DIAGNOSTICS

Product Correction
Immediate Action Required

Abbott

Date Issued	June 18, 2018

Product

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

Explanation

Abbott has developed Alinity s System software V2.0 (LN 04U76-07) to address known issues and enhance the overall Alinity s System (LN 06P16-01).

Donor/ Patient Safety Impact

Refer to **Appendix A** for details related to the issues identified in Alinity s System Software version 1.30 and any donor/patient or safety impact. Software version 2.0 will address these software issues.

Necessary Actions

Your Abbott representative will be scheduling mandatory upgrades of your Alinity s System to install Alinity s System software V2.0 in the upcoming weeks. In the interim refer to **Appendix A** for necessary actions required until software V2.0 can be installed. In addition to correcting these software issues, the software update includes a number of changes intended to improve performance and reliability.

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 1.30 issues

Issue	Donor/Patient or Safety Impact	Necessary Actions until mandatory upgrade is completed
If the Reagent Cartridge Preparation Station (RCPS) experiences a hardware failure while re-suspending the microparticles in a reagent cartridge, and this reagent cartridge is reintroduced to the Alinity s, the reagent cartridge is placed on the reagent carousel.	There is a potential for incorrect test results if the reagent cartridge has not been completely re-suspended.	If the Reagent Cartridge Preparation Station (RCPS) experiences a hardware failure while re-suspending the microparticles in a new reagent cartridge, manually remove the cartridge from the RCPS. Please dispose of the cartridge as the proper re-suspension of the microparticles will not occur prior to it being loaded into the reagent carousel. The message history log may be reviewed for the following message codes: Message code1012 "Reagent cartridge (Load Error) for assay () lot () SN ()" or Message code 5647 "Reagent cartridge preparation station () error". If both errors have not occurred concurrently within the log, the issue has not occurred.
Message code "9999: Unable to run the system. One or more maintenance procedures are overdue", is not translated.	No donor/patient or safety impact.	If this message is seen, please call customer support for assistance in translating the message. Ensure there are no maintenance procedures overdue before attempting to put the instrument in a running state.
Operations Manual has incorrect causes and actions for message code: 5740 No reagent cartridge detected at reagent carousel position (0).	No donor/patient or safety impact.	If the message is seen, please call customer support for further actions.
Changes to Assay Availability status are not reflected in the Order screen when in the running state.	No donor/patient or safety impact.	Please ensure the instrument is Idle or Stopped before enabling or disabling an assay in the Assay Parameters screen.
The general assay installation instructions do not appear in the Assay Installation report when the selected printer is configured with A4 paper.	No donor/patient or safety impact.	Please refer to the Alinity s Operations Manual, Section 2, Installation procedures and special requirements on installing assays.
Order query failure when using ISBT-128 barcodes. User may choose not to display data identifier and flags. An order query failure may occur.	No donor/patient or safety impact.	When using ISBT-128 formatted specimen barcodes, please configure the system configuration option to Show Data Identifier and Flag (on the Bar Codes configuration screen).
Instrument status is displayed as the stopping state even though the instrument is in the stopped state.	No donor/patient or safety impact.	Please reboot the system if it remains in the Stopping state instead of transitioning to the Stopped state when there are no tests in progress and no remaining movements to complete (i.e. unload racks to RSM).