4 | 80 | 8.1 | 0.18 | 2.2 | 0.17 | 2.1 | 0.03 | 0.4 | 0.05 | 0.6 |
| | CV L5 | 80 | 4.1 | 0.15 | 3.7 | 0.14 | 3.4 | 0.04 | 1.0 | 0.03 | 0.7 |

*Precision (Whole Blood)*

The whole blood precision of the i-STAT Sodium, Potassium, Chloride, and BUN Tests on i-STAT 1 Analyzer were evaluated using venous whole blood (native or altered) samples targeted to three levels within the test reportable range.

One test cartridge lot was used across 3 point of care sites. At each site, each sample was tested 3 times on each of 7 i-STAT 1 Analyzers (total of 21 test results per sample per instrument). The results of the whole blood precision using the i-STAT 1 Analyzer are shown in **Table 2**.

| Table 2: Whole Blood Precision Results – i-STAT 1 Wireless Analyzer | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| i-STAT Test | Level | Site | N | Mean | Within-Analyzer | | Total | | | |
| | | | | | SD | %CV | SD | SD 95% CI | %CV | %CV 95% CI |
| Sodium (mmol/L) | ≤ 134 | 01 | 21 | 110.3 | 0.49 | 0.4 | 0.49 | 0.39 to 0.78 | 0.4 | 0.4 to 0.7 |
| | | 02 | 21 | 123.9 | 0.38 | 0.3 | 0.38 | 0.31 to 0.57 | 0.3 | 0.3 to 0.5 |
| | | 03 | 21 | 108.3 | 0.44 | 0.4 | 0.49 | 0.39 to 0.84 | 0.5 | 0.4 to 0.8 |
| | 135-145 | 01 | 21 | 139.2 | 0.58 | 0.4 | 0.58 | 0.48 to 0.83 | 0.4 | 0.3 to 0.6 |
| | | 01 | 21 | 138.0 | 0.22 | 0.2 | 0.22 | 0.17 to 0.35 | 0.2 | 0.1 to 0.3 |
| | | 01 | 21 | 136.5 | 0.65 | 0.5 | 0.68 | 0.54 to 1.13 | 0.5 | 0.4 to 0.8 |
| | | 02 | 20 | 138.3 | 0.45 | 0.3 | 0.45 | 0.36 to 0.73 | 0.3 | 0.3 to 0.5 |
| | | 02 | 14 | 141.8 | 0.46 | 0.3 | 0.46 | 0.38 to 0.81 | 0.3 | 0.3 to 0.6 |
| | | 02 | 21 | 141.9 | 0.31 | 0.2 | 0.31 | 0.25 to 0.48 | 0.2 | 0.2 to 0.3 |
| | | 02 | 21 | 140.0 | 0.38 | 0.3 | 0.38 | 0.31 to 0.63 | 0.3 | 0.2 to 0.5 |
| | | 02 | 21 | 138.9 | 0.44 | 0.3 | 0.48 | 0.38 to 0.83 | 0.3 | 0.3 to 0.6 |
| | | 02 | 21 | 138.3 | 0.53 | 0.4 | 0.53 | 0.44 to 0.76 | 0.4 | 0.3 to 0.5 |
| | | 03 | 21 | 140.9 | 0.31 | 0.2 | 0.36 | 0.29 to 0.64 | 0.3 | 0.2 to 0.5 |
| | | 03 | 21 | 141.0 | 0.22 | 0.2 | 0.22 | 0.17 to 0.35 | 0.2 | 0.1 to 0.2 |
| | | 03 | 21 | 142.1 | 0.31 | 0.2 | 0.31 | 0.25 to 0.48 | 0.2 | 0.2 to 0.3 |
