December 2020



Urgent Field Safety Notice

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

Dear Valued Abbott Point of Care Customer,

This letter contains important information regarding the i-STAT[®] CG8+ and EG7+ cartridges noted above. If you are using these cartridges, your facility may be impacted, and further review and action may be required.

Note: information in this letter is lot number specific.

PRODUCT DESCRIPTION

The i-STAT CG8+ cartridge contains eight measured tests (sodium, potassium, ionized calcium, pH, pC02, pO2, glucose and hematocrit) and the i-STAT EG7+ cartridge contains seven measured tests (sodium, potassium, ionized calcium, pH, pC02, pO2, and hematocrit).

The test for ionized calcium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of ionized calcium in arterial, venous, or capillary whole blood.

DESCRIPTION OF THE ISSUE

The i-STAT CG8+ and EG7+ cartridge Instructions for Use (IFU) indicate that these cartridges can be stored for 2 months at room temperature (18 to 30°C). Abbott routinely tests the performance of i-STAT cartridges, including stability testing of the i-STAT CG8+ and EG7+ cartridges at various time intervals after storage in the refrigerator and at 30°C.

Through this internal testing process after storage at 30°C for 14 days, Abbott Point of Care observed approximately 5.2% of cartridges reporting higher than expected results for ionized calcium. Abbott Point of Care observed 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
- 7 days for lot numbers *20340 and above
- Where * = lot letter A, K, L, M, N, W or Y.

Abbott Point of Care has <u>not</u> 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 indicated above.

Abbott Point of Care has <u>not</u> observed this issue for any tests on the i-STAT CG8+ or EG7+ other than the ionized calcium test.

Abbott Point of Care is communicating this information to potentially impacted customers. Clinicians should be advised to consider a patient's signs, symptoms, history, and results of other diagnostic tests when interpreting the ionized calcium results from these cartridges. If the results do not match the patient's clinical presentation, the patient sample should be retested using an alternate i-STAT cartridge or method. Treatment of falsely high ionized calcium may result in harm, by precipitating hypocalcemia. Abbott Point of Care has determined that the overall likelihood of harm associated with this issue is rare. The most common symptoms of hypocalcemia include paresthesia, muscle spasms, cramps, tetany, circumoral numbness, and seizures. Although improbable, in the most extreme cases, hypocalcemia could potentially result in sudden cardiac death. Abbott Point of Care has **not** received any reports of patient harm associated with this issue.

RECOMMENDED ACTIONS

Our records show that your facility is an i-STAT CG8+ or EG7+ cartridge user. While Abbott Point of Care continues to investigate this issue, if reporting ionized calcium is required, **it is recommended that the i-STAT CG8+ and EG7+ cartridges be used only:**

 within 3 days of removal from refrigerated storage for lot numbers between *20100 and *20339

• within 7 days of removal from refrigerated storage for lot numbers *20340 and above Where *= lot letter A, K, L, M, N, W and Y

If your facility is unable to manage to the recommended 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.

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

APOC2020-007

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



If you have forwarded any i-STAT CG8+ and EG7+ cartridges to another facility, we request that you please provide a copy of this letter to them.

We are providing, as an attachment, a list of the potentially impacted i-STAT CG8+ and EG7+ cartridge lots that have been distributed as of the date of this letter. Please continue to follow the recommended actions in this communication for all newly received i-STAT CG8+ and EG7+ lots until your facility receives an updated communication from Abbott Point of Care.

ADDITIONAL INFORMATION

Your Abbott Point of Care sales and support team are available to review interim solutions for the challenges this communication may bring. 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 <u>oustechsvc@apoc.abbott.com</u>.

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.

Abbott Point of Care is fully committed to addressing this situation as a top priority and supporting you throughout this process. Abbott Point of Care will provide timely follow up communications when there is data to support longer storage at room temperature and after completion of the investigation.

The appropriate Competent Authorities have been made aware of this action.



Resources for customization for the i-STAT Alinity instrument:

- Go to <u>https://www.pointofcare.abbott/int/en/home</u> 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 <u>https://www.pointofcare.abbott/int/en/home</u> 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 <u>https://www.pointofcare.abbott/int/en/home</u> and navigate to Support >
 - i-STAT 1 Resources Login > User Documentation > i-STAT 1 System Manuals
 - i-STAT Customers <u>without</u> i-STAT/DE or CDS, refer to the i-STAT System Manual, i-STAT 1 Analyzer 2 Art:714364, *Changing the Profile* for guidance on navigating to the Results menu, then the Units and Ranges menu to change the setting.



Customizing Analyte Enable Options using the i-STAT 1 Analyzer Keypad

New analyzers or replacement analyzers will have standard unit sets installed and all analytes enabled. To disable or set a different unit of measurement for a particular analyte globally, access *Change Customization > Units and Ranges*. Perform the following steps:

NOTE: This setting will apply globally to all cartridge types used. To disable analytes by i-STAT Cartridge panel, users must use i-STAT/DE or CDS.

