Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden, Germany

Product Correction

Urgent - Immediate Action Required

Cc **Chairman Medical Board and relevant Head-of-Department**

Date Issued March 8, 2019

Product

Product Name	List Number	Serial Number	UDI
Alinity ci-series System Control Module (SCM)	03R70-01	All	N/A

Explanation

Alinity ci-series issues resolved in software version 2.6.0

Abbott has identified the following issues with the Alinity ci-series which may present potential performance issues in Alinity ci-series Software version 2.5.1. Abbott is releasing Alinity ci-series Software version 2.6.0 to correct these issues (see details in **Appendix A**).

1. On Alinity i, an incomplete Trigger Solution or Pre-Trigger Solution dispense may lead to incorrect results.
2. Pre-Trigger Solution stored on-board the Alinity i longer than 16 days may produce elevated RLU readings, potentially impacting results.
3. Critical messages, which are missing meaningful information, have been updated.
4. Under certain conditions, the Alinity c can transition to Running with the procedure key in the On setting and with the front processing cover open.
5. If the "Disable Reagent on Control Failure" is configured to ON, patient results are not properly flagged with CNTL.

Patient Impact

These issues may result in incorrect patient results or impact to operator safety.

Refer to **Appendix A** for details concerning any patient results or operator safety impact related to the issues identified in Alinity ci-series System Software version 2.5.0.

Necessary Actions

1. Your Abbott representative will schedule a mandatory upgrade of your Alinity ci-series to software version 2.6.0 to resolve each of these issues. Refer to **Appendix A** for necessary actions required until software version 2.6.0 can be installed.

   Software version 2.6.0 also provides enhancements and additional changes to increase the usability of your system. If you require additional information, please contact Abbott Customer Service.

Necessary Actions continued

2. The Alinity ci-series Operations Manual distributed with software version 2.6.0 requires supplemental instructions for the following message:
    - Message code 3696 - The sample probe is not washed after aspirating a whole blood or red blood cell sample.

    If message code 3696 occurs, perform the following:

    a. Perform As-needed Maintenance procedure *5906 Clean Sample and Reagent Probes (c-series)* to clean the sample probe unless one of the following actions occurred before the initiation of assay processing:
        - The sample probe was replaced.
        - Daily maintenance procedure 5501 Daily Maintenance (c-series) was performed.

    b. Additional messages that are associated with this message can be used to determine the appropriate corrective action. Perform View additional messages that are associated with a message in the Alinity ci-series Operations Manual.

For the incomplete Trigger Solution or Pre-Trigger Solution dispense issue, we have reviewed all available instrument data provided via AbbottLink from March 1, 2018 through February 28, 2019. If any potentially incorrect results with an RLU value of less than 16 that were generated without an exception were identified, Abbott will provide an additional letter with that information. If you have immediate questions, please contact your local area Customer service.

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

We sincerely regret any inconvenience this may have caused your laboratory.

If you or any of the health care providers you serve have any 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 issues resolved in version 2.6.0

	Issue	System/Assay Impacted	Patient Results or Operator Safety Impact	Necessary Actions until mandatory upgrade is completed
1.	On Alinity i, an incomplete Trigger or Pre-Trigger bulk solution dispense may lead to incorrect results. Insufficient Trigger or Pre-Trigger will cause an unexpectedly low RLU (relative light unit) reading, resulting in lower than expected values for direct assays (upward slope calibration curves), or higher than expected values in indirect assays (downward slope calibration curves). These events may be accompanied by message codes 1043, 1044, 1072, 2101, 1401, and 1402. To improve the detection of these events, software 2.6.0 contains a change to exception code 1403 Unable to process test. Final read failure. All tests with an RLU value of less than 16 generate the exception and no results are produced.	Alinity i-series	There is the potential for incorrect patient results due to this issue for any assay run on the system. The incorrect results could be falsely low or high depending on the assay methodology (direct or indirect).	Do not use or report any Quality Control, Calibration, or specimen test results with an RLU value of less than 16. Use one of the following two methods to view RLU values for previous or future results: 1. Review the results individually from the Result Details screen. 2. Perform the *Archive the results* procedure in the Alinity ci-series Operations Manual. After archiving, review the results using software to view the Excel file format. It is recommended to sort the results by the RLU column to view results less than 16.
2.	Pre-Trigger Solution stored on-board the Alinity i longer than 16 days may produce elevated RLU readings. Depending on the calibration date for a specific assay, this may impact the results. Therefore, the on-board stability limit for Pre-Trigger Solution is being reduced from 28 days to 16 days. After installation of V2.6.0 software if the Pre-Trigger Solution onboard stability is less than 24 hours and the volume remaining in the reservoir is less than 350 mL, *2500 Daily Maintenance* procedure will flush the Pre-Trigger reservoir until the level sensor indicates that the reservoir is empty. If the volume remaining in the reservoir is greater than 350 mL, the reservoir must be manually emptied.	Alinity i-series	Based on Abbott's assessment of the Alinity i assays, there is potential for incorrect patient results for the following assays: HBsAg Qualitative II assay (LN 08P10), HBeAg assay (LN 07P64), HAVAb IgM assay (LN 02R28), Total b-hCG assay (LN 07P51), and STAT High Sensitive Troponin-I (LN 08P13).	The Alinity ci system software counts down Pre-Trigger Solution stability from 28 days. To ensure the Pre-Trigger Solution is not used after being onboard for 16 days, the user must replace the Pre-Trigger Solution in the Pre-Trigger reservoir when the onboard stability reaches 12 days in the user interface (UI). When the onboard stability reaches 12 days, perform *Empty the bulk solution reservoirs (i-series)* procedure in the Alinity ci-series Operations Manual, to empty any remaining solution from the reservoir.