| | | 03 | 21 | 143.0 | 0.22 | 0.2 | 0.22 | 0.17 to 0.35 | 0.2 | 0.1 to 0.2 |
| | | 03 | 21 | 139.8 | 0.44 | 0.3 | 0.44 | 0.35 to 0.71 | 0.3 | 0.3 to 0.5 |
| | ≥ 146 | 01 | 21 | 150.1 | 0.62 | 0.4 | 0.62 | 0.51 to 0.88 | 0.4 | 0.3 to 0.6 |
| | | 02 | 21 | 163.2 | 0.49 | 0.3 | 0.49 | 0.40 to 0.70 | 0.3 | 0.2 to 0.4 |
| | | 03 | 21 | 150.1 | 0.38 | 0.3 | 0.38 | 0.31 to 0.57 | 0.3 | 0.2 to 0.4 |
| Potassium (mmol/L) | 2.75-3.25 | 1 | 21 | 2.80 | 0.022 | 0.8 | 0.022 | 0.017 to 0.035 | 0.8 | 0.6 to 1.3 |
| | | 2 | 21 | 2.80 | 0.000 | 0.0 | 0.000 | 0.000 to 0.000 | 0.0 | 0.0 to 0.0 |
| | | 3 | 21 | 3.05 | 0.058 | 1.9 | 0.058 | 0.048 to 0.083 | 1.9 | 1.6 to 2.7 |
| | >3.25 - <5.55 | 1 | 21 | 4.30 | 0.000 | 0.0 | 0.000 | 0.000 to 0.000 | 0.0 | 0.0 to 0.0 |
| | | 1 | 21 | 4.00 | 0.022 | 0.6 | 0.022 | 0.017 to 0.035 | 0.6 | 0.4 to 0.9 |
| | | 1 | 21 | 3.98 | 0.049 | 1.2 | 0.049 | 0.040 0.070 | 1.2 | 1.0 to 1.8 |
| | | 2 | 20 | 4.95 | 0.059 | 1.2 | 0.059 | 0.049 to 0.085 | 1.2 | 1.0 to 1.7 |
| | | 2 | 14 | 4.20 | 0.000 | 0.0 | 0.000 | 0.000 to 0.000 | 0.0 | 0.0 to 0.0 |
| | | 2 | 21 | 4.13 | 0.053 | 1.3 | 0.053 | 0.044 to 0.076 | 1.3 | 1.1 to 1.8 |
| | | 2 | 21 | 4.24 | 0.058 | 1.4 | 0.058 | 0.048 to 0.082 | 1.4 | 1.1 to 1.9 |
| | | 2 | 21 | 4.29 | 0.038 | 0.9 | 0.038 | 0.031 to 0.057 | 0.9 | 0.7 to 1.3 |
| | | 2 | 21 | 4.10 | 0.000 | 0.0 | 0.000 | 0.000 to 0.000 | 0.0 | 0.0 to 0.0 |
| | | 3 | 21 | 4.80 | 0.031 | 0.6 | 0.032 | 0.025 to 0.052 | 0.7 | 0.5 to 1.1 |
| | | 3 | 21 | 3.97 | 0.053 | 1.3 | 0.053 | 0.044 to 0.078 | 1.3 | 1.1 to 2.0 |
| | | 3 | 21 | 4.00 | 0.000 | 0.0 | 0.000 | 0.000 to 0.000 | 0.0 | 0.0 to 0.0 |
| | | 3 | 21 | 3.40 | 0.000 | 0.0 | 0.000 | 0.000 to 0.000 | 0.0 | 0.0 to 0.0 |
| | 5.55 - 6.05 | 1 | 21 | 5.80 | 0.022 | 0.4 | 0.022 | 0.017 to 0.035 | 0.4 | 0.3 to 0.6 |
| | | 2 | 21 | 5.85 | 0.058 | 1.0 | 0.058 | 0.048 to 0.083 | 1.0 | 0.8 to 1.4 |
| | | 3 | 21 | 5.71 | 0.038 | 0.7 | 0.038 | 0.031 to 0.057 | 0.7 | 0.5 to 1.0 |
| | 7.25 - 7.75 | 1 | 21 | 7.60 | 0.000 | 0.0 | 0.000 | 0.000 to 0.000 | 0.0 | 0.0 to 0.0 |
| | | 2 | 21 | 7.64 | 0.053 | 0.7 | 0.053 | 0.044 to 0.081 | 0.7 | 0.6 to 1.1 |
| | | 3 | 21 | 7.73 | 0.053 | 0.7 | 0.053 | 0.044 to 0.078 | 0.7 | 0.6 to 1.0 |

