



## Product Correction

Immediate Action Required

**Date Issued**

October 16, 2017

**Product**

Product	List Number (LN)	UDI
Alinity s System	06P16-01	N/A

**Explanation**

Abbott has identified updates to the following components of the Alinity s System:

1. Incubation track and dampener parts on Reaction Vessel (RV) Process Path
2. Alinity s System Software

**Patient/Safety Impact**

1. The current incubation track and dampener allows for droplets of reaction mixture to splash higher than expected on the walls of the RV, which has the potential to result in falsely depressed (false negative) donor or patient results in rare cases. Updated incubation track and dampener parts will address this issue.
2. Refer to **Appendix A** for details related to the issues identified in Alinity s System Software version 1.11 and any patient or safety impact. Software version 1.2 will address these software issues.

**Necessary Actions**

Your Abbott representative will be scheduling mandatory upgrades of your Alinity s System to resolve each of these issues in the upcoming weeks. In the interim:

1. No immediate action is required due to the incubation track and dampener issue.
2. Refer to **Appendix A** for necessary actions required until software version 1.2 can be installed.

Follow your laboratory procedures and 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 your customers or health care providers you serve have any questions regarding this information please contact your local area Customer Service.

## Appendix A - Alinity s System Software version 1.11 issues

Issue	Patient or Safety Impact	Necessary Actions until mandatory upgrade is completed
Static in the optics turret can create undesirable read profiles and tests with these read profiles are not sent to exception.	No new patient or safety impact.	The issue with static in the optics turret was previously communicated in August. Your Abbott Representative will continue to complete weekly lubrication until Software version 1.2 is installed. No further customer actions are necessary.
If a manually placed test order is placed for a non-barcoded (or non-readable barcode) sample without specifying carrier and position location of the sample, it is possible for a sample ID mismatch to occur if an operator inadvertently swaps another non-barcoded (or non-readable barcode) sample for this sample between racks.	Potential for SID mismatch.	If using tubes with no barcode or non-readable barcodes, ensure manually placed test orders are placed specifying carrier and position location of the sample.
Some samples of insufficient quality may not be flagged as having an aspiration error.	Potential for incorrect results.	Ensure proper sample preparation and handling.
The software does not prevent the operator from being able to delete an assay control exception in the Results Exception screen before the system creates the rerun. This can result in a failure to automatically reorder the assay control during rerun.	No patient or safety impact.	Do not delete the assay control exception in the Results Exception screen before the software creates the rerun.
"Your file is not found" message appears when selecting the "Help?" button on certain screens.	No patient or safety impact.	Access online help through the home screen or contact local area Customer Service.
If two racks of assay controls are loaded, the second rack of assay controls remains on the Reagent Sample Manager (RSM) after pending QC specimens are released during the assay control interval. The operator is not notified that the rack was not run.	No patient or safety impact.	Load new rack with assay controls or remove second rack and reinsert.
Certain Screen Text, Message and Maintenance and Diagnostic resources appear in English only. Additionally, 4 common error messages require correction to the translation.	No patient or safety impact.	If the translations are not available, or 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. Alternatively, contact your local area Customer Service.
During Maintenance and Diagnostic (M&D) procedures, a maintenance cartridge or diagnostic kit can be stranded in the carousel if there is an error when moving cartridges into the carousel. If an assay reagent was in the carousel prior to initiating the M&D, the system may not recognize it has been replaced with a maintenance cartridge or diagnostic kit. Samples may be tested using the maintenance cartridges or diagnostic kits instead of the correct reagent cartridge.	No patient or safety impact.	Request an unload of the impacted reagent cartridge. Refer to Section 5, Operating Instructions. Any result generated would be sent to exception and the test should be repeated.
Unexpected software shutdown can occur while trying to move barcodes/reports to a USB drive if the USB drive does not have sufficient storage space. The system also does not notify the operator that sufficient space is not available.	No patient or safety impact.	Verify there is sufficient storage space on the USB flash drive before utilizing.