



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.



Abbott

i-STAT CG8+ and EG7+ cartridge lots

List of the potentially impacted i-STAT CG8+ and EG7+ cartridge lots that have been distributed as of 02 June 2021. 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.

Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number
EG7+	L20106A	EG7+	N20188	CG8+	W20259	EG7+	N20334	EG7+	N21055
CG8+	W20106	CG8+	W20188	CG8+	W20260	EG7+	N20335	EG7+	N21055A
CG8+	W20108	CG8+	W20188A	CG8+	W20261	EG7+	N20226	CG8+	W21055
EG7+	L20107	EG7+	L20189	EG7+	N20262	CG8+	W20336	CG8+	W21055A
EG7+	L20108A	CG8+	W20191	CG8+	W20262	CG8+	W20337	CG8+	W21056
CG8+	W20110	CG8+	W20191A	EG7+	N20263	EG7+	N20338	EG7+	N21057
EG7+	L20110A	CG8+	W20191B	CG8+	W20263	CG8+	L20339	CG8+	W21057
CG8+	W20111	CG8+	W20191C	CG8+	W20263A	EG7+	N20339	EG7+	N21058
CG8+	W20112A	CG8+	W20192	EG7+	N20264	CG8+	W20339	EG7+	W21058
CG8+	W20113	CG8+	W20192A	CG8+	W20265	CG8+	W20339A	EG7+	N21059
EG7+	N20113	EG7+	N20193	CG8+	W20266	EG7+	N20341	CG8+	W21059
EG7+	N20114	CG8+	W20193	CG8+	W20268	CG8+	L20341A	CG8+	W21060
CG8+	W20113A	CG8+	W20194	EG7+	N20269	CG8+	W20341	CG8+	W21060A
CG8+	W20114	CG8+	W20194A	CG8+	L20270	EG7+	N20342	EG7+	N21061
EG7+	N20115	EG7+	W20194B	CG8+	L20270A	EG7+	N20342A	CG8+	W21062
CG8+	W20116	EG7+	N20195	CG8+	W20270	CG8+	W20342	CG8+	W21063
EG7+	N20117	EG7+	N20196	CG8+	W20271	EG7+	N20343	CG8+	W21064
CG8+	W20117	EG7+	N20196A	CG8+	W20272	CG8+	W20343	EG7+	N21065
CG8+	W20117A	EG7+	N20197	CG8+	W20272A	EG7+	N20344	EG7+	N21065A
CG8+	W20118	CG8+	W20197	EG7+	N20273	CG8+	W20345	CG8+	W21065
EG7+	N20119	EG7+	N20198	CG8+	W20273	CG8+	W20346	CG8+	W21065A
CG8+	W20119	EG7+	N20198A	EG7+	N20274	EG7+	N20348A	EG7+	N21066
EG7+	N20120	CG8+	W20198	CG8+	W20275	CG8+	W20348	CG8+	W21066
CG8+	W20120	CG8+	W20198A	EG7+	N20276	CG8+	W20348A	EG7+	N21067
EG7+	N20121	EG7+	N20199	CG8+	W20276	EG7+	N20349	EG7+	N21067A
EG7+	N20121A	CG8+	W20199	EG7+	N20277	EG7+	N20350	CG8+	W21067
CG8+	W20122	EG7+	N20200	CG8+	W20277	CG8+	W20350	CG8+	W21068
EG7+	N20124	EG7+	N20200A	CG8+	W20279	EG7+	N20351	EG7+	N21069
CG8+	W20124	CG8+	W20200	CG8+	W20279A	CG8+	W20351A	EG7+	N21069A
CG8+	W20126	EG7+	N20201	CG8+	W20280	CG8+	W20352	CG8+	W21069
CG8+	W20126A	EG7+	N20201A	CG8+	W20280A	EG7+	N20353	CG8+	W21070
EG7+	N20127	EG7+	N20202	EG7+	N20281A	EG7+	N20354	CG8+	W21070A
CG8+	W20127	EG7+	N20203	EG7+	N20282	CG8+	W20357	CG8+	W21071
EG7+	N20128	EG7+	N20204	CG8+	W20282	CG8+	W20358	EG7+	N21072
EG7+	L20129	EG7+	N20204A	EG7+	N20283	CG8+	L20359	CG8+	W21072
CG8+	W20129	CG8+	W20204	CG8+	W20284	EG7+	N20363	CG8+	W21073
EG7+	N20130	CG8+	W20205	CG8+	W20285	EG7+	N20363A	EG7+	N21074
CG8+	W20131	CG8+	W20205A	EG7+	N20286	CG8+	L20363	EG7+	N21076

