Abbott Laboratories
1921 Hurd Drive
Irving, Texas 75038 USA

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

CORE DIAGNOSTICS

Urgent Field Safety Notice

Urgent Product Correction

Immediate Action Required

Date Issued April 28, 2022

Product

Product Description	List Number (LN)	Serial Number/ Lot Number	US / EU UDI
Alinity s System	06P16-01	Refer to Attachment A	
Alinity s HIV Ag/Ab Combo Reagent Kit*	06P0155	29500BE00	(01)00380740102982(17)220504(10)29500BE00
		31187BE00	(01)00380740102982(17)220629(10)31187BE00
		32548BE00	(01)00380740102982(17)220806(10)32548BE00
		34351BE00	(01)00380740102982(17)221129(10)34351BE00
		35406BE00	(01)00380740102982(17)230102(10)35406BE00
		37452BE00	(01)00380740102982(17)230301(10)37452BE00
		38494BE00	(01)00380740102982(17)230401(10)38494BE00

*Legal Manufacturer is Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany. SRN DE-MF-000009455.
NOTE: This communication applies to Alinity s HIV Ag/Ab Combo Reagent Kit lots listed above and all future lots.

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, the 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.

Explanation continued

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 or PI1001-2022, or PI1002-2022. The investigation also included a projected performance analysis for HIV Ag/Ab Combo when running on the same processing lane as the Anti-HCV II assay (LN 04W5655). Abbott has updated the Alinity s Anti-HCV II assay file 260_007 (LN 04W56-1C) to automatically separate the Anti-HCV II and HIV Ag/Ab Combo assays by processing lane.

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).
- There is potential for falsely reactive Alinity s HIV Ag/Ab Combo test results if the assay is run on the same processing lane as the Alinity s Anti-HCV II assay.

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.

Alinity s HBsAg Confirmatory Assay

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.

Alinity s System R1 Probe Wash Software Programming Error Investigation and follow-up to FA03FEB2022, PI1001-2022, PI1002-2022

The investigation for the R1 probe wash cycle software programming error included a projected performance analysis for HIV Ag/Ab Combo when running on the same processing lane as the Anti-HCV II assay. The prospective analysis could not entirely exclude that single replicates may be falsely reactive upon return to the correct R1 probe wash cycle. Based on the prospective analysis, Abbott has updated the Alinity s Anti-HCV II assay file 260_007 (LN 04W56-1C) to automatically separate the Anti-HCV II and HIV Ag/Ab Combo assays by processing lane. The Anti-HCV II assay file 260_007 is required to be installed on your Alinity s System.

Necessary Actions to be Taken by Customer continued

Please refer to the following until your system can be