Abbott
1300 E. Touhy Ave.
Des Plaines, IL 60018

Urgent Field Safety Notice
Molecular Diagnostics at Abbott
Product: Alinity m System
List Number: 08N53-002
Not Serial Specific
Unique Device Identifier (UDI): 00884999048034

October 14, 2022

Dear Abbott Customer,

This letter contains important information regarding your Alinity m System; specifically, the current software installed on your Alinity m System. Please review this information carefully.

Background

Abbott has identified four potential performance issues for the Alinity m System Software and will release an updated Alinity m System Software version to correct these issues (see details in **Appendix A**).

1. In a unique scenario, the waste chute flapper was found to not open when the Systems Solution drawer was closed and locked.
2. Sample preparation drawer #1 barcode information is used instead of sample prep drawer #2 when the scanned data is not sent to the System Control Center before the next bottle barcode in sample prep drawer#2 is scanned.
3. Under a specific condition, while the system is processing tests and a new test request is made, when the level of the bulk solution is too low to process a test, the software would error stop the system and try to complete all in-process tests.
4. 4 to 6 replicates of the same auto calibrator orders can be run with 2 different sets of calibrator materials on the same rack. It was discovered during internal testing, when running 4 to 6 replicates of a calibrator, it is possible for the user to use 2 separate lots of material which is not detected by the System Control Center (SCC).

Potential Impact

Refer to **Appendix A** for details concerning any hazards identified due to the issues found in the Alinity m System software

Necessary Actions

Please refer to **Appendix A** for available actions until your Alinity m System receives the software upgrade. Please review this information with laboratory personnel and retain this communication for future reference.

Your Abbott representative will schedule a mandatory upgrade of your Alinity m Series software. Anticipated release of the software update is scheduled for the end of October 2022. Software will be available upon local regulatory approval.

Please complete and return the Customer Reply Form.

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If you have any questions regarding this communication, please contact your local Abbott representative. We apologize for any inconvenience this may have caused your laboratory.

Sincerely,

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Albert Chianello
Director, Quality Assurance
Molecular Diagnostics at Abbott

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Appendix A

Alinity m System			
	Issue	**Hazards and Impact**	**Available Actions Until Mandatory Upgrade is Complete**
1.	Flapper door does not open when Bulk Fluidics drawer was closed. It was found that the software will cause the flapper door to stay in the closed position when the drawer is closed and locked if the flapper had previously been moved out of position.	There is the potential for incorrect results if overflow of the tips or reaction vessels cause contamination in the instrument. There is also the potential of a biohazard exposure during clean-up of any build of tips or reaction vessels that fall outside the waste container.	This occurrence was only found in-house under non-standard operating conditions. Prior to instrument use, empty waste container. If waste overflow occurs, please follow internal bio-hazardous waste cleaning procedures.
2.	Sample preparation (prep) drawer #1 barcode information is used instead of sample prep drawer #2.	There is the potential for delay in results when two different Alinity m assay types are run (RNA/DNA). The SCC may receive the information from drawer 1 (RNA assay) as the data for drawer #2 (DNA assay) resulting in internal control failure. There is also the potential for incorrect results if two different lots are used when running an Alinity m quantitative assay. Specifically, when the SCC receives the information from drawer #1 (lot A) as the data for drawer #2 (lot B), results would be generated using the wrong calibration curve potentially causing incorrect results.	To help mitigate potential occurrence, the following can be done: 1) Verify that only ONE lot of sample prep kit material is on the system at a time. 2) Load one sample prep drawer at a time. Once the first drawer is scanned, verify the scanned information is correct on the SCC. After drawer 1 information has been verified to be correct, load the second drawer. After scanning, verify the correct information for drawer 2 is correct on the SCC.

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	Issue	Hazards and Impact	Available Actions Until Mandatory Upgrade is Complete
3.	Instrument Embedded Controller (IEC): Error stopping due to low level of bulk reagents when a test order is received. When this occurs, an internal counter is reset which can cause RVs already present in Amp Detect Unit (ADU) to remain there and not be moved to waste. If the RVs are not removed and new RVs are transferred into the ADU, the RVs would "double stack" such that that the amp detect could error causing the system to not run when restarted.	In the worst-case scenario of the RV stacking scenario, FSE may be required to visit the customer site to remediate an event. This may cause a potential delay in results.	Take the module out of service per M&D 2752 **or** clean out the amp detect RVs via M&D 1401, Contact your Abbott representative for further guidance.
4.	4 to 6 replicates of the same auto calibrator orders can be run with 2 different sets of calibrator materials on the same rack. If this were to occur, the calibration curve would be created using 2 separate material lots. In normal use scenario, this curve would be made using only 1 lot of material.	There is a potential for delay in results if 2 different sets of materials are used to calibrate. The calibration would need to be reran to obtain a valid curve. There is also the potential of incorrect results. The curve generated with 2 different material lots could potentially generate incorrect results.	If loading 2 or more tubes of calibrator material, verify that they are from the same lot.