| Table 2: Whole Blood Precision Results – i-STAT 1 Wireless Analyzer | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| i-STAT Test | Level | Site | N | Mean | Within-Analyzer | | Total | | | |
| | | | | | SD | %CV | SD | SD 95% CI | %CV | %CV 95% CI |
| Chloride (mmol/L) | <80 | 01 | 21 | 77.0 | 0.53 | 0.7 | 0.53 | 0.44 to 0.80 | 0.7 | 0.6 to 1.0 |
| | | 02 | 21 | 77.4 | 0.95 | 1.2 | 0.95 | 0.78 to 1.40 | 1.2 | 1.0 to 1.8 |
| | | 03 | 21 | 76.9 | 0.62 | 0.8 | 0.66 | 0.53 to 1.11 | 0.9 | 0.7 to 1.4 |
| | 90-112 | 01 | 21 | 102.0 | 0.62 | 0.6 | 0.62 | 0.51 to 0.89 | 0.6 | 0.5 to 0.9 |
| | | 01 | 21 | 97.0 | 0.31 | 0.3 | 0.32 | 0.25 to 0.52 | 0.3 | 0.3 to 0.5 |
| | | 01 | 21 | 102.3 | 0.53 | 0.5 | 0.53 | 0.44 to 0.78 | 0.5 | 0.4 to 0.8 |
| | | 02 | 21 | 100.2 | 0.32 | 0.3 | 0.37 | 0.29 to 0.66 | 0.4 | 0.3 to 0.7 |
| | | 02 | 21 | 101.3 | 0.53 | 0.5 | 0.53 | 0.44 to 0.90 | 0.5 | 0.4 to 0.9 |
| | | 02 | 21 | 103.5 | 0.38 | 0.4 | 0.52 | 0.40 to 0.99 | 0.5 | 0.4 to 1.0 |
| | | 02 | 21 | 102.1 | 0.31 | 0.3 | 0.31 | 0.25 to 0.48 | 0.3 | 0.2 to 0.5 |
| | | 02 | 21 | 101.4 | 0.44 | 0.4 | 0.51 | 0.41 to 0.91 | 0.5 | 0.4 to 0.9 |
| | | 02 | 21 | 101.0 | 0.22 | 0.2 | 0.22 | 0.17 to 0.35 | 0.2 | 0.2 to 0.3 |
| | | 03 | 21 | 104.0 | 0.49 | 0.5 | 0.50 | 0.40 to 0.82 | 0.5 | 0.4 to 0.8 |
| | | 03 | 21 | 104.0 | 0.62 | 0.6 | 0.62 | 0.50 to 0.95 | 0.6 | 0.5 to 0.9 |
| | | 03 | 21 | 103.1 | 0.49 | 0.5 | 0.54 | 0.43 to 0.94 | 0.5 | 0.4 to 0.9 |
| | | 03 | 21 | 101.0 | 0.31 | 0.3 | 0.32 | 0.25 to 0.52 | 0.3 | 0.2 to 0.5 |
| | | 03 | 21 | 99.8 | 0.44 | 0.4 | 0.44 | 0.36 to 0.64 | 0.4 | 0.4 to 0.6 |
| | >120 | 01 | 21 | 126.1 | 0.58 | 0.5 | 0.58 | 0.47 to 0.86 | 0.5 | 0.4 to 0.7 |
| | | 02 | 21 | 123.8 | 0.69 | 0.6 | 0.69 | 0.57 to 0.98 | 0.6 | 0.5 to 0.8 |
| | | 03 | 21 | 123.2 | 0.44 | 0.4 | 0.55 | 0.43 to 1.00 | 0.4 | 0.3 to 0.8 |
| BUN (mg/dL) | < 10 | 01 | 21 | 5.0 | 0.00 | 0.0 | 0.00 | 0.00 to 0.00 | 0.0 | 0.0 to 0.0 |
| | | 01 | 21 | 5.5 | 0.49 | 8.9 | 0.51 | 0.41 to 0.86 | 9.4 | 7.5 to 15.6 |
| | | 02 | 21 | 7.0 | 0.00 | 0.0 | 0.00 | 0.00 to 0.00 | 0.0 | 0.0 to 0.0 |
| | | 03 | 21 | 6.9 | 0.31 | 4.5 | 0.36 | 0.29 to 0.64 | 5.3 | 4.2 to 9.3 |
| | 10-25 | 01 | 21 | 14.0 | 0.00 | 0.0 | 0.00 | 0.00 to 0.00 | 0.0 | 0.0 to 0.0 |
| | | 02 | 20 | 18.0 | 0.23 | 1.3 | 0.23 | 0.18 to 0.37 | 1.3 | 1.0 to 2.1 |
| | | 02 | 14 | 23.5 | 0.60 | 2.5 | 0.60 | 0.50 to 1.00 | 2.5 | 2.1 to 4.3 |
| | | 02 | 21 | 20.9 | 0.38 | 1.8 | 0.38 | 0.31 to 0.57 | 1.8 | 1.5 to 2.7 |
| | | 02 | 21 | 10.0 | 0.00 | 0.0 | 0.00 | 0.00 to 0.00 | 0.0 | 0.0 to 0.0 |
| | | 03 | 21 | 11.0 | 0.22 | 2.0 | 0.22 | 0.17 to 0.35 | 2.0 | 1.5 to 3.2 |
| | | 03 | 21 | 14.0 | 0.00 | 0.0 | 0.00 | 0.00 to 0.00 | 0.0 | 0.0 to 0.0 |
| | | 03 | 21 | 13.9 | 0.31 | 2.2 | 0.31 | 0.25 to 0.48 | 2.2 | 1.8 to 3.5 |
| | 25-50 | 01 | 21 | 38.0 | 0.44 | 1.1 | 0.50 | 0.40 to 0.88 | 1.3 | 1.1 to 2.3 |
| | | 02 | 21 | 46.0 | 1.11 | 2.4 | 1.12 | 0.89 to 1.81 | 2.4 | 1.9 to 3.9 |
| | | 03 | 21 | 27.8 | 0.62 | 2.2 | 0.71 | 0.56 to 1.24 | 2.6 | 2.0 to 4.5 |
| | > 110 | 01 | 21 | 111.8 | 2.82 | 2.5 | 2.82 | 2.31 to 4.20 | 2.5 | 2.1 to 3.8 |
| | | 02 | 21 | 125.0 | 1.72 | 1.4 | 1.97 | 1.56 to 3.44 | 1.6 | 1.2 to 2.8 |
| | | 03 | 21 | 118.6 | 1.83 | 1.5 | 1.83 | 1.50 to 2.71 | 1.5 | 1.3 to 2.3 |

