



April 2020

## UPDATE: i-STAT CG4+ (blue) and G3+ (blue) Blood Gas Cartridges May be Used in Moderate Complexity Laboratories During the COVID-19 Public Health Emergency

Product Name	List Number	Assays
i-STAT G3+ (blue) cartridge	03P78-50	pH, PO <sub>2</sub> , PCO <sub>2</sub> , TCO <sub>2</sub> <sup>*</sup> , HCO <sub>3</sub> <sup>*</sup> , BE <sup>*</sup> , sO <sub>2</sub> <sup>*</sup>
i-STAT CG4+(blue) cartridge	03P85-50	pH, PO <sub>2</sub> , PCO <sub>2</sub> , lactate, TCO <sub>2</sub> <sup>*</sup> , HCO <sub>3</sub> <sup>*</sup> , BE <sup>*</sup> , sO <sub>2</sub> <sup>*</sup>

\*calculated

Dear Valued Abbott Point of Care Customer,

We are writing to advise that in light of 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 CG4+(blue) and i-STAT G3+ (blue) blood gas cartridges in laboratories and facilities that hold a Certificate of Compliance or Accreditation to run tests of moderate complexity.

Specifically, during the COVID-19 pandemic Abbott Point of Care may continue to distribute the i-STAT CG4+ (blue) and i-STAT G3+ (blue) cartridges, and facilities that possess a non-waived CLIA certificate (i.e., facilities that hold a Certificate of Compliance or Accreditation) may use them with venous and arterial whole blood samples as tests of moderate complexity. This is a change from the last customer communication Abbott Point of Care provided to customers on January 15<sup>th</sup>, 2020.

This applies to all i-STAT CG4+(blue) and i-STAT G3+ (blue) cartridges, including those that you may already have on hand. Until the end of the COVID-19 public health emergency, please order the i-STAT CG4+ (blue) and i-STAT G3+ (blue) cartridges using the list numbers in the above table. Abbott Point of Care will provide additional information regarding the disposition of these tests at the termination of the COVID-19 pandemic.

### NEXT STEPS

Download and review the i-STAT CG4+ (blue) and i-STAT G3+ (blue) cartridge Instructions for Use (IFU) from the Abbott Point of Care website ([www.pointofcare.abbott](http://www.pointofcare.abbott)).

If you have forwarded any i-STAT CG4+ (blue) and i-STAT G3+ (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](mailto:apoc_productupdates@abbott.com) or visit [www.pointofcare.abbott](http://www.pointofcare.abbott).

CMS will update their publicly posted Frequently Asked Questions (FAQs) in the coming days. If you have any questions regarding the use of the i-STAT CG4+ (blue) and i-STAT G3+ (blue) cartridges with venous and arterial whole blood samples as tests of moderate complexity, please contact your accreditation body.

Abbott Point of Care understands the challenges you are facing during the COVID-19 public health emergency 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.

Katie Mims  
General Manager, US

### APOC2020-001B and APOC2020-002A

i-STAT is a registered trademark of the Abbott Group of Companies in various jurisdictions.