CORE DIAGNOSTICS

Abbott Laboratories
1915 Hurd Drive
Irving TX, 75039 USA

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

Urgent Field Safety Notice

Product Correction

Immediate Action Required

Date Issued

November 13, 2025

Product

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

Explanation

Abbott has identified four (4) potential issues with the Alinity ci-series System software versions 3.6.1 and lower. Abbott is releasing Alinity ci-series System software version 3.7.0 (LN 04V20-29) to correct these potential issues. (See details in **Appendix A**). Alinity ci-series System software version 3.7.0 is expected to be available for installation worldwide November 2025.

Your Abbott Field Service Representative will schedule a mandatory upgrade of the Alinity ci-series System to software version 3.7.0.

Impact on Donor/Patient Results

Refer to **Appendix A** for details concerning potential impact to patient results due to the issues identified in Alinity ci-series System software versions 3.6.1 and lower.

Necessary Actions to be Taken by Customer

Please follow the Necessary Actions required in **Appendix A** until software version 3.7.0 is installed.

Complete and return the Customer Reply Form.

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

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. 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 at http://www.fda.gov/MedWatch/report.htm, by phone (1-800-332-1088), or 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 – Necessary Actions

These potential issues impact the Alinity i Processing Module only.			
#	**Issue Description**	**Impact to Donor/Patient Results**	**Necessary Actions required until software version 3.7.0 is installed**
1	Inadequate wash cycle can result in salt buildup on the induction heater (IH) assembly which can reduce sample pipettor wash performance, increasing the risk of sample carryover.	There is the potential for incorrect results to be generated from potential sample carryover. As of issuance of this letter, there have been no reported occurrences of impact to patient management.	Perform the *Weekly maintenance procedures (i-series) 2630 Manual Wash Cup Cleaning (i-series)* per Section 9 of the Alinity ci-series Operations Manual.
2	Small changes in Relative Light Units (RLU) values may occur if a sample's reading coincides with another RV being inserted. This occurs because RV loading moves the process path disk, altering RV alignment at the optics and affecting RLU measurements.	There is the potential for incorrect results to be generated from RLU shift. As of issuance of this letter, there have been no reported occurrences of impact to patient management.	Your Abbott Field Service Representative will contact you to schedule installation of software version 3.7.0.
3	When a new reagent cartridge is loaded, it undergoes mixing before sampling. Sampling should occur after 300 seconds but can occur after 200 seconds, potentially reducing reagent homogeneity and affecting sample-reagent interaction.	Due to reduced mixing time, there is potential for incorrect results to be generated if interaction between the sample and reagent is compromised. As of issuance of this letter, there have been no reported occurrences of impact to patient management.	Your Abbott Field Service Representative will contact you to schedule installation of software version 3.7.0.

Appendix A – Necessary Actions (Continued)

This potential issue impacts the Alinity c Processing Module only.			
#	**Issue Description**	**Impact to Donor/Patient Results**	**Necessary Actions required until software version 3.7.0 is installed**
4	The Alinity c Processing Module may have a R1 or R2 pipettor probe movement restriction but not report the expected message codes *5744 R1 pipettor movement restricted at (0) position (1)* and *5745 R2 pipettor movement restricted at (0) position (1).* In this case, the R1 or R2 pipettor probe may be bent from the contact and system will continue processing and the operator is unaware of the condition.	There is the potential for incorrect results when insufficient reagent is dispensed into a sample due to a bent pipettor. As of issuance of this letter, there have been no reported occurrences of impact to patient management.	It is recommended to perform the *Pipettor diagnostic procedures (c-series) 4109 Probe Alignment Test (c-series)* daily for R1 and R2 pipettor probes per Section 9 of the Alinity ci-series Operations Manual until software version 3.7.0 is installed. If you observe a bent pipettor probe (R1, R2), perform the component replacement procedure, *Replace the reagent probes (c-series)* per Section 9 of the Alinity ci-series Operations Manual.