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DIAGNOSTICS

Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

Date Issued	June 10, 2019

Product

Product Name	List Number	Serial Number	UDI
Alinity ci-series System Control Module	03R70-01	All*	N/A

*Only includes Alinity ci-series System Control Modules which are configured with Alinity i Processing Modules

Explanation

Abbott has identified an issue with all on-market versions of Alinity ci-series Software where re-use of reaction vessels (RVs) may occur after a system Stop. This issue only occurs if the system is transitioned from Processing to Stopped to Idle and has the potential to cause incorrect results.

The following specific sequence of events are required to experience this issue:

1. The system is processing tests.
2. A processing module 'stop' event occurs. The stop event can be system initiated (for example, due to a hardware failure that places the system in Stopped status) or due to an operator request to **Stop** the system.
3. The operator requests a **Start** on the module that stopped. The system performs an initialization to transition to the Idle state.
4. The operator requests a **Run** to transition the system to Running.

If the prior run ended with a stop while sample or reagent are in the process of being aspirated or dispensed into RVs there could be sample/reagent in the RVs between the sample dispense and the stat diverter. Up to 4 RVs would be retained in the clean lane and could be used for future tests.

Note: If the operator does not perform step 3 (Start), the issue does not occur.

Abbott will be releasing Alinity ci-series Software version 2.6.2 to resolve this issue.

Patient Impact

This issue has the potential to cause incorrect patient results for any Alinity i assay.

Necessary Actions	To mitigate the issue until Software version 2.6.2 is available, operator should follow the steps below: 1. When system is stopped, go directly to running 2. If the system is in a Stopped state and the operator transitions to an Idle state, the operator must clear all RVs from the process path. Perform process path diagnostic procedure 1520 RV Load and Unload Test to unload and load all RVs from the process path. **Note:** For detailed instructions see **Appendix A**. Alinity ci-series Software version 2.6.2 is expected to be available by the end of July 2019. Your Abbott representative will schedule a mandatory upgrade of your Alinity ci-series Software to version 2.6.2 to resolve this issue. If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter. 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 the health care providers you serve have any questions regarding this information, U.S. Customers please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online (http://www.fda.gov/MedWatch/report.htm), by mail (http://www.fda.gov/MedWatch/getforms.htm), by phone (1-800-332-1088), or by fax (1-800-FDA-0178). If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.

Appendix A

Procedure to remove used RVs in the Process Path		
IF the processing module is in…		THEN…

Stopped state	The instrument is stopped due to a hardware failure or operator stop request during the processing of samples.	1. On the menu bar, tap the **Home** icon.
		
		2. On the Home screen, perform one of the following steps:
		  • Tap one or more of the processing modules or the RSM.
		  • Tap one or more of the processing modules and the RSM.
		
		3. Tap **Run**.

Idle state	The instrument is stopped due to a hardware failure or operator stop request during the processing of samples and transitioned to Idle.
	
	Note: Pressing Stop from the Idle state and then transitioning to Run will not clear the used RVs.
		1. On the menu bar, tap the Procedures icon.
		
		2. On the Procedures screen, perform the following steps:
		  • Tap the Diagnostics tab.
		  • Tap the Process Path category.
		  • Select diagnostic procedure 1520 RV Load and Unload Test.
		  • Select Perform.
		  • Select 'OK' (If procedure key is in the correct position).
		  • Tap Proceed on the 1st Instructions window.
		  • Tap Both on the 2nd Instructions window.
		  • Tap Process Path on the 3rd Instructions window.
		  • Tap End Procedure upon completion of the test.
		  • Tap Done.