### b. Linearity

The study was designed based on CLSI EP06-A: *Evaluation of the linearity of quantitative measurement procedures.*

The linearity of the i-STAT Sodium, Potassium, Chloride, and BUN tests on the i-STAT 1 Analyzer was evaluated by preparing whole blood samples of varying analyte levels that spanned the reportable range of the tests. The i-STAT Sodium, Potassium, Chloride, and BUN tests demonstrated linearity over the reportable range as shown in **Table 3**. Regression summary of the Sodium, Potassium, Chloride, and BUN response

versus the concentration of the whole blood samples of varying analyte levels is also provided in **Table 3**.

| Table 3: Regression Summary for the i-STAT tests on the i-STAT 1 Analyzer | | | | | |
|---|---|---|---|---|---|
| **i-STAT Test** | **Reportable Range** | **Range Tested** | **Slope** | **Intercept** | **$R^2$** |
| **Sodium (mmol/L)** | 100 - 180 | 89 – 205 | 1.077 | -5.244 | 0.9994 |
| **Potassium (mmol/L)** | 2.0 – 9.0 | 1.7 – 10.4 | 1.109 | -0.136 | 0.9999 |
| **Chloride (mmol/L)** | 65 – 140 | 76 – 158 WB<br>54 – 157 Plasma | 0.867<br>0.969 | 7.353<br>2.130 | 0.9983<br>0.9987 |
| **BUN (mg/dL)** | 3 – 140 | 2 - 143 | 0.946 | 0.209 | 0.9950 |

### c. Limit of Quantitation (LoQ)

The study was based on the CLSI EP17-A2: *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline–Second Edition.*

The LoQs of the i-STAT Sodium, Potassium and BUN tests were evaluated on the i-STAT 1 Analyzer using whole blood that was altered to low sodium (<100 mmol/L), potassium (< 2.0 mmol/L), or BUN (<3 mg/dL) concentrations and two test cartridge lots. For Chloride, plasma samples that were altered to <65 mmol/L were evaluated as whole blood samples altered to achieve a chloride concentration <65 mmol/L have been found to hemolyze. The LoQs for the i-STAT Sodium Potassium, Chloride, and BUN tests on the i-STAT 1 Analyzer were determined to be 91 mmol/L, 1.5 mmol/L, 56 mmol/L, and 1 mg/dL, respectively.

