CORE DIAGNOSTICS
Abbott Laboratories
1915 Hurd Drive
Irving TX, 75039 USA

Single Registration Number (SRN):
US-MF-000017777

Urgent Product Correction

Immediate Action Required

Date Issued

May 30, 2023

Product

Product Description	List Number	Serial Number	UDI
Alinity ci-series System Control Module (SCM)	03R70-01	See Attachment A	

Explanation

Abbott has identified potential performance issues found in the Alinity ci‑series System software versions 3.4.0 and lower. Abbott is releasing Alinity ci‑series System software version 3.5.0 to correct these potential issues. (See details in **Appendix A).**

Impact on Donor/Patient Results/ Operator Safety

Refer to **Appendix A** for details concerning any patient results impacted due to the potential issues identified in Alinity ci-series System software version 3.4.0 and lower.

Necessary Actions to be Taken by Customer

Please follow the Necessary Actions required in **Appendix A** until software version 3.5.0 is installed.

Your Abbott representative will schedule a mandatory upgrade of the Alinity ci-series to software version 3.5.0.

Complete and return the Customer Reply Form.

If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.

Please retain this letter for your laboratory records.

Contact Information

If you or any of the health care providers you serve have questions regarding this information, U.S. Customers please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online (http://www.fda.gov/MedWatch/report.htm), by mail (http://www.fda.gov/MedWatch/getforms.htm), by phone (1-800-332-1088), or by fax (1-800-FDA-0178).

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.

Appendix A – Alinity ci-series software potential issues resolved in version 3.5.0

These potential issues impact both the Alinity i Processing Module and the Alinity c Processing Module.			
#	**Issue Description**	**Impact to Donor/Patient Results or Operator Safety**	**Necessary Actions required until software version 3.5.0 is installed**
1	Due to an intermittent software error, a cartridge or onboard vial rack could be loaded onto a reagent carousel position that is already occupied with another cartridge or onboard vial rack.	There is the potential for incorrect results, chemical and biohazard exposure from spillage. As of issuance of this letter, there have been no adverse events related to this issue.	If message code 5819 occurs due to this issue, remove the cartridges and onboard vial rack. Discard all cartridges and all samples in the onboard vial racks impacted by this issue per your laboratory procedure. If a cartridge or onboard vial rack has fallen over inside the reagent carousel, contact Customer Service to clean any potential spill.
2	When a printed report is requested from the Sample Status Screen, an incorrect Sample ID (SID) is printed on the second page and any subsequent pages of a Sample Laboratory Report if all the results for the SID do not fit on one page.	There is the potential to report incorrect results when the wrong SID is printed on the Sample Laboratory report. As of issuance of this letter, there have been no adverse events related to this issue.	Avoid printing the Sample Laboratory report from the Sample Status Screen. If the Sample Laboratory report is printed verify the correct SID is printed in the header of pages following the printing of the first page.

Appendix A continued

These potential issues impact the Alinity c Processing Module only			
#	**Issue Description**	**Impact to Donor/Patient Results or Operator Safety**	**Necessary Actions required until software version 3.5.0 is installed**
3	When the barcode of the calibrator carton is scanned for the Alinity c-series, calibrator values are not updated from the default lot for calibrators with values that change from lot to lot.	There is a potential for incorrect results from incorrect calibrator values. As of issuance of this letter, there have been no adverse events related to this issue.	For lot-to-lot value assigned calibrators, the barcode of the calibrator carton should not be scanned to update calibrator values for new lots. Refer to the following note under the procedure "*Create a new calibrator master lot*" found in Section 2 of the Alinity ci-series Operations Manual: **IMPORTANT:** When the barcode on the calibrator carton is scanned, only the master lot number and the expiration date are updated. The calibrator values remain from the previously configured master lot. To configure a new master lot for calibrators that have lot-specific calibrator values, the supervisor must verify that the correct values are entered and must edit them if necessary, or the supervisor must configure the master lot by importing the calibrator.

Appendix A continued

These potential issues impact the Alinity c Processing Module only			
#	**Issue Description**	**Impact to Donor/Patient Results or Operator Safety**	**Necessary Actions required until software version 3.5.0 is installed**
4	When a user-defined assay is incorrectly configured with more than 40 cuvette SmartWashes or 40 total reagent probe R1 and reagent probe R2 SmartWashes, it will cause other tests to remain in a scheduled status.	There is potential for delay of results when the orders remain in a scheduled state for an extended time and are not processed after they are created. As of issuance of this letter, there have been no adverse events related to this issue.	Do not create a user defined assay with more than 40 Cuvette SmartWashes or 40 total reagent probe R1 and R2 SmartWashes. Refer to *Edit SmartWash settings (c-series)* found in Appendix C of the Alinity ci-series Operations Manual to delete SmartWashes. Ensure that no more than 40 cuvette SmartWashes or no more than 40 total reagent probe R1 and reagent probe R2 SmartWashes are configured. **NOTE:** The **All** setting can be used to replace individual reagent probe R1 or reagent probe R2 SmartWashes. Reagent probe settings that use the **All** setting need to be configured last.
5	When a user-defined photometric assay is created and no water volume is entered for the sample dilution, the software does not evaluate the total sample volume limits. In this case the total sample volume may be below or above the defined sample volume limits.	There is a potential for incorrect results for the user-defined orders configured with inaccurate dilution volumes. As of issuance of this letter, there have been no adverse events related to this issue.	If there is no water volume to be added in a user defined assay, enter zero in the water volume field. This will result in evaluation of the correct sample volume. For additional information, refer to the procedure, *Create a user-defined assay (c-series photometric),* found in Appendix C of the Alinity ci-series Operations Manual.

Appendix A continued

These potential issues impact the Alinity c Processing Module only			
#	**Issue Description**	**Impact to Donor/Patient Results or Operator Safety**	**Necessary Actions required until software version 3.5.0 is installed**
6	When the Avery labels specified in the Alinity ci-series Operations Manual for user-defined 1D reagent barcode labels are not used, there is a potential for the labels to not adhere to the Alinity c R1 reagent bottle. If the 1D reagent barcode label does not adhere to the reagent cartridge it may cause damage to the system and lead to one or more of the following: Message code: 5022 (0) controller failed. 0 = Motor Message code: 5115 (0) pick sensor failed. 0 = Sensor Message code: 5672 Reagent supply center load error at processing module. Message code: 5723 Reagent cartridge or rack at reagent carousel position (1) no longer detected by reagent transport. 1 = Position	This event represents a potential for a biohazard, chemical exposure, and incorrect results. As of issuance of this letter, there have been no adverse events related to this issue.	The label stock must meet the guidelines in 1D reagent barcode label requirements (c-series) in Section 4 of the Alinity ci-series Operations Manual and be compatible with Avery label templates 5520, L4773, or L7060. Do not use paper and tape as a substitute to label stock. Refer to the corrective actions for the message codes that are generated for this scenario.
7	The Supplies screen will not display an Expired status for the ICT module when the warranty period of 20,000 samples is exceeded prior to reaching the ICT Module expiration date.	There is a potential for incorrect results when the patient tests executed beyond the expiration date are not labelled with an EXP flag. As of issuance of this letter, there have been no adverse events related to this issue.	On the Home screen under the information area, if the processing module supply status button is displayed in yellow, review the ICT module status in the Supplies screen. If the ICT module status is exceeded with more than 20,000 samples processed, then confirm the expiration date of the ICT module before performing ICT assay testing.