Abbott Laboratories
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CORE DIAGNOSTICS

Single Registration Number (SRN): N/A

Urgent Field Safety Notice
Urgent Product Correction

Immediate Action Required

Date Issued September 29, 2021

Product

Product Description	List Number	Serial Number	US UDI	EU UDI
ARCHITECT i1000SR	1L86 1L87	See Attachment A	N/A	N/A
ARCHITECT i2000SR	3M74			
ARCHITECT i2000	1G17 8C89			
ARCHITECT c4000	2P24 1P86 1R24 1R25			
ARCHITECT c8000	1G06			
ARCHITECT c16000	3L77			

Explanation

Abbott has identified three potential performance issues for the ARCHITECT Software version 9.41 and earlier. Abbott is releasing ARCHITECT Software versions 9.45 and 9.50 to correct these issues (see details in **Appendix A**).

1. When an Error Code 3382, 'Unable to process test, internal wash pressure (x) error (y) pipettor' occurs, the ARCHITECT c4000 and the ARCHITECT c16000 are incorrectly placed into a 'Scheduled Pause' status rather than a 'Stopped' status. As a result, the processing module continues to process tests after the hardware error is detected. This may cause incorrect results to be generated.

2. When configuring a Calibrator Sample Volume on the Configure Assays screen, if the user selects multiple assays, the calibrator sample volume from one assay may be carried into the calibrator sample volume for another assay. Incorrect calibrator sample volumes have the potential to generate incorrect calibration curves which may lead to incorrect results and delay of results due to the need to reconfigure assay parameters.

3. When performing a backup on the ARCHITECT while the iARM is replenishing the wash buffer at the same time, the iARM loses communication with the System Control Center. The loss of communication may cause the wash buffer container to overflow. This has the potential to lead to physical and chemical hazards.

Impact on Patient Results	Refer to **Appendix A** for details concerning any patient results impacted due to the issues identified in ARCHITECT Software version 9.41 and earlier.
Necessary Actions to be Taken by Customer	Please follow the Necessary Actions required in **Appendix A** until software version 9.45 or software version 9.50 is installed. Your Abbott representative will schedule a mandatory upgrade of your ARCHITECT Software version 9.45 or ARCHITECT Software version 9.50 depending on your system configuration. 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 (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 – ARCHITECT software issues resolved in versions 9.45 and 9.50

ARCHITECT c			
	Issue	**Patient Results or Operator Safety Impact**	**Necessary Actions to be taken by the customer until mandatory upgrade is completed**
1.	When an Error Code 3382, 'Unable to process test, internal wash pressure (x) error (y) pipettor' occurs, the ARCHITECT c4000 and the ARCHITECT c16000 are incorrectly placed into a 'Scheduled Pause' status rather than a 'Stopped' status. As a result, the processing module continues to process tests after the hardware error is detected, and the tests may not have the necessary reagent dispenses from the pipettor with the error.	There is the potential to generate incorrect results on tests produced after an Error Code 3382.	Stop the processing module and discard any results produced after an Error Code 3382. Perform Corrective Actions for Error Code 3382. For detailed information, refer to ARCHITECT System Operations Manual, Section 10: Troubleshooting and diagnostics.
2.	When configuring a Calibrator Sample Volume on the Configure Assays screen, if the user selects multiple assays, the calibrator sample volume from one assay may be carried into the calibrator sample volume for another assay.	There is the potential to generate incorrect results if test results are obtained from a calibration curve that used incorrect calibrator sample volumes. There is the potential for delay of results when assay re-configuration is required.	Verify the correct calibrator sample volume is configured in the Configure assay parameters window – Calibration Volumes view by comparing to the assay specific assay parameters page in the Instructions for Use (IFU) for each assay. If the assay parameters page is not available in the IFU, contact your area customer support. Do this for all chemistry assays on your menu. When configuring Calibrator Sample Volumes from the Configure Assays Parameters screen, only select a single assay. Note: Do not select multiple assays. For detailed information, refer to ARCHITECT System Operations Manual, Section 2: Installation procedures and special requirements; *Configuring Abbott assays* and *Configuring user-defined assays*.

ARCHITECT i			
3.	When performing a backup on the ARCHITECT while the iARM is replenishing the wash buffer at the same time, the iARM loses communication with the System Control Center. The loss of communication may result in the wash buffer container to be overfilled and overflow. This has the potential to lead to physical and chemical hazards.	There is a potential for chemical or physical (slip/fall) hazards if the wash buffer container overfills. The Concentrated Wash Buffer contains 5-Bromo-5-nitro-1,3-dioxane, which may produce an allergic reaction when in contact with skin. It also contains sodium azide which is classified as harmful by ingestion.	Before performing a system backup, verify that the iARM is not in the process of replenishing the wash buffer. View the Supply Status Screen to confirm that *FILL IN PROGRESS* does not display for the Wash Buffer. For detailed information, refer to ARCHITECT System Operations Manual, Section 5: Operating instructions; *Verify supply and waste inventory*.