### d. Interference

The interference performance of the i-STAT Sodium, Potassium, Chloride, and BUN tests on the i-STAT 1 System was evaluated using whole blood samples based on CLSI EP07 ED3: *Interference Testing in Clinical Chemistry, Third Edition*. The effect of each substance was evaluated by comparing the performance of a control sample, spiked with blank solvent solution, with the test results from a sample spiked with the potentially interfering substance at the toxic/pathological concentration based on CLSI EP37 ED1: *Supplemental Tables for Interference Testing in Clinical Chemistry, First Edition*, as applicable. A substance was identified as an interferent if the difference between the control and test samples was outside of the allowed error (Ea) for the i-STAT test.

**Tables 4, 5, 6 and 7** contain the list of potentially interfering substances tested for the i-STAT Sodium, Potassium, Chloride, and BUN tests and the interference results.

### *i-STAT Sodium Test*

| Table 4: Summary of Substance Tested and Interference Results for the i-STAT Sodium test | | | | |
|---|---|---|---|---|
| **Substance** | **Test Concentration** | | **Interference (Yes/No)** | **Interference Results** |
| | **mmol/L** | **mg/dL** | | |
| Acetaminophen | 1.03 | 15.6 | No | |
| N-Acetyl-L-Cysteine | 0.92 | 15.0 | No | |
| Acetylsalicylic Acid | 0.167 | 3.0 | No | |
| Ammonium Chloride | 2.0[a] | 10.7 | No | |
| Ascorbic Acid | 0.298 | 5.25 | No | |
| Bilirubin | 0.684 | 40 | No | |
| Lithium Bromide | 37.5[a] | 325.69 | No | |
| β-Hydroxybutyric Acid | 6.0[a] | 62.47 | No | |
| Calcium Chloride | 5 | 20 | No | |
| Hemoglobin | 10 g/L | 1000 | No | |
| Sodium Heparin | 3.30 U/mL | 330 U/dL | No | |
| Ibuprofen | 1.06 | 21.9 | No | |
| Lithium Lactate | 10 | 90 | No | |
| Lithium Chloride | 3.2[a] | 13.6 | No | |
| Lithium Salicylate | 0.207 | 2.86 | No | |
| Magnesium Chloride | 4.1 | 10 | No | |
| Sodium Thiosulfate | 16.7[a] | 264.04 | Yes | Increased results ≥ 3.1 mmol/L |
| Triglyceride | 16.94 | 1500 | No | |
| Uric Acid | 1.4 | 23.5 | No | |
| Cholesterol | 10.3 | 400 | No | |

### *i-STAT Potassium Test*

| Table 5: Summary of Substance Tested and Interference Results for the i-STAT Potassium test | | | | |
|---|---|---|---|---|
| **Substance** | **Test Concentration** | | **Interference (Yes/No)** | **Interference Results** |
| | **mmol/L** | **mg/dL** | | |
| Acetaminophen | 1.03 | 15.6 | No | |
| N-Acetyl-L-Cysteine | 0.92 | 15.0 | No | |
| Ammonium Chloride | 2.0[a] | 10.7 | No | |
| Ascorbic Acid | 0.298 | 5.25 | No | |
| Benzalkonium Chloride | 0.03 | 1.13 | No | |
| β-Hydroxybutyric Acid | 6.0[a] | 62.47 | No | |
| Bilirubin | 0.684 | 40 | No | |
| Lithium Bromide | 37.5[a] | 325.69 | No | |
| Calcium Chloride | 5.0 | 20 | No | |
| Hemoglobin | 10 g/L | 1000 | No | |
| Lithium Lactate | 10 | 90 | No | |
| Lithium Chloride | 3.2[a] | 13.6 | No | |
| Magnesium Chloride | 4.1 | 10 | No | |
| Lithium Salicylate | 0.207 | 2.86 | No | |

[a] No CLSI EP37 test concentration available. The molecular weight of the substance tested was used to convert the test concentration from mmol/L to mg/dL. The molecular weight of each substance could vary depending on the form chosen.

| Table 5: Summary of Substance Tested and Interference Results for the i-STAT Potassium test | | | | |
|---|---|---|---|---|
| **Substance** | **Test Concentration** | | **Interference (Yes/No)** | **Interference Results** |
| | **mmol/L** | **mg/dL** | | |
| Sodium Thiosulfate | 16.7[aa] | 264.04 | No | |
| Triglyceride | 16.94 | 1500 | No | |
| Cholesterol | 10.3 | 400 | No | |