	Issue	System/Assay Impacted	Patient Results or Operator Safety Impact	Necessary Actions until mandatory upgrade is completed
3.	The following critical message is missing meaningful information regarding the specific system issue: • 9351 - Unknown processing module error (129) • 9351 - Unknown processing module error (42) • 9351 - Unknown processing module error (239) Software version 2.6.0 will updated the message codes to: • 129: "3696 - The sample probe is not washed after aspirating a whole blood or red blood cell sample." • 42: "5813 - Unable to turn on (0). 0 = Device" • 42: "5814 - Unable to turn off (0). 0 = Device" • 239: "5028 - The (0) sensor failed. 0 = RSM transport or latch"	Alinity c-series	Critical message "9351 - Unknown processing module error (129)" may cause incorrect patient results as a result of sample carryover.	If critical message "9351 - Unknown processing module error (129)" occurs, perform the following: a. Perform As-needed Maintenance procedure *5906 Clean Sample and Reagent Probes (c-series)* to clean the sample probe unless one of the following actions occurred before the initiation of assay processing: • The sample probe was replaced. • Daily maintenance procedure *5501 Daily Maintenance (c-series)* was performed. b. Additional messages that are associated with this message can be used to determine the appropriate corrective action. Perform *View additional messages that are associated with a message* in the *Alinity ci-series Operations Manual*. No additional instructions are required for the following error codes: • 9351 - Unknown processing module error (42) • 9351 - Unknown processing module error (239)
4.	Under certain conditions, an operator can transition the Alinity c into the Running status with the procedure key positioned in the On setting and with the front processing center cover open.	Alinity c-series	This issue could lead the user to initiate a run with an open cover, potentially impacting operator safety.	Labeling already addresses this issue regarding the safety concerns with use of the procedure key to override the cover interlocks. Refer to *Mechanical hazards* in the Alinity ci-series Operations Manual.

	Issue	System/Assay Impacted	Patient Results or Operator Safety Impact	Necessary Actions until mandatory upgrade is completed
5.	When the "Disable Reagent on Control Failure" feature is configured as On, patient results completed after a control failure, but before the reagent is disabled, are not correctly flagged with CNTL. After the reagent is disabled, no further patient results will be reported.	Alinity ci-series	Because of the lack of the CNTL flags, the user may not know that the patient results completed after a control that was out of range should be flagged CNTL. Incorrect test results may be reported.	If the "Disable Reagent on Control Failure" feature is enabled, the operator must review the results for assays with controls out of range using information in the *Results screen and Quality control analysis* in the Alinity ci-series Operations Manual. Review results that completed after the control failure and before the reagent was disabled.
6.	In a multimodule configuration with more than one processing module of the same type, some rerun orders on quality control samples are not processed on the modules that processed the original tests.	Alinity ci-series	No patient results or operator safety impact.	Perform *Rerun a test or an exception for a specimen or control* in the Alinity ci-series Operations Manual. Use one of the following options to ensure rerun orders are processed on the same processing module as the original sample. 1. Instead of selecting all orders targeted for the multimodule, when creating rerun order, filter orders with module first, then select the tests, and create rerun orders. 2. Select individual tests and create the rerun order.
7.	When the system language is configured as Chinese or Japanese, the software will shut down when the operator prints the Diagnostic History Report.	Alinity ci-series	No patient results or operator safety impact.	When the system language is configured as Chinese or Japanese, it is recommended to not print the Diagnostic History report.
8.	ASTM communications are disconnected several times per day on software v2.5.0 and v2.5.1. Transmitted messages time out after an inactivity period of 15 minutes or greater.	Alinty ci-series	No patient results or operator safety impact.	When the ASTM host interface is disconnected, perform *Enable or disable the host connection* in the Alinity ci-series Operations Manual to disable and then re-enable the host interface.

