



April 2020

i-STAT CG4+ (Blue) Cartridge: Now U.S. FDA 510(k) Cleared

Dear Valued Abbott Point of Care Customer,

As a follow up to our January 2020 letter to you, Abbott Point of Care is writing to inform you that the **i-STAT CG4+ (blue) cartridge is now U.S. FDA 510(k) cleared for use with venous and arterial whole blood samples in non-waived settings (i.e., facilities that hold a Certificate of Compliance or Accreditation). This clearance was received on April 9th, 2020.**

Specifically, this clearance applies to all measured assays previously contained on the i-STAT CG4+ (blue) cartridge including pH, **PCO₂**, **PO₂** and lactate. In addition, the i-STAT CG4+ (blue) cartridge continues to offer calculated measurements of TCO₂, HCO₃, base excess (BE) and saturated oxygen (sO₂).

While the physical cartridge has not changed, as previously communicated, capillary whole blood is **no** longer an acceptable sample type with the i-STAT CG4+ (blue) cartridge. Arterial and venous whole blood samples must be collected in syringes with balanced heparin or tubes with lithium heparin anticoagulant.

Abbott Point of Care has updated the i-STAT CG4+ (blue) cartridge product labeling accordingly, and as previously communicated, replaced the individual assay-specific Cartridge and Test Information (CTI) Sheets with one cartridge-based i-STAT CG4+ cartridge "Instructions for Use," which is available on the Abbott Point of Care website (www.pointofcare.abbott). Please note the following modifications contained within the new i-STAT CG4+ (blue) cartridge Instructions for Use:

- You will find that the i-STAT CG4+ (blue) cartridge performance data has been updated.
- Use of a sample collected without an anticoagulant is not supported
- The reportable range for the i-STAT CG4+ pH, **PCO₂**, **PO₂** have been updated. The reference ranges are unchanged.

Assay	Current Reportable range	Updated Reportable range*
pH (pH units)	6.500 to 8.200	7.000 to 7.700
PCO₂ (mmHg)	5.0 to 130.0	15.0 to 130.0
PO₂ (mmHg)	5 to 800	15 to 530
Lactate (mmol/L)	0.30 to 20.00	No change

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

The 510(k) clearance applies to all i-STAT CG4+ (blue) cartridges, including any cartridges that you may already have on hand. You may use these cartridges until expiry with venous and arterial whole blood samples and in alignment with the updated Instructions for Use. At the time of the Fall 2020 software (JAMS/CLEW) update, the i-STAT CG4+ (blue) cartridge list number will be updated from 03P85-50 to 03P85-51. After your facility has completed the Fall 2020 software update, please order i-STAT CG4+ (blue) cartridges using list number 03P85-51.

As previously communicated, during the COVID-19 public health emergency, the U.S. Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS) are allowing the use of the i-STAT G3+ (blue) blood gas cartridge in laboratories and facilities that hold a Certificate of Compliance or Accreditation to run tests of moderate complexity.

NEXT STEPS

Download and review the updated i-STAT CG4+ (blue) cartridge Instructions for Use (IFU), available April 16th, 2020 (ART 767935-00 Rev. A), from the Abbott Point of Care website (www.pointofcare.abbott).

Update the pH, **PCO₂** and **PO₂** reportable ranges on the i-STAT 1 analyzers running i-STAT CG4+ (blue) cartridges. Please see *i-STAT Technical Bulletin - Reportable Range Customization on the i-STAT 1 Handheld* (ART 730009-00C). In order to use the Custom Reportable Range feature, you must have the i-STAT 1 handheld and either the Central Data Station Version 5.x or i-STAT/DE version 2.3 or higher data management applications. This

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feature is not customizable through the i-STAT 1 handheld keypad. Changes to the reportable range may require a change to the Laboratory Information System (LIS) interface.

If you have forwarded any i-STAT CG4+ (blue) cartridges to another facility, we request that you please provide a copy of this letter to them.

If you have any questions regarding this information, please contact your Abbott Point of Care Sales Specialist, Abbott Point of Care Technical Support at 1-844-256-9532 or via email at apoc_productupdates@abbott.com or visit www.pointofcare.abbott

Abbott Point of Care understands the recent i-STAT CG4+ (blue) cartridge field action created challenges for you. We sincerely apologize and are fully committed to partnering with you to achieve our shared mission of improving the quality and efficiency of care for the patients we serve.

A handwritten signature in blue ink, appearing to read 'Katie Mims', is positioned above the printed name.

Katie Mims
General Manager, US