



AMENDED URGENT MEDICAL DEVICE CORRECTION

Product Name	List Number	Product Name	List Number
i-STAT CG8+ cartridges	03P88-25	i-STAT EG7+ cartridges	03P76-25

June 2021

Dear Valued Abbott Point of Care Customer,

As a follow up to our December 2020 communication, Abbott Point of Care is writing to provide an update regarding the progress to restore the two-month room temperature storage for the i-STAT® CG8+ and EG7+ cartridges noted above. Your review of the updated recommended storage and usage conditions below is requested.

As previously communicated, Abbott Point of Care observed, in internal testing after storage of i-STAT CG8+ and EG7+cartridges at 30°C for 14 days, approximately 5.2% of such cartridges reported higher than expected results for ionized calcium. Additionally, Abbott Point of Care observed that ionized calcium on **some** i-STAT CG8+ and EG7+ cartridges, may **exhibit higher than expected reported results** when stored at room temperature (18 to 30°C) for periods of time in excess of:

- 3 days for lot numbers *20100 to *20339 and
- 7 days for lot numbers *20340 and above.

Where * = lot letter A, K, L, M, N, W or Y.

Note: information in this letter is lot number specific.

INVESTIGATION UPDATE

To date, the Abbott Point of Care investigation has identified one lot of a raw material, used in the manufacturing of the i-STAT CG8+ and EG7+ cartridge calibrant packs, as the main contributing factor to the higher than expected results for ionized calcium after storage at 30°C.

Abbott Point of Care has stopped using the identified lot of the raw material and has implemented additional quality control testing for such raw material. Additionally, Abbott Point of Care has increased quality control testing for i-STAT CG8+ and EG7+ cartridges in order to support the room temperature storage recommendations communicated in December 2020.

Abbott Point of Care is providing an updated recommendation, for 4 weeks at room temperature storage, for the specific cartridge lots identified below. Please note, the recommendation communicated in December 2020, of 3 or 7 days, still apply as appropriate for the lots as indicated below. Abbott Point of Care will provide a follow up communication when additional data to support the restoration of the two-month room temperature storage for the i-STAT CG8+ and EG7+ cartridges is available.

Abbott Point of Care has **not** received any reports of patient harm associated with this issue.

RECOMMENDED ACTIONS

While Abbott Point of Care continues to investigate and implement corrective actions regarding this issue, we are providing the following updated recommendation on storage and usage conditions.

If reporting ionized calcium is required with i-STAT CG8+ and EG7+ cartridges, initiate the following actions:

- **for lot numbers *21135 and above, use within 4 weeks of removal from refrigerated storage. Where *= lot letter A, K, L, M, N, W and Y**



As a reminder, the recommendations for the lot numbers listed below remain unchanged;

- for lot numbers *20100 to *20339, use within 3 days of removal from refrigerated storage
- for lot numbers *20340 to *21134, use within 7 days of removal from refrigerated storage

Where *= lot letter A, K, L, M, N, W and Y

Abbott Point of Care has **not** observed higher than expected reported results for the ionized calcium test when i-STAT CG8+ and EG7+ cartridges are removed from refrigerated storage and warmed to room temperature for use within the number of days or weeks indicated above.

As previously communicated, if your facility is unable to manage to the action outlined above, Abbott Point of Care recommends that your facility disable and not report the ionized calcium test on the i-STAT CG8+ and EG7+ cartridges and use an alternate i-STAT cartridge or method for reporting ionized calcium.

If your facility decides to proceed with disabling the ionized calcium test, instructions are available on the Abbott Point of Care website www.pointofcare.abbott. For instructions using i-STAT/DE, see i-STAT/DE Customizing Analyte Enable Options (ART 770545). For instruction using the i-STAT 1 analyzer directly see the i-STAT System Manual Section 2 – i-STAT Analyzer, (ART 714364) subsection Procedures for Customization using the analyzer keypad. If ionized calcium is interfaced through the Laboratory Information System (LIS) interface, disabling the analyte may require a change to the interface. Please contact your interface vendor for support.

If you have forwarded any i-STAT CG8+ or EG7+ cartridges to another facility, we request that you please provide a copy of this letter to them. Please use this communication to update the recommendations provided in December 2020.

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

ADDITIONAL INFORMATION

Over the next 6-8 weeks, Abbott Point of Care plans to transition to shipping cartridge lot numbers that are recommended for use within 4 weeks of removal from refrigerated storage.

Please review this letter with your Accrediting Organization to ensure your facility is compliant with any standards regarding vendor notices or communications.

If you have any questions regarding this information, please contact Abbott Point of Care Technical Support at 1-844-256-9531, or via email at apoc_productinformation@abbott.com or visit the Abbott Point of Care website www.pointofcare.abbott. Additionally, please report any questions or concerns about the performance of the ionized calcium test on the i-STAT CG8+ and EG7+ cartridges to Abbott Point of Care Technical Support at 1-800-366-8020 option 1, or via email at techsvc@apoc.abbott.com.

Abbott Point of Care is fully committed to addressing this situation as a top priority and supporting you throughout this process.