### *i-STAT Chloride Test*

| Table 6: Summary of Substance Tested and Interference Results for the i-STAT Chloride test | | | | |
|---|---|---|---|---|
| **Substance** | **Test Concentration** | | **Interference (Yes/No)** | **Interference Results** |
| | **mmol/L** | **mg/dL** | | |
| Acetaminophen | 1.03 | 15.6 | No | |
| N-Acetyl-L-Cysteine | 0.92 | 15.0 | No | |
| L-Ascorbic Acid | 0.298 | 5.25 | No | |
| Bicarbonate | 35.0[a] | 294 | No | |
| Bilirubin | 0.684 | 40 | No | |
| Lithium Bromide | 37.5 | 325.69 | Yes | Increased results ≥ 2.4 mmol/L |
| β-Hydroxybutyric Acid | 6.0[a] | 62.47 | No | |
| Hemoglobin | 10 g/L | 1000 | No | |
| Sodium Iodide | 2.99[a] | 44.82 | No | |
| Lithium Lactate | 10 | 90 | No | |
| Sodium Oxalate | 0.09 | 1.206 | No | |
| Lithium Salicylate | 0.207 | 2.86 | No | |
| Lithium Thiocyanate | 0.898 | 5.22 | No | |
| Sodium Thiosulfate | 16.7[a] | 264.04 | Yes | Increased results ≥ 4.19 mmol/L |
| Triglyceride | 16.94 | 1500 | No | |
| Cholesterol | 10.3 | 400 | No | |

### *i-STAT BUN Test*

| Table 7: Summary of Substance Tested and Interference Results for i-STAT BUN test | | | | |
|---|---|---|---|---|
| **Substance** | **Test Concentration** | | **Interference (Yes/No)** | **Interference Results** |
| | **mmol/L** | **mg/dL** | | |
| Acetaminophen | 1.03 | 15.6 | No | |
| N-Acetyl-L-Cysteine | 0.92 | 15.0 | No | |
| L-Ascorbic Acid | 0.298 | 5.25 | No | |
| β-Hydroxybutyric Acid | 6.0[a] | 62.47 | No | |
| Bilirubin | 0.684 | 40 | No | |
| Lithium Bromide | 37.5[a] | 325.69 | No | |
| Hemoglobin | 10 g/L | 1000 | No | |
| Hydroxyurea | 0.405 | 3.08 | No | |
| Lithium Lactate | 10 | 90 | No | |

[a] No CLSI EP37 test concentration available. The molecular weight of the substance tested was used to convert the test concentration from mmol/L to mg/dL. The molecular weight of each substance could vary depending on the form chosen.

| Table 7: Summary of Substance Tested and Interference Results for i-STAT BUN test | | | | |
|---|---|---|---|---|
| **Substance** | **Test Concentration** | | **Interference (Yes/No)** | **Interference Results** |
| | **mmol/L** | **mg/dL** | | |
| pH | 8.0 pH units | N/A | No | |
| Lithium Salicylate | 0.207 | 2.86 | No | |
| Lithium Thiocyanate | 0.898 | 5.22 | No | |
| Sodium Thiosulfate | 16.7[a] | 264.04 | No | |
| Triglyceride | 16.94 | 1500 | Yes | Increased results ≥ 10.2 mmol/L |
| Cholesterol | 10.3 | 400 | No | |

***Comparison Study***

### e. Method Comparison with Predicate Device

Method comparison was demonstrated in a study comparing the i-STAT Sodium Potassium, Chloride, and BUN tests performance on the i-STAT 1 System to the Beckman DxC. The study was based on CLSI guideline EP09c-ED3. Venous and arterial blood specimens were evaluated and analyzed on the i-STAT 1 Analyzer against plasma specimens on the Beckman DxC. A Passing-Bablok linear regression analysis was performed using the first replicate result from the i-STAT 1 Analyzer versus the singlicate result of the comparative method.

| Table 8: Method Comparison Results | | | | |
|---|---|---|---|---|
| **i-STAT Test** | **N** | **Slope** | **Intercept** | **r** |
| **Sodium** | 187 | 1.00 | 2.00 | 0.96 |
| **Potassium** | 189 | 1.00 | 0.00 | 0.99 |
| **Chloride** | 176 | 1.000 | 0.000 | 0.96 |
| **Bun** | 184 | 0.940 | 1.675 | 0.99 |

## 8. Conclusion

The results of these studies demonstrate that performance of the i-STAT CHEM8+ Sodium, Potassium, Chloride and BUN test with the i-STAT 1 System are substantially equivalent to the comparative method.