



January 2020

URGENT PRODUCT CORRECTIVE ACTION

For United States Customers only

Product Name	List Number
i-STAT CHEM8+ cartridges (blue)	09P31-25
i-STAT CG4+ cartridges (blue)	03P85-50

Dear Valued Abbott Point of Care Customer,

This letter contains important information regarding the i-STAT® BLUE CHEM8+ and CG4+ cartridges noted above. If you are using these cartridges, your facility is impacted, and further review and action is required.

Abbott Point of Care is communicating this information to all potentially impacted customers in the United States (U.S.).

BACKGROUND

The i-STAT CHEM8+ cartridge contains nine measured assays (sodium, potassium, chloride, blood urea nitrogen (BUN), ionized calcium, TCO₂, glucose, creatinine and hematocrit) and the i-STAT CG4+ cartridge contains four measured assays (pH, pCO₂, pO₂ and lactate). Both of these cartridges have been marketed for use with venous, arterial, and capillary specimens in CLIA non-waived settings and the CHEM8+ has also been marketed for use with venous whole blood specimens in CLIA waived settings.

Since obtaining FDA clearance for the WHITE i-STAT CHEM8+ and CG4+ cartridges and CLIA waived status for the WHITE i-STAT CHEM8+ cartridge, Abbott Point of Care ("Abbott") modified the WHITE CHEM8+ and CG4+ cartridges to introduce a BLUE CHEM8+ and CG4+ cartridge.

After these modifications, changes were observed in the performance of these cartridges. Abbott did not pursue FDA clearance or CLIA waived categorization for the BLUE CHEM8+ and CG4+ cartridges. Currently, the i-STAT BLUE CHEM8+ and CG4+ cartridges are not FDA cleared and do not have CLIA waived status.

Following an evaluation and discussions with FDA, Abbott has filed a 510(k)-notification seeking FDA clearance for the BLUE CHEM8+ cartridges for use with venous and arterial specimens. Abbott also plans to pursue FDA clearance for the BLUE CG4+ cartridges for use with venous and arterial specimens after completing ongoing studies. However, Abbott has decided not to pursue clearance for the BLUE CHEM8+ and CG4+ cartridges for use with capillary blood samples since Abbott does not currently have the data necessary to demonstrate performance with capillary blood. Abbott also does not currently plan to pursue CLIA waived status for the BLUE CHEM8+ cartridges because Abbott currently does not have data demonstrating adequate performance in a CLIA-waived setting.

Abbott is working closely with the U.S. Food and Drug Administration to bring these cartridges into compliance with all regulatory requirements and plans to submit this as a recall.

RECOMMENDED ACTIONS

Facilities using the i-STAT BLUE CHEM8+ cartridges in CLIA waived settings should transition to alternate CLIA waived testing methods or engage a reference laboratory for the tests your facility requires.

Facilities should discontinue use of the i-STAT BLUE CHEM8+ and CG4+ cartridges with capillary samples.

Facilities should use an alternate method, if available, for the tests included in the i-STAT BLUE CHEM8+ and CG4+ cartridges for arterial and venous specimens. If an alternate method is not available, the BLUE CHEM8+ and CG4+ cartridges will still be available while Abbott is working toward FDA clearance for facilities in non-waived settings (i.e., facilities that hold a Certificate of Compliance or Accreditation). Abbott will notify customers if/when the products receive FDA clearance for use with arterial and venous whole blood samples in non-waived settings. However:

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- Facilities that continue to use the BLUE CHEM8+ and CG4+ cartridges for arterial and venous specimens should inform clinicians and laboratory staff that the performance of these cartridges has not yet been fully characterized.
- Clinicians should be advised to consider a patient's signs, symptoms, history, and results of other diagnostic tests when interpreting results from these cartridges. If the results do not match the patient's clinical presentation, the patient sample should be retested using an alternate test method or a reference laboratory.

In order to mitigate risk associated with the performance of these products not yet being fully characterized, Abbott will be actively monitoring the performance of these cartridges. Please report any questions or concerns you have about their performance to Abbott Point of Care Technical Support at 1-800-366-8020 option 1, or via email at techsvc@apoc.abbott.com.

Other actions:

Please confirm receipt and understanding of this communication by responding to the business reply card included with this letter.

If you have forwarded any BLUE i-STAT CHEM8+ or CG4+ cartridges to another facility, we request that you please provide a copy of this letter to them.

ADDITIONAL INFORMATION

As of May 1, 2020, new list numbers, as indicated below, will be required for ordering the i-STAT BLUE CHEM8+ and CG4+ cartridges.

Product Name	Current List Number	New List Number
i-STAT CHEM8+ cartridges	09P31-25	09P31-26
i-STAT CG4+ cartridges	03P85-50	03P85-51

If you have any questions regarding this information or navigating the transition from waived to non-waived testing, capillary to venous/arterial, or to an alternate testing method, please contact 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 sincerely apologizes for any inconvenience this may create for your facility. We appreciate your understanding in this matter and are fully committed to supporting you moving forward.

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