CORE DIAGNOSTICS

ABBOTT S.r.l
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Single Registration Number (SRN):
IT-MF-000026893

Product Correction

Immediate Action Required

Date Issued December 5, 2024

Product

Product Description	List Number (LN)	Serial Number	UDI
AlinIQ AMS 3.02	03R89-63	See Attachment A	(01) 00380740202736 (10) 3.02 (240) 03R8963

Explanation

Abbott has identified a potential performance issue with the AlinIQ AMS software version 3.02.

Analyzer flags are not being transmitted when validated results are sent to Laboratory Information System (LIS). This issue is only applicable if your laboratory utilizes analyzer flags within your LIS to manage patient samples and results.

To correct this issue, Abbott is releasing an update to the AlinIQ AMS 3.02. Your Abbott representative will contact you to schedule the mandatory installation of the AlinIQ AMS 3.02 1+, which is anticipated in Q1 2025.

Impact on Donor/Patient Results

The results transmitted to the LIS are accurate. However, the corresponding analyzer flags will not be available even if the LIS is capable of displaying and utilizing analyzer flags. As such, there is the potential for incorrect evaluation of the sample and results in the LIS causing the potential for incorrect results. This could also lead to a delay in results.

At time of issuance, there are no documented cases of impact to patient management.

Necessary Actions to be Taken by Customer

If your laboratory utilizes analyzer flags within your LIS to manage patient samples and results, check AMS or analyzer reports for sample and results flags until the AlinIQ AMS 3.02 1+ is installed on your system.

Complete and return the Customer Reply Form.

If you have additional locations that access AlinIQ AMS 3.02, please inform them of this Product Correction and provide them with 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 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.