Abbott Laboratories
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Product Correction

Immediate Action Required

CC

Chairman Medical Board and relevant Head-of-Department

Date Issued

March 11, 2019

Product

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

Explanation

Abbott has developed Alinity s System software V2.5.0 (LN 04U76-11) 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 in the Alinity s System Software and any donor/patient or safety impact. Software V2.5.0 will address these software issues.

Necessary Actions

Your Abbott representative will be scheduling a mandatory upgrade of your Alinity s System to install Alinity s System software V2.5.0 in the upcoming weeks. In addition to correcting software issues, the software update includes several 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 Issues

Issue	Donor/Patient or Safety Impact	Available Actions until Mandatory Upgrade is Completed
When performing Maintenance and Diagnostic procedure 7110 Pipettor Calibration and Straightness during system installation, if the pipettors are not aligned the pipettor probes may have an interference at the wash station and cause a slight bend to the pipettor probe. In addition, the procedure can incorrectly state that the overall procedure passes a probe straightness test, however intermediate steps within this procedure could fail.	There is a potential for incorrect test results. A slightly bent pipettor probe can cause splashing in the RV (reaction vessel) which could potentially lead to contamination.	The Alinity s System Operations Manual provides Corrective actions associated with a probe that is not straight in Section 10, Troubleshooting, Observed problems, Sample results observed problems, Erratic results or poor precision table, Probable cause: *The sample, R1, or R2 pipettor probe is not straight.*
Maintenance and Diagnostic procedure 7110 Pipettor Calibration and Straightness incorrectly states the calibration option will also check the probe straightness. Probe straightness is separate from the calibration and is not automatically performed as part of the calibration option. If the probe straightness test is not performed, this could allow a slightly bent pipettor probe to go undetected.	There is a potential for incorrect test results. A slightly bent pipettor probe can cause splashing in the RV which could potentially lead to contamination.	The Alinity s System Operations Manual provides Corrective actions associated with a probe that is not straight in Section 10, Troubleshooting, Observed problems, Sample results observed problems, Erratic results or poor precision table, Probable cause: *The sample, R1, or R2 pipettor probe is not straight.*
When the system is processing tests and goes to a Stopped status prior to completing all the tests in process, an RV with sample and reagents may be present at the wash zone. During the subsequent initialization, the wash zone probes may enter this RV and could potentially become obstructed or contaminated.	There is a potential for incorrect test results. If the system is processing tests and goes into a Stopped state, wash zone probes can become contaminated by entering an RV with sample or reagents. If the event causes a wash zone probe to be obstructed, subsequent tests may have a message code generated. This would send affected tests to exception.	Instructions for initially reactive results may be found in the respective Alinity s assay Instructions for Use. The Alinity s System Operations Manual provides Corrective actions associated with potential message codes in Section 10, Troubleshooting, Message codes.
If a rack or cartridge is inserted into the reserved priority bay by a user at the same time the RSM (Reagent and Sample Manager) transport arm is attempting to place a rack or cartridge into that position, the Alinity s System will go to Stopped. The RSM indicator lights will alternate flashing amber and green to identify the priority bay which contains the loaded rack or cartridge. User removal of the rack or cartridge from the priority bay may cause a spill as a result of unintentional contact with the rack or cartridge on the RSM transport.	There is a potential for biohazard exposure. Unintentional contact between the rack or cartridge and the RSM transport could cause the contents to spill. If the Alinity s System goes to a Stopped state, scheduled tests will be sent to exception.	The Alinity s System Operations Manual provides instructions and CAUTION statements for loading racks and cartridges into the priority bay in Section 5, Operating instructions. The Alinity s System Operations Manual provides Corrective actions associated with potential message codes in Section 10, Troubleshooting, Message codes.

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Air can enter the fluidics system during a Concentrated Wash Buffer lot change procedure and is not adequately flushed out before returning to the Running state. As a result, tests may be sent to exception with message codes for pipettor aspiration and dispense pressure monitoring.	No donor/patient or safety impact.	The Alinity s System Operations Manual provides Corrective actions associated with potential message codes in Section 10, Troubleshooting, Message codes.
The user interface may not respond when: • attempting to manually rerun exceptions. • attempting to manually order and load Abbott release controls or unload Abbott release controls from the Cal/QC Inventory screen while the instrument initialization completes verification of inventory. • attempting to manually order release controls at the same time the QC scheduler automatically orders release controls.	No donor/patient or safety impact.	The Alinity s System Operations Manual provides Corrective actions associated with the user interface not responding in Section 10, Troubleshooting, Observed problems, User interface (UI) computer observed, User interface does not respond table.
The reagent manager temperature monitor connection conversion specification is incorrect in the Alinity s System Operations Manual. The 4 mA = -50°C specification is missing the negative sign in front of the 50°C value.	No donor/patient or safety impact.	The correct specification is: 4 mA = -50°C 20 mA = +50°C No additional action is necessary.
When manually ordering and running multi-constituent non-Abbott release controls the Alinity s System may incorrectly apply CNTL-L and CNTL-H flags to the control results. The control result S/CO values are properly reported and evaluated correctly to release specimen results.	No donor/patient or safety impact.	No action is associated with this issue other than installation of Alinity s System software V2.5.0.
A sample rack may not be repositioned for a retest order but the RSM indicator light remains amber, indicating the rack is in use and cannot be removed from the RSM. If this occurs, the RSM indicator light will remain amber even though the sample rack is not being processed.	No donor/patient or safety impact.	The Alinity s System Operations Manual provides instructions on how to suspend the processing of a sample in Section 5, Operating instructions, Specimen, calibration, and control orders, Suspend the processing of a sample. Performing this procedure allows the sample to be accessed from the RSM when the status indicator is amber without an impact to instrument processing.