	Issue	System/Assay Impacted	Patient Results or Operator Safety Impact	Necessary Actions until mandatory upgrade is completed
9.	After depleting a cartridge of Acid Probe Wash during *5501 Daily Maintenance* procedure, the reagent carousel does not move to the second cartridge. The first cartridge is resampled, causing the second cartridge to be flagged as Empty.	Alinity c-series	No patient results or operator safety impact.	1. Perform *Load onboard solutions and sample diluents on the reagent and sample manger (RSM) (c-series)* in the Alinity ci-series Operations Manual to load a new cartridge of Acid Probe Wash. 2. Refer to *Perform a maintenance procedure or a diagnostic procedure* in the Alinity ci-series Operations Manual and repeat *5501 Daily Maintenance (c-series).*
10.	User-defined calibrator sets that use water as a blank and are created on systems configured for languages other than English contain one additional calibrator level. When "Water" is translated, it is not recognized as a blank.	Alinity c-series	No patient results or operator safety impact.	Perform *Configure general settings* in the Alinity ci-series Operations Manual to change the system language to English before creating a new user-defined calibrator set that uses water as a blank. Once the calibrator set is created, perform the same procedure to return the system language to the previous language.
11.	The QC Summary Report, QC Analysis Report and the QC Levey-Jennings Report print only the first 75 rows of data selected in the Quality Control Summary screen. Data selected after row 75 is blank in the report.	Alinity ci-series	No patient results or operator safety impact.	Select only the first 75 rows of data in the Quality Control Summary screen when performing *Print a report* in the Alinity ci-series Operations Manual to print a QC Summary Report, QC Analysis Report or QC Levey-Jennings Report.
12.	No reagent probe washes are performed when the All setting for the reagent probe SmartWash is configured.	Alinity c-series	No patient results or operator safety impact.	When using user-defined assays, perform *Configure and verify SmartWash settings (c-series)* in the Alinity ci-series Operations Manual to configure individual reagent probe SmartWash settings for each assay that requires a reagent probe SmartWash. The SmartWash All is not used on Abbott assays, but is available as an option for user-defined assays. The user is responsible for the verification of user-defined assays.

	Issue	System/Assay Impacted	Patient Results or Operator Safety Impact	Necessary Actions until mandatory upgrade is completed
13.	Sample distribution does not occur as expected on a dual Alinity c module configuration resulting in degraded throughput. This is due to a defective load balancing algorithm related to ICT calibration test counts.	Alinity c-series	No patient results or operator safety impact.	Perform *Stop the processing module and the reagent and sample manager (RSM)* procedure in the Alinity ci-series Operations Manual to stop both processing modules. Then perform *Start the processing module and the reagent and sample manager (RSM)* procedure to initialize them. This resets the test count to 0 for both processing modules. After that point, if both modules run the same number of ICT calibrations, then proper load balancing will occur.
14.	When printing a 1D reagent barcode label report, the labels are shifted to the left and top when using Avery label template J4773. All labels from the second line are unusable because they do not match the label limits.	Alinity c-series	No patient results or operator safety impact.	It is not possible to print a complete set of labels.
15.	The date format on In Process tab of the Maintenance Procedures screen and the Diagnostic Procedures screen differs from the selected system configuration option.	Alinity ci-series	No patient results or operator safety impact.	No action is necessary.
16.	Diagnostic procedure 1610 Reagent and Sample Manager Test does not stop the highest processing module in an error condition, leaving a processing module in the Idle state.	Alinity ci-series	No patient results or operator safety impact.	If a failure occurs, the operator should reinitialize all processing modules. Perform *Start the processing module and the reagent and sample manager (RSM)* procedure in the Alinity ci-series Operations Manual.
17.	Load platform placement failure during barcode scan fails to clean up associated carrier data.	Alinity ci-series	No patient results or operator safety impact.	In order to reuse the rack, the operator must perform *Cycle power to the processing module and the reagent and sample manager (RSM)* in the Alinity ci-series Operations Manual.