

Single Registration Number (SRN): N/A



Urgent Field Safety Notice Product Correction

Urgent - Immediate Action Required

Date Issued July 26, 2021

Product

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

Explanation

Abbott has identified three potential performance issues for the Alinity ci-series Software version 3.2.3 and earlier. Abbott is releasing Alinity ci-series Software version 3.3.0 to correct these issues (see details in **Appendix A**).

1. There is the potential on Alinity c and Alinity i for onboard reagents past their lot expiration date or onboard stability time to be incorrectly displayed on the Reagent Status screen with a status of "OK". In this scenario, the expired reagent will remain in the carousel for sample processing.
2. Performing monthly maintenance procedure *5701 Clean ICT Drain Tip* on Alinity c incorrectly may potentially cause issues such as damaged connector or leaking connection.
3. A sample exception with message code 150 "Unable to process test. Previous processing module error" on Alinity c is produced without notifying the operator of a reagent pipettor failure. The processing module transitions into the Pausing state. Tests initiated prior to the sample exception may continue to process without dispense of reagents, potentially leading to incorrect results.

**Impact on
Donor/Patient
Results**

Refer to **Appendix A** for details concerning any patient results impacted due to the issues identified in Alinity ci-series System Software versions 3.2.3 and earlier.

**Necessary
Actions**

Please follow the Necessary Actions required in **Appendix A** until software version 3.3.0 is installed.

Your Abbott representative will schedule a mandatory upgrade of your Alinity ci-series to software version 3.3.0.

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 complete the included Abbott Customer Reply Form.

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 issues resolved in version 3.3.0

Alinity ci-series			
	Issue	Patient Results or Operator Safety Impact	Necessary Actions until mandatory upgrade is completed
1.	There is the potential for onboard reagents past their lot expiration date or onboard stability time to be incorrectly displayed on the Reagent Status screen with a status of “OK”. In this scenario, the expired reagent will remain in the carousel for sample processing.	There is the potential for incorrect results if tests are performed with an expired reagent cartridge.	<p>Manually verify reagent expiration at the beginning of daily operation.</p> <ul style="list-style-type: none"> • Print Reagent Status Report • Review reagent lot expiration date to ensure no reagents have expired • Select one reagent that has been onboard greater than one day and confirm the stability time has been correctly counted down. <p>For additional information, to <i>Print a report</i>, refer to the Alinity ci-series Operations Manual, section 5.</p> <p>If the operator suspects that the reagent expiration is not being tracked correctly in the Alinity ci-series software, cycle power to the system to reinitiate the reagent expiration tracking function.</p>

Alinity c-series			
2.	Performing monthly maintenance procedure 5701 <i>Clean ICT Drain Tip</i> incorrectly may potentially cause issues such as damaged connector or leaking connection.	There is a potential for biological, chemical, physical, or electrical hazards from damaged or leaking ICT drain tip connections.	<p>Procedure 5701 has not been changed. However, the following steps have been updated to include additional information.</p> <p>Step 3: Remove the ICT drain tip. Grasp the drain tip near where it enters the ICT drain port. Pull the tip upwards and out of the drain port.</p> <p>IMPORTANT: Do not remove the drain tip by pulling only on the tubing above the drain tip. This may cause the tubing to separate from the tip.</p> <p>Step 6: Replace the drain tip securely into the ICT drain port. It is the center opening.</p>
3.	A sample exception with message code 150 <i>“Unable to process test. Previous processing module error”</i> is produced without notifying the operator of a reagent pipettor failure. The processing module transitions into the Pausing state. Tests initiated prior to the sample exception may continue to process without dispense of reagents, potentially leading to incorrect results.	There is the potential for incorrect results for tests that continue without dispense of reagents.	<p>If the processing module has transitioned from Running status to a Pausing or Stopped status without generating an alert message AND a single sample went to exception with message code <i>“150 Unable to process test. Previous processing module error”</i>, perform the following:</p> <ul style="list-style-type: none"> • Review results reported after the sample exception message code 150 for suspect results. • Initialize the processing module by performing <i>Start the processing module and the reagent and sample manager (RSM)</i> procedure. For additional information, refer to <i>Alinity ci-series Operations Manual, section 5</i>. • Contact Customer Service to resolve the reagent pipettor failure.