



AMENDED URGENT MEDICAL DEVICE CORRECTION FINAL COMMUNICATION

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

December 2021

Dear Valued Abbott Point of Care Customer,

Abbott Point of Care is pleased to provide this notification as follow up to our previous APOC2020-007 and APOC2020-007A communications to inform you of the restoration of the two-month room temperature storage for the specific cartridge lots of i-STAT® CG8+ and EG7+ cartridges identified below. Your review of the updated recommended storage and usage conditions outlined below is requested. **Note: information in this letter and recommended actions are lot number specific.**

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. The Abbott Point of Care investigation identified a raw material, used in the manufacturing of the i-STAT CG8+ and EG7+ cartridge calibrant packs, as the factor contributing to the higher-than-expected results for ionized calcium after storage at 30°C. Abbott Point of Care has implemented additional quality control testing for this material.

NEW INFORMATION IN THIS COMMUNICATION

Cartridge lot numbers W21195A, N21197, W21198 and W21198A should not be used for reporting ionized calcium. These four lots were identified as having potentially 1.0% of cartridges reporting higher-than-expected results for ionized calcium when stored at room temperature for 4 weeks at 30°C, due to the specific calibrant packs used to manufacture only these four CG8+ and EG7+ cartridge lots.

At this time, Abbott Point of Care is recommending a return to two months room temperature storage for the specific cartridge lots identified in the Recommended Actions below.

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

RECOMMENDED ACTIONS

Abbott Point of Care is providing the following updated recommendation on storage and usage conditions for the i-STAT CG8+ and EG7+ cartridges.

As previously communicated:

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

For lot numbers *21135 and higher, use within 2 months of removal from refrigerated storage:

- **provided, however, for lot numbers W21195A, N21197, W21198 and W21198A, are not used for reporting ionized calcium. There is no impact to the other assays included in these cartridge lots.**

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 for lots *20100 to *21134 and W21195A, N21197, W21198 and W21198A, Abbott Point of Care recommends that your facility disable and not report the ionized calcium test on such i-STAT CG8+ and EG7+ cartridges and use an alternate i-STAT cartridge or method for reporting ionized calcium. There is no impact to the other assays included in these cartridge lots.**

If your facility decides to proceed with disabling the ionized calcium test, instructions are available on the Abbott Point of Care website www.globalpointofcare.abbott. For the i-STAT 1, 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 9 – Customization, (ART 714371) subsection Procedures for Customization using the analyzer keypad. For i-STAT Alinity, AlinIQ CWi is required to customize this feature. 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. 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 the previous APOC2020-007 and APOC2020-007A communications.

ADDITIONAL INFORMATION

The update to 2-month room temperature storage applies to any cartridge in your inventory **for lot numbers *21135 and above, provided however, that cartridge lot numbers W21195A, N21197, W21198 and W21198A are not used to report ionized calcium.** Current lots being distributed are above lot number *21250, and therefore lot numbers W21195A, N21197, W21198 and W21198A are no longer being shipped. All cartridge lots between *20100 to *21105 are currently expired.

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.

We thank you for your continued support of Abbott and Abbott products.