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Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number
EG7+	N20132	EG7+	N20206A	CG8+	W20287	CG8+	W20363	CG8+	W21076
CG8+	W20132	EG7+	N20206B	EG7+	N20288	CG8+	L20364	EG7+	N21077
EG7+	N20133	EG7+	N20207	EG7+	N20288A	CG8+	W20364	CG8+	W21077
CG8+	W20133	EG7+	N20207A	EG7+	N20289	EG7+	N20365	EG7+	N21078
CG8+	W20134	EG7+	N20208	EG7+	N20290	EG7+	N20365A	CG8+	W21078
CG8+	W20135	EG7+	N20208A	CG8+	W20290	CG8+	L20365	EG7+	N21079
EG7+	N20136	EG7+	N20209	EG7+	N20291	CG8+	W20365	CG8+	W21079
CG8+	W20136	EG7+	N20209A	EG7+	N20291A	CG8+	W20366	EG7+	N21080A
EG7+	N20137	CG8+	W20209	CG8+	W20291	EG7+	N21002	CG8+	W21080
CG8+	W20137	CG8+	W20209A	CG8+	W20292	CG8+	W21002	CG8+	W21080A
CG8+	W20137A	EG7+	N20210	CG8+	W20293	CG8+	W21002A	EG7+	N21081
CG8+	W20138	CG8+	W20210	EG7+	N20294	EG7+	N21003	CG8+	W21081
EG7+	N20139	CG8+	W20211	EG7+	N20294A	EG7+	N21003A	EG7+	N21082
CG8+	W20139	EG7+	N20212	CG8+	W20294	CG8+	W21004	EG7+	N21083
EG7+	N20140	CG8+	W20212	CG8+	W20294A	EG7+	N21005	EG7+	N21083
CG8+	W20140	EG7+	N20213	CG8+	W20294B	CG8+	W21005	EG7+	N21084
CG8+	W20140A	EG7+	N20214	EG7+	N20295	CG8+	W21006	CG8+	W21084
CG8+	W20141	EG7+	N20214A	EG7+	N20295A	EG7+	N21007	EG7+	N21085
CG8+	W20142A	CG8+	W20214	EG7+	N20295B	EG7+	N21007A	CG8+	W21085A
EG7+	N20143A	CG8+	W20215	CG8+	W20295	CG8+	W21007	EG7+	N21087
CG8+	W20143	CG8+	W20216	CG8+	W20295A	CG8+	W21007A	EG7+	N21091
CG8+	W20143A	EG7+	N20220	EG7+	N20296	EG7+	N21008	CG8+	W21091
CG8+	W20144	EG7+	N20220A	EG7+	N20296A	CG8+	W21008	CG8+	W21092
EG7+	N20145B	EG7+	N20222	EG7+	N20297	EG7+	N21009	EG7+	N21093
CG8+	W20145	EG7+	N20223	EG7+	N20297A	EG7+	N21010	CG8+	W21093
CG8+	W20145A	CG8+	W20223	EG7+	N20298	CG8+	W21010	EG7+	N21094
EG7+	L20146	CG8+	W20223A	EG7+	N20298A	EG7+	N21011	CG8+	W21094
EG7+	N20146	EG7+	N20224	EG7+	N20300	CG8+	W21011	CG8+	W21095
CG8+	W20146	EG7+	N20224A	CG8+	W20300	EG7+	N21012	EG7+	N21096
EG7+	N20147	CG8+	W20224	EG7+	N20301	CG8+	W21012	CG8+	W21096
CG8+	W20147	EG7+	N20225	CG8+	W20301	EG7+	N21013	EG7+	N21098
EG7+	N20148	CG8+	W20226	EG7+	N20302	CG8+	W21013	CG8+	W21098
CG8+	W20148	EG7+	N20227	EG7+	N20302A	EG7+	N21014	EG7+	N21099
EG7+	N20149	CG8+	W20227	EG7+	N20303	CG8+	W21014	EG7+	W21099
EG7+	N20149A	EG7+	N20228	CG8+	W20303	EG7+	N21015	EG7+	N21100
EG7+	W20149	EG7+	N20228A	EG7+	N20304	CG8+	W21015	EG7+	W21101
EG7+	N20150	EG7+	N20229	CG8+	W20304	EG7+	N21016	EG7+	N21102
EG7+	N20150A	CG8+	W20229	EG7+	N20305	EG7+	N21016A	CG8+	W21102
EG7+	W20152	CG8+	W20229A	EG7+	N20305A	CG8+	W21016	EG7+	N21103
CG8+	W20152A	EG7+	N20230	CG8+	W20305	CG8+	W21016A	CG8+	W21104
CG8+	W20153	EG7+	N20230A	CG8+	W20305A	EG7+	N21017	EG7+	N21105
CG8+	W20154	CG8+	W20230	CG8+	W20306	EG7+	N21018A	CG8+	W21105

