i-STAT CG8+

Blood Gases & Chemistries

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



INTENDED USE[1]

The *i-STAT CG8+* cartridge with the *i-STAT® 1 System* is intended for use in the *in vitro* quantification of sodium, potassium, ionized calcium, glucose, hematocrit, pH, partial pressure of oxygen (PO_2), and partial pressure of carbon dioxide (PCO_2) in arterial or venous whole blood in point of care or clinical laboratory settings.

The *i-STAT CG8+* cartridge with the *i-STAT 1 System* is intended for use in the *in vitro* quantification of sodium, glucose, hematocrit, pH, partial pressure of oxygen (PO_2), and partial pressure of carbon dioxide (PCO_2) in capillary whole blood in point of care or clinical laboratory settings.

- Sodium (Na) measurements are used for monitoring electrolyte imbalances.
- Potassium (K) measurements are used in 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, tetany, and disturbances related to surgical and intensive care.
- Glucose (Glu) measurements are used in the diagnosis, monitoring, and treatment of carbohydrate metabolism disorders including, but not limited to, diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.
- 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_2, and PCO_2 measurements are used in the diagnosis, monitoring, and treatment of respiratory, metabolic, and acid-base disturbances.

KEY BENEFIT OF PRODUCT

The *i-STAT CG8+* 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, hypoglycemia, 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

- 03P88-25 *i-STAT CG8+* 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	CG8+
Test/Analyte(s)	Na, K, iCa, Glu, Hct, pH, PO_2, PCO_2
Sample Size	95uL
Sample Type	- Na, Glu, Hct, pH, PO_2, and PCO_2: Arterial, venous, or capillary whole blood - Na, Glu, Hct, K, iCa, pH, PO_2, and PCO_2: Arterial or venous whole blood
Reportable Range	Na: 100-180 mmol/L | K: 2.0-9.0 mmol/L| iCa: 0.25-2.50 mmol/L | Glu: 20-700 mg/dL | Hct: 15-75 %PCV | pH: 6.50-7.80 | PO_2: 5-700 mmHg | PCO_2: 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. Equilibration	- 5 minutes for a single cartridge - 1 hour for an entire box
Reference Range	It is recommended each facility should establish its own reference range to assure proper representation of specific populations
Traceability	**pH**: Traceable to NIST SRMs 186-I, 186-II, 185 and 187 **PO_2, PCO_2**: 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 **Glu:** Traceable to NIST SRM 965
Latex Rubber	Sample Well Gasket includes natural rubber latex
Cartridge Box	2.75" (H) x 8.00" (W) x 3.81" (D)
Quantity Per Box	25 pouches
Cartridge Pouch	2.64" (H) x 3.74" (W)

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For *in vitro* diagnostic use only.

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	- Each box contains 20 ampules (4 ampules of each of 5 levels) - 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
Cal/Ver Box	2.69" (H) x 2.75" (W) x 2.81" (D)

SYSTEM COMPATIBILITY

The *i-STAT CG8+* 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 CG8+* Instructions for Use.

For *in vitro* diagnostic use only.
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| *i-STAT CG8+* - Product Specifications | APOC-25002616.1 07/25

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