Abbott Laboratories
1921 Hurd Drive
Irving, Texas 75038 USA

CORE DIAGNOSTICS

Single Registration Number (SRN): US-MF-000017778

Urgent Field Safety Notice

Urgent Product Correction

Immediate Action Required

Date Issued April 28, 2022

Product

Product Description	List Number (LN)	Serial Number	US / EU UDI
Alinity s System	06P16-01	Refer to Attachment B	

Explanation

Abbott has identified a potential issue with Alinity s System software versions 2.8.0 and prior. Abbott is releasing Alinity s System software version 2.8.1 (LN 04U76-16) to correct this issue. The potential exists for the assay Quality Control (QC) requirement to be bypassed for the first use of an Alinity s HBsAg Confirmatory Reagent Kit (LN 06P03). This event can occur if

- the QC run includes the Alinity s HBsAg Reagent Kit (LN 06P02), and
- the QC run is already in-progress, and
- a newly introduced Alinity s HBsAg Confirmatory Reagent Kit is loaded onto the reagent carousel, and
- the Alinity s HBsAg screening assay calibration status has transitioned to *QC in Process*.

If all the above occur, the Alinity s HBsAg Confirmatory assay calibration status will incorrectly indicate *QC in* Process; although, assay QC has not been scheduled for the newly onboarded Alinity s HBsAg Confirmatory Reagent Kit. Once the initial onboarding to the reagent carousel is completed and the reagent kit barcode has been scanned and recorded into the reagent inventory, all subsequent uses of the Alinity s HBsAg Confirmatory Reagent Kit will perform as intended and require assay QC to be performed, minimally, every 24 hours when the Alinity s System is in use.

In addition to resolving the issue described above, Alinity s System software version 2.8.1 addresses the R1 probe wash cycle programming error communicated via FA03FEB2022, FA03FEB2022 Revision 01, PI1002-2022 or PI1003-2022.

Impact on Donor / Patient Results

There is potential for incorrect Alinity s HBsAg Confirmatory donor / patient results if required QC is not performed as stated within the Alinity s HBsAg Confirmatory Reagent Kit Instructions for Use (IFU).

Necessary Actions to be Taken by Customer

Your Abbott representative will be scheduling a mandatory upgrade of your Alinity s System to install Alinity s System software version 2.8.1. Installation of Alinity s System software version 2.8.1 will become available as Abbott receives country-specific approval to distribute the updated software in each country. Please refer below for the necessary actions to follow when utilizing the Alinity s System prior to the software v2.8.1 upgrade.

When introducing a new Alinity s HBsAg Confirmatory Reagent Kit onboard the reagent carousel,

- Check the reagent inventory screen prior to initiating a QC run.
- Load all required assay kits needed to process the QC run.
- Ensure all required quantities of Alinity s HBsAg Confirmatory Reagent Kit cartridges are loaded prior to initiating the QC run.
- If determined while the QC is in-process that a second Alinity s HBsAg Confirmatory Reagent Kit cartridge is needed, wait until the QC run has completed prior to loading a new Alinity s HBsAg Confirmatory Reagent Kit cartridge.
- Verify QC has been processed and is within expected target range before releasing test results.

Please review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported test results.

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 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, 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.