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Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number	Cartridge	Lot Number
EG7+	N20155	CG8+	W20231	EG7+	N20307	EG7+	N21020	EG7+	N21106
CG8+	W20155	CG8+	W20231A	EG7+	N20308	CG8+	W21020	CG8+	W21106A
CG8+	W20156	CG8+	W20231B	EG7+	W20308	EG7+	N21021	EG7+	N21107
EG7+	N20158	EG7+	N20233	EG7+	N20309	CG8+	W21021	CG8+	W21107
EG7+	N20159	CG8+	W20233	EG7+	W20309	CG8+	W21021A	CG8+	W21107A
CG8+	W20159	CG8+	W20233A	EG7+	W20309A	EG7+	N21022	CG8+	W21109
EG7+	N20160	CG8+	W20234	EG7+	N20310	EG7+	N21023	EG7+	N21111
CG8+	W20160	EG7+	N20236	CG8+	W20310A	CG8+	W21023	CG8+	W21111
CG8+	W20161	CG8+	W20236	EG7+	N20311	CG8+	W21023A	CG8+	W21112
EG7+	W20161A	EG7+	N20237	CG8+	W20311	CG8+	W21028	EG7+	N21113
EG7+	N20162	CG8+	W20237	EG7+	N20312	CG8+	W21030	CG8+	W21114
CG8+	W20162	EG7+	N20238	CG8+	W20312A	EG7+	N21035	EG7+	N21116
EG7+	N20163	CG8+	W20238	CG8+	W20312	CG8+	W21035	EG7+	N21118
CG8+	W20163	CG8+	W20240	EG7+	N20313	EG7+	N21036	EG7+	N21120
EG7+	N20164	CG8+	W20240A	EG7+	N20314	EG7+	N21037B	CG8+	W21120
EG7+	N20166A	EG7+	N20241	EG7+	N20315	EG7+	N21037C	CG8+	W21120A
CG8+	W20167	EG7+	N20241A	CG8+	W20316	EG7+	N21038	CG8+	W21120
CG8+	W20167A	CG8+	W20242	EG7+	N20317	CG8+	W21038	EG7+	N21121
EG7+	W20168	EG7+	N20243	CG8+	W20317	EG7+	N21039	EG7+	N21121A
EG7+	N20170	EG7+	N20244	EG7+	N20318	EG7+	N21040	CG8+	W21121
EG7+	L20175	CG8+	W20244	CG8+	W20318	CG8+	W21041	EG7+	N21122
EG7+	N20175	EG7+	N20245	CG8+	W20319	EG7+	N21042A	CG8+	W21122
CG8+	W20176	CG8+	W20245	CG8+	W20319A	CG8+	W21043	EG7+	N21123
CG8+	W20176A	EG7+	N20246	EG7+	N20320	CG8+	W21043A	EG7+	N21124
CG8+	W20178	CG8+	W20246	CG8+	W20321	EG7+	N21044	CG8+	W21124
EG7+	L20179	EG7+	N20247A	EG7+	N20323	CG8+	W21044	CG8+	W21126A
CG8+	W20179	EG7+	N20251A	CG8+	W20323	EG7+	N21045	EG7+	N21127
EG7+	W20179A	EG7+	N20252	EG7+	N20324	EG7+	N21046	CG8+	W21127
EG7+	W20179B	CG8+	W20253	CG8+	W20324	CG8+	W21046	CG8+	W21127A
EG7+	W20180	EG7+	N20254	EG7+	N20325	CG8+	W21046A	EG7+	N21128
CG8+	W20181	EG7+	N20255	CG8+	W20325	EG7+	L21047	CG8+	W21128
CG8+	W20181A	CG8+	W20255	CG8+	W20325A	CG8+	W21047	CG8+	W21129
CG8+	W20182	EG7+	N20256	EG7+	N20327	EG7+	N21050	CG8+	W21131
CG8+	W20182A	CG8+	W20256	CG8+	W20327	CG8+	W21050	EG7+	N21132
EG7+	L20183	CG8+	L20257	EG7+	N20329	EG7+	L21051A	CG8+	W21132
CG8+	L20183A	EG7+	N20257	EG7+	N20330	EG7+	N21051	CG8+	W21133
CG8+	W20183	CG8+	W20257	EG7+	N20331	CG8+	W21051	EG7+	N21134
CG8+	W20184	EG7+	N20258	CG8+	W20331	CG8+	W21052	CG8+	W21134
CG8+	W20184A	CG8+	W20258	CG8+	W20332	EG7+	W21053	CG8+	W21134A
CG8+	W20187	CG8+	L20259	EG7+	N20333	EG7+	W21054		

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BUSINESS REPLY FORM

**Abbott Point of Care
Product Action Program**

APOC2020-007A

Please complete this form and return to Inmar within **ten (10)** business days by fax (**xxxxxx**) or e-mail (**xxxxx**).

Return of this form acknowledges that you have read and understood the updated recommendations and have taken the appropriate action. Refer to letter included for additional information. Your timely response to this notification is requested.

Customer Name _____

Address _____

City _____ State _____ Zip _____

Contact Name (please print) _____ Telephone # _____

Contact Signature _____ Date _____

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

If you have any questions regarding this form please contact xxx at xxx.

Please fax this form to: xxxx or xxxx