

i-STAT CG4+

Blood Gases & Chemistries

pH, PO₂, PCO₂, AND LACTATE RESULTS IN ≈2 MINUTES

RESULTS IN
≈2 MINUTES



INTENDED USE¹

The *i-STAT CG4+* cartridge with the *i-STAT® 1 System* is intended for use in the *in vitro* quantification of pH, PO₂, PCO₂ in arterial, venous, or capillary whole blood and lactate in arterial or venous whole blood in point of care or clinical laboratory settings.

- pH, PO₂ and PCO₂ measurements are used in the diagnosis, monitoring, and treatment of respiratory, metabolic, and acid-base disturbances.
- Lactate measurements are used in (1) the diagnosis and treatment of lactic acidosis in conjunction with measurements of blood acid/base status, (2) monitoring tissue hypoxia and strenuous physical exertion, and (3) diagnosis of hyperlactatemia.

KEY BENEFIT OF PRODUCT

Rapid assessment of acid-base status and respiratory function is critical for managing patients in emergency, critical care, and surgical settings. The *i-STAT CG4+* cartridge enables timely clinical decision making at the point of care with real-time blood gas and lactate results to assess the respiratory status of a patient or determine the presence of hyperlactatemia all without leaving the patient's bedside.

PRODUCT CODE/LIST NUMBER

- 03P85-25 *i-STAT CG4+* Cartridge
- 06F12-01 *i-STAT* Control Level 1
- 06F13-01 *i-STAT* Control Level 2
- 06F14-01 *i-STAT* Control Level 3
- 06F15-01 *i-STAT* Calibration Verification Set

Alternatively

- 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	CG4+
Test/Analyte(s)	pH, PO ₂ , PCO ₂ , and Lactate
Sample Size	95uL
Sample Type	- pH, PO ₂ , and PCO ₂ : Arterial, venous, or capillary whole blood - Lactate: Arterial or venous whole blood
Reportable Range	pH: 6.50-7.80 PO ₂ : 5-700 mmHg PCO ₂ : 5-130 mmHg Lactate: 0.30-20.00 mmol/L
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 PO₂, PCO₂: Traceable to NIST SRMs via commercially available certified specialty medical gas materials Lactate: Certified Standard Reference Material not available at present; traceable to i-STAT manufacturer's working calibrator (MWC) prepared from sodium L-lactate (Sigma-Aldrich Fluka, >99 % purity)
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)

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 CG4+* 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 Lactate 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 CG4+* Instructions for Use.

For *in vitro* diagnostic use only.

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

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i-STAT CG4+ - Product Specifications | APOC-25002511.1 07/25

