CORE DIAGNOSTICS
Abbott Laboratories
1915 Hurd Drive
Irving TX, 75039 USA

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

Urgent Field Safety Notice

Urgent Product Correction

Immediate Action Required

Date Issued September 27, 2024

Product

System Affected	List Number	Serial Number	UDI
ARCHITECT i2000SR Processing Module	03M74-01	iSR03435	(01)00380740006235(21)iSR03435

Dear Valued Customer,

The purpose of this communication is to inform you of an issue related to the ARCHITECT *i*2000SR Processing Module listed above.

Explanation

Abbott has investigated an occurrence where an aspiration error code was not generated on the Alinity i Processing Module due to an incorrect Pressure Monitoring (PM) algorithm value. As a part of this investigation, Abbott evaluated all of our systems and available AbbottLink[1] data to assess potential impact to patient safety. Based on this analysis, we have identified that a PM algorithm on your system had an incorrect value after installation, which then failed to properly flag results with aspiration errors. Assay results were therefore not sent to exception and could have been impacted.

In reviewing available data for your instruments obtained via AbbottLink, we found that the algorithm on your system had an incorrect value for a period of time.

Our systems have additional methods for detecting potential sample or reagent integrity issues, including read validity checks, reagent volume tracking and calibration validity checks, which are not impacted by this issue.

Impact on Patient Results

There is a potential for incorrect results when sample results with aspiration errors were not flagged and sent to exception.

[1]Abbott's AbbottLink software only collects operational and instrument data. It does not gather or access patient, sensitive health or other identifiable personal information ("Personal Data"). For the complete AbbottLink data usage statement, please refer to your current system operations manual

Necessary Actions to be Taken by Customer	Based on the data collected from AbbottLink, Abbott Medical Directors have suggested a subset of assay results, which may require further review due to the potential impact to patient management. Your Abbott representative will provide you with detailed information regarding results generated during the impacted time period. Please review this letter with your medical team or healthcare providers. It is the responsibility of the laboratory to follow your policies and quality system in determining the scope of a retrospective review and potential need for re-testing within the clinical context of each patient. Please also complete and return the Customer Reply Form and 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, or if you have experienced any patient or user injury caused by this issue, please contact your local area Customer Service

Abbott continuously strives to ensure patient safety by providing you with high quality diagnostics products and solutions. We are evaluating options to prevent such occurrences in the future. We apologize for any inconvenience this may cause your laboratory.