



AMENDED URGENT MEDICAL DEVICE CORRECTION INTERIM COMMUNICATION

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 previous APOC2020-007 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 with the APOC2020-007 letter.

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 previously communicated, 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.

Please see additional information below on how to disable the ionized calcium test for these cartridges. If your facility decides to proceed with disabling the ionized calcium test, resources are included at the end of this communication. 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.

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 the previous APOC2020-007 communication.

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.

If you have any questions regarding this information, please contact your local Abbott Point of Care Support services representative. Additionally, please report any questions or concerns about the performance of the ionized calcium test on the i-STAT CG8+ and EG7+ cartridges to your local Abbott Point of Care Technical Support or via oustechsvc@apoc.abbott.com.

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



Resources for customization for the i-STAT Alinity instrument:

- Go to <https://www.pointofcare.abbott/int/en/home> and navigate to Support > i-STAT Alinity Resources Login > Operator Documentation > i-STAT Alinity System Operations Manual (Language: English) :
 - **Customers using AlinIQ CWi**, refer to i-STAT Alinity System Operations Manual, Section 3.1 - AlinIQ CWi - Customization Workspace for i-STAT, *Analyte Settings Category, Enable/Disable Analyte* for information on customizing this option.
NOTE: To customize this feature AlinIQ Cwi is required.

Resources for customization for the i-STAT 1 Analyzer:

- Go to <https://www.pointofcare.abbott/int/en/home> and navigate to Support > i-STAT 1 Resources Login > Administrator Documentation > Technical Bulletins (Language: English United Kingdom) > Data Management User Documentation and select i-STAT DE Documentation:
 - Refer to the i-STAT DE User Guide v2.10 Art:754472, Section 3.15 Customizing Analyte Enable Options
- Go to <https://www.pointofcare.abbott/int/en/home> and navigate to Support > i-STAT 1 Resources Login > Operator Documentation > i-STAT 1 System Manuals
 - i-STAT **Customers without i-STAT/DE**, refer to the i-STAT System Manual, i-STAT 1 Analyzer Art:714364, *Changing the Profile* for guidance on navigating to the Results menu, then the Units and Ranges menu to change the setting.