

Single Registration Number (SRN): US-MF-000017777



Urgent Product Correction

Immediate Action Required

Date Issued

June 2, 2022

Product

Product Description	List Number	Serial Number	US/EU UDI
Alinity ci-series System Control Module (SCM)	03R70-01	See Attachment A	

Explanation

Abbott has identified a potential performance issue found in the Alinity ci-series software versions 3.3.3 and lower. Abbott is releasing Alinity ci-series software version 3.4.0 to correct this issue.

When using a multimodule system with at least one onboard vial rack stored in the reagent carousel, there is a potential for the onboard vial rack to be undetected by the system software. This may occur after the onboard vial rack has completed testing on a different processing module than the processing module where it was stored. The issue occurs under the following specific conditions:

- The onboard vial rack is stored on a processing module with a status of Idle.
- The reagent and sample manager (RSM) removes the onboard vial rack from that processing module and sends it to another processing module for testing.
- While the rack is on the second processing module for testing, the original processing module completes initialization due to a start or run request.
- The RSM returns the onboard rack to the original module where it is loaded into the reagent carousel but not displayed on the Current tab of the Reagents Screen for that processing module
- The Cal/QC Inventory screen displays the onboard vial rack with dashes (---) in the module and position column, incorrectly indicating that it is no longer stored onboard the processing module.

Note: If initialization occurs on the original processing module a second time before any reagents or onboard vial racks are loaded on the reagent carousel, then the undetected onboard vial rack is unloaded to the RSM.

Impact on Donor/Patient Results and Operator Safety

If the RSM attempts to load a reagent cartridge or an onboard vial rack into the position that is occupied by the undetected onboard vial rack, this could cause the reagent cartridge or either onboard vial racks to be dislodged and spill.

Depending on the products involved, this could create a biohazard or chemical hazard.

There is also potential for the spill to contaminate products in the reagent carousel which could lead to incorrect results.

**Necessary
Actions to be
Taken by
Customer**

Please follow the necessary action that is required until software version 3.4.0 is installed:

For a multimodule Alinity ci-series, before making a start or run request on a processing module with an instrument status of Idle:

- Check the Current Tab of the Reagents screen and ensure no onboard vial rack has a Load status of Processing.
- Wait until testing is completed and the onboard vial rack is returned to the reagent carousel.

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.

Complete and return the Customer Reply Form.

Please retain this letter for your laboratory records.

**Contact
Information**

If you or any of the health care providers you serve have 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.
