## i-STAT EG7+

**Blood Gases & Chemistries** 

# Na, K, HCT, iCa, AND BLOOD GAS RESULTS IN ≈2 MINUTES



#### **INTENDED USE<sup>1</sup>**

The *i-STAT EG7+* cartridge with the *i-STAT® 1 System* is intended for use in the *in vitro* quantification of Sodium, Potassium, Ionized Calcium, Hematocrit, pH, oxygen partial pressure, and carbon dioxide partial pressure in arterial or venous whole blood.

The *i-STAT EG7+* cartridge with the *i-STAT 1 System* is intended for use in the *in vitro* quantification of Sodium, Hematocrit, pH, oxygen partial pressure, and carbon dioxide partial pressure in capillary whole blood.

- Sodium (Na) measurements are used for monitoring electrolyte imbalances.
- Potassium (K) measurements are used for the diagnosis and monitoring of diseases and clinical conditions that manifest high and low potassium levels.
- Ionized Calcium (iCa) measurements are used in the diagnosis, monitoring, and treatment of conditions, including, but not limited to, parathyroid disease, a variety of bone diseases, chronic renal disease and tetany and disturbances related to surgical and intensive care.
- Hematocrit (Hct) measurements can aid in the determination and monitoring of normal or abnormal total red cell volume status that can be associated with conditions including anemia, erythrocytosis, and blood loss related to trauma and surgery.
- pH, PO<sub>2</sub>, and PCO<sub>2</sub> measurements are used in the diagnosis, monitoring, and treatment of respiratory disturbances and metabolic and respiratory-based acid-base disturbances.
- Bicarbonate is used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

#### **KEY BENEFIT OF PRODUCT**

The *i-STAT EG7*+ cartridge is a unique combination assay with simultaneous rapid measurement of blood chemistries, gases, and hematology parameters. The cartridge provides chemistries that are important in the diagnosis and treatment of patients with hypertension, dehydration, cardiac distress, renal impairment, and dysfunction of enzymatic membrane transport at a cellular level. It also provides precision hematocrit and blood gas results to assess blood oxygenation and respiratory status.

#### PRODUCT CODE/LIST NUMBER

- 03P76-25 i-STAT EG7+ Cartridge
- 05P71-01 i-STAT TriControls Control Level 1
- 05P72-01 i-STAT TriControls Control Level 2
- 05P73-01 i-STAT TriControls Control Level 3
- 05P70-01 i-STAT TriControl Calibration Verification

#### CARTRIDGE SPECIFICATIONS

Panel Name	EG7+
Test/Analyte(s)	Na, K, iCa, Hct, pH, PO <sub>2</sub> , PCO <sub>2</sub>
Sample Size	95uL
Sample Type	<ul> <li>Na, Hct, pH, PO<sub>2</sub>, and PCO<sub>2</sub>: Arterial, venous, or capillary whole blood</li> <li>Na, Hct, K, iCa, pH, PO<sub>2</sub>, and PCO<sub>2</sub>: Arterial or venous whole blood</li> </ul>
Reportable Range	Na: 100-180 mmol/L   K: 2.0-9.0 mmol/L   iCa: 0.25-2.50 mmol/L   Hct: 15-75 %PCV   pH: 6.50-7.80   PO <sub>2</sub> : 5-700 mmHg   PCO <sub>2</sub> : 5-130 mmHg
Analysis Time	~130–200 seconds
Shipment Time- Temperature Indicator	Included in shipment; time-temperature indicator that provides a visual non-reversible record of temperature exposure at or above 10°C and 34°C for exposure period of 5 days at 30°C and 3 hours at 34°C
Refrigerated Storage	35°-46°F / 2°-8°C until date indicated on box and pouch
Room Temp. Storage	64°-86°F / 18°-30°C for 2 months
Room Temp.	- 5 minutes for a single cartridge
Room Temp. Equilibration	<ul><li>5 minutes for a single cartridge</li><li>1 hour for an entire box</li></ul>
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Equilibration Reference Range	- 1 hour for an entire box  It is recommended each facility should establish its own reference range to assure proper representation of specific populations pH: Traceable to NIST SRMs 186-I, 186-II, 185 and 187  PO <sub>2</sub> , PCO <sub>2</sub> : Traceable to NIST SRMs via commercially available certified specialty medical gas materials
Equilibration Reference Range	- 1 hour for an entire box  It is recommended each facility should establish its own reference range to assure proper representation of specific populations  pH: Traceable to NIST SRMs 186-I, 186-II, 185 and 187  PO <sub>2</sub> , PCO <sub>2</sub> : Traceable to NIST SRMs via commercially available certified specialty medical gas materials  Na, K, iCa: Traceable to NIST SRM 956  Hct: Traceable to CLSI H07-A3 procedure for determining packed cell volume by the
Equilibration  Reference Range  Traceability	- 1 hour for an entire box  It is recommended each facility should establish its own reference range to assure proper representation of specific populations  pH: Traceable to NIST SRMs 186-I, 186-II, 185 and 187  PO <sub>2</sub> , PCO <sub>2</sub> : Traceable to NIST SRMs via commercially available certified specialty medical gas materials  Na, K, iCa: Traceable to NIST SRM 956  Hct: Traceable to CLSI H07-A3 procedure for determining packed cell volume by the microhematocrit method  Sample Well Gasket includes natural
Equilibration Reference Range Traceability  Latex Rubber	- 1 hour for an entire box  It is recommended each facility should establish its own reference range to assure proper representation of specific populations pH: Traceable to NIST SRMs 186-I, 186-II, 185 and 187  PO <sub>2</sub> , PCO <sub>2</sub> : Traceable to NIST SRMs via commercially available certified specialty medical gas materials  Na, K, iCa: Traceable to NIST SRM 956  Hct: Traceable to CLSI H07-A3 procedure for determining packed cell volume by the microhematocrit method  Sample Well Gasket includes natural rubber latex



#### **CONTROL SPECIFICATIONS**

Control Levels	Levels 1, 2, and 3
Quantity Per Box	- Each box contains 10 ampules
	- Each ampule contains 1.7 mL of aqueous fluid
Storage Conditions	Refrigerated storage at 2° to 8°C (35° to 46°F) should be maintained until the printed expiration date on the box and ampule labels. Shelf life is 18 months from manufacture. Control fluids may also be stored at room temperature for up to 5 days (18° to 30°C or 64° to 86°F). Prolonged storage at temperatures greater than 30°C (86°F) may cause changes in the values of some analytes
Room Temp. Equilibration	For best results, ampules, cartridges, and instruments should be at the same temperature
Control Box	2.69" (H) x 6.06" (W) x 0.75" (D

# CALIBRATION VERIFICATION SET SPECIFICATIONS

Cal/Ver Levels	Levels 1, 2, 3, 4, and 5 representing analyte levels across the reportable range of each test
Quantity Per Box	<ul><li>Each box contains 20 ampules (4 ampules of each of 5 levels)</li><li>Each ampule contains 1.7 mL of aqueous fluid</li></ul>
Storage Conditions	Refrigerated storage at 2° to 8°C (35° to 46°F) should be maintained until the printed expiration date on the box and ampule labels. Shelf life is 18 months from manufacture. Control fluids may also be stored at room temperature for up to 5 days (18° to 30°C or 64° to 86°F). Prolonged storage at temperatures greater than 30°C (86°F) may cause changes in the values of some analytes
Room Temp. Equilibration	For best results, ampules, cartridges, and instruments should be at the same temperature
Cal/Ver Box	2.69" (H) x 2.75" (W) x 2.81" (D)

### SYSTEM COMPATIBILITY

The *i-STAT EG7*+ cartridge is part of a broad menu of tests compatible with the *i-STAT 1 System*.

The October 2025 and any subsequent software releases support the update of the i-STAT® 1 analyzer software to the latest approved reportable ranges for those customers not customizing their ranges in *i-STAT/DE*. *i-STAT/* DE users can customize their reportable ranges to match the approved reportable ranges in the IFU. Customers can modify the testing profiles on the i-STAT 1 analyzer to avoid K and iCa being reported on capillary samples.



### TRAINING AND COMPLIANCE

Resources designed to ensure competency of *i-STAT*® *System* users and to assist in meeting regulatory compliance requirements are available for download from our website (see below).

### **ADDITIONAL INFORMATION**

To obtain additional product information and support, visit www.globalpointofcare.abbott.

#### REFERENCES

1. i-STAT EG7+ Instructions for Use.

For in vitro diagnostic use only.

This material is intended for a U.S. audience only.

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Abbott | Point of Care Diagnostics | 400 College Road East | Princeton, NJ 08540 USA 609 454 9000 | www.globalpointofcare.abbott i-STAT EG7+ - Product Specifications | APOC-25002618.1 07/25

