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August 2025

URGENT MEDICAL DEVICE CORRECTION
UPDATED PRODUCT CLEARANCE
For United States Customers only

Product Name	List Number
i-STAT CG4+ cartridge (white)	03P85-25

Dear Valued Abbott Customer,

Abbott has received an updated (U.S.) FDA 510(k) clearance for the *i-STAT CG4+* cartridge (white).

This letter contains important information regarding actions you should take if you are using the *i-STAT CG4+* cartridge noted above. If you are using these cartridges, your facility will be impacted by this new clearance, and further review and action is required.

BACKGROUND

The *i-STAT CG4+* cartridge with the *i-STAT 1* System is intended for use in the *in vitro* quantification of pH, partial pressure of oxygen (***P***O_2), partial pressure of carbon dioxide (***P***CO_2) and lactate. In addition, the *i-STAT CG4+* cartridge provides calculated values for TCO_2, HCO_3, base excess (BE) and saturated oxygen (sO_2).

Abbott has received an updated U.S. FDA 510(k) clearance for the *i-STAT CG4+* cartridge for use with arterial and venous whole blood samples for lactate and for arterial, venous, and capillary whole blood samples for pH, ***P***CO_2 and ***P***O_2. This updated 510(k) clearance applies to all *i-STAT CG4+* cartridges (white) that you may already have on hand. Currently, the *i-STAT CG4+* cartridges (03P85-25) are not FDA cleared for the measurement of lactate in capillary whole blood samples. Please note the following modifications contained within the new *i-STAT CG4+* cartridge Instructions for Use as shown in the table below:

Assay/Units	Parameter	Current	Update
pH (pH units)	Reportable range*	6.500 to 8.200	**6.500 to 7.800**
	Sample types	Arterial, venous, and capillary	**No change**
PCO_2 (mmHg)	Reportable range*	5.0 to 130.0	**No change**
	Sample types	Arterial, venous, and capillary	**No change**
PO_2 (mmHg)	Reportable range*	5 to 800	**5 to 700**
	Sample types	Arterial, venous, and capillary	**No change**
Lactate (mmol/L)	Reportable range*	0.30 to 20.00	**No change**
	Sample types	Arterial, venous, and capillary	**Arterial and venous**

*Results outside the updated reportable range have not been validated for accuracy

Abbott has submitted this communication regarding the product updates to the U.S. Food and Drug Administration. Abbott has not received reports of patient harm associated with the use of the *i-STAT CG4+* cartridges.

RISK TO HEALTH

Abbott does not currently have the data necessary to demonstrate performance with capillary whole blood for the lactate test. Due to the risks posed by inaccurate lactate results, capillary whole blood samples are not suitable for testing lactate.

Please report any questions or concerns you have about the performance of the *i-STAT CG4+* cartridge (03P85-25) to Abbott Point of Care Technical Support at 1-844-256-9531, or via email at apoc_productupdates@abbott.com.

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RECOMMENDED ACTIONS

As this update applies to all *i-STAT CG4+* cartridges (03P85-25) that you may already have on hand, please download, review and implement the updated *i-STAT CG4+* cartridge Instructions for Use (IFU), available August 21, 2025 (ART 788332-00 Rev. B), from the Abbott Point of Care website (www.globalpointofcare.abbott).

Discontinue use of the *i-STAT CG4+* cartridges for testing of capillary whole blood samples for lactate. Use venous or arterial whole blood or an alternate method for testing capillary whole blood for lactate.

Update the pH and ***P***O_2 reportable ranges on the *i-STAT 1* analyzers running *i-STAT CG4+* cartridges. This feature is not customizable through the *i-STAT 1* handheld keypad, please see the *i-STAT DE Quick Reference Guide - Customizing Reportable Ranges* (ART 770547-00 Revision A). To use the Custom Reportable Range feature, you must have the *i-STAT 1* handheld and *i-STAT DE* version 2.3 or higher. Changes to the reportable range may require a change to the Laboratory Information System (LIS) interface.

Please confirm receipt and understanding of this communication by responding to the business reply card included with this letter. If you have forwarded any *i-STAT CG4+* cartridges to another facility, we request that you please provide a copy of this letter to them.

ADDITIONAL INFORMATION

If you have any questions regarding this information for the *i-STAT CG4+* cartridge, please contact Abbott Point of Care Technical Support at 1-844-256-9531, or via email at apoc_productupdates@abbott.com or visit www.globalpointofcare.abbott.

Abbott understands the inconvenience this may create for your facility and is committed to supporting you through this transition. We appreciate and thank you for your continued support of Abbott and Abbott products.

Adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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