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

Product Correction

Immediate Action Required

Date Issued

October 04, 2017

Product

Product	List Number (LN)	UDI
Alinity i Processing Module	03R65-01	N/A
Alinity ci-series System Control Module (SCM)	03R70-01	N/A

Explanation

Abbott has identified the following issues with the Alinity ci-series:

1. Exposed edge on RV Hopper door on Alinity i-series processing module prior to serial number Ai01106.
2. Refer to **Appendix A** for a list of issues related to Alinity ci-series System Software version 1.1. Software version 2.00 will correct these software issues.
3. Refer to **Appendix B** for a list of issues that will be addressed with improved instructions in the Alinity ci-series Operations Manual included in software version 2.00.

Patient/Safety Impact

1. The exposed edge on the RV hopper door has the potential to cause physical harm to an operator.
2. Refer to **Appendix A and Appendix B** for details concerning any patient or safety impact related to the issues identified in Alinity ci-series System Software version 1.1.

Necessary Actions

Your Abbott representative will be scheduling mandatory upgrades of your Alinity ci-series SCM and Alinity i-series Processing Module to resolve each of these issues in the upcoming weeks:

1. Use precaution when working around the RV Loader door until the exposed edge can be addressed.
2. Refer to **Appendix A and Appendix B** for necessary actions required until software version 2.00 can be installed. If you require additional information, please contact Abbott Customer Service.

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 please contact your local area Customer Service.

Appendix A - Alinity ci-series System Software version 1.1 issues

Issue	System/Assay Impacted	Patient or Safety Impact	Necessary Actions until mandatory upgrade is completed
Load failure on the carrier positioner may result in the tilting of a reagent cartridge or rack.	Alinity ci-series	Potential for a sample rack to be bumped and tilted during unload, causing sample to be spilled from specimen tubes.	If you have a carrier position error, remove the rack before attempting to reinitialize.
During reagent cartridge loading or unloading, if an error occurs while a reagent cartridge is on the reagent positioner, the system allows the RSM to re-initialize before the cartridge is removed. If the RSM is re-initialized before the reagent cartridge is removed, the reagent cartridge will be tipped over.	Alinity ci-series	A tipped reagent cartridge has the potential to result in a chemical spill and biohazardous situation.	Remove the reagent cartridge that experienced the load/unload errors before re-initializing the RSM.
Multiple Maintenance and Diagnostic procedures can cause a wash cup overflow if an error occurs while the system is flushing during the procedure.	Alinity i-series	Potential for a spill if fluid leaks from the system requiring cleanup of fluids and a biohazardous situation	Perform fluid hazard clean up per the Alinity ci-series Operations Manual, Section 8: Hazard—Spill Cleanup.
An operator is able to move the procedure key to the “On” setting while the processing module is Running or Processing. The module does not stop or display an alert.	Alinity i-series	Potential to generate incorrect results. Additionally, the user could open the processing module covers while the module is processing tests and expose themselves to a moving mechanical device.	Do not position the procedure key in the “On” setting while processing or running. Refer to Section 9, Descriptions of procedure key settings.
A test may remain in the “Scheduled” status, but is not processed. Once the processing module transitions to stopped or idle, the test is sent to exception.	Alinity i-series	Potential for a delay in patient result reporting.	If you suspect that a test has remained in the “Scheduled” status, pause the processing module to transition the module to the “Idle” status. Repeat any exceptions that may have been generated. Refer to Section 5, System cycle power, start, pause and stop.
Maintenance and Diagnostic procedure 4102 Sample Pipettor Calibration (c-series) may require additional attempts to optimize pipettor positioning.	Alinity c-series	There is the potential for incorrect results if the Sample Pipettor is not calibrated correctly.	Visually verify the alignment of the sample pipettor. Repeat Maintenance and Diagnostic procedure 4102 Sample Pipettor Calibration (c-series) if necessary.

Appendix A – Alinity ci-series System Software version 1.1 issues (continued)

<table>
<tr><th>Issue</th><th colspan="2">System/Assay Impacted</th><th>Patient or Safety Impact</th><th>Necessary Actions until mandatory upgrade is completed</th></tr>
<tr><td rowspan="7">A potential to generate incorrect results for assays using the Spline calibration method when the calibrator values are entered with a comma as the decimal separator.</td><td>Alinity c Assay</td><td>LN</td><td rowspan="7">Potential for incorrect results, however invalid control results would be generated.</td><td rowspan="7">Change the Thousand/Decimal Separator option to Comma and Period or None and Period. Refer to Configure General Settings in Section 2, System configuration.</td></tr>
<tr><td>CRP Vario</td><td>07P56</td></tr>
<tr><td>Urine/CSF Protein</td><td>07P59</td></tr>
<tr><td>Vancomycin</td><td>08P52</td></tr>
<tr><td>Microalbumin</td><td>08P04</td></tr>
<tr><td>Digoxin</td><td>08P37</td></tr>
<tr><td>Transferrin</td><td>08P38</td></tr>
<tr><td>Diagnostic procedures 4103 R1 Pipettor Calibration (c-series) and 4104 R2 Pipettor Calibration (c-series) do not home the reagent carousel and the reagent door before executing the procedure.</td><td colspan="2">Alinity c-series</td><td>No patient or safety impact.</td><td>If the procedure fails, perform a processing module initialization prior to repeating the procedure. Refer to Section 5, System cycle power, start, pause and stop.</td></tr>
<tr><td>If power is lost when a reagent cartridge is being unloaded, the reagent cartridge is given an unload error status. This prevents the processing module from being initialized.</td><td colspan="2">Alinity c-series</td><td>No patient or safety impact.</td><td>Identify the reagent cartridge that was being unloaded and contact Abbott Customer Service for assistance to delete.</td></tr>
<tr><td>Unable to enter values using a comma for the decimal separator when configuring a new quality control level while the system is Running or Processing.</td><td colspan="2">Alinity ci-series</td><td>No patient or safety impact.</td><td>Pause the processing module to transition the module to the Idle status before entering quality control values if you use a comma for the decimal separator.</td></tr>
<tr><td>An unexpected system shutdown occurs while attempting to save 1D bar codes or reports to a USB flash drive using the Print to File option.</td><td colspan="2">Alinity ci-series</td><td>No patient or safety impact.</td><td>Cycle power to the processing module and the reagent and sample manager (RSM). Verify there is sufficient storage space on the USB flash drive before utilizing. Refer to Section 5, System cycle power, start, pause and stop.</td></tr>
<tr><td>Multiple diagnostic procedures have the potential to fail if the system language is not English.</td><td colspan="2">Alinity i-series</td><td>No patient or safety impact.</td><td>If the procedure fails, change the system language to English to perform the procedure and then return to the original language. Refer to Section 2, System configuration.</td></tr>
</table>

Appendix A – Alinity ci-series System Software version 1.1 issues (continued)

Issue	System/Assay Impacted		Patient or Safety Impact	Necessary Actions until mandatory upgrade is completed
A calculated assay will not complete if the Host Setup is configured with the Transmission Option of Single (not Collated) and the Release Mode of Automatic. The constituent results used in the formula for the calculated assay are not available because they were previously auto-released.	**Alinity i Assay**	**LN**	No patient or safety impact.	Change option to collated (automatic release and collated) or manual (default) release. Refer to Section 2, System configuration
	Tox IgG Avidity	07P46		
	CMV IgG Avidity	07P43		
	HBSAg confirmatory	08P09		

Appendix B – Alinity ci-series Operations Manual issues

Issue	System/Assay Impacted	Patient or Safety Impact	Necessary Actions until mandatory upgrade is completed
Replacement bulk solution level sensors are not labeled with the bulk solution name.	Alinity ci-series	Potential for patient result impact due to bulk solution cross contamination if 2 level sensors are removed at the same time and returned to the incorrect reservoir.	To ensure that the correct bulk solution level sensor is placed in the correct bulk solution reservoir, remove one level sensor at a time.
Incorrect placement of the light shield could cause unload diverter errors and cause processing module not to transition into a running status.	Alinity i-series	No patient or safety impact.	Ensure the left side of the light shield is placed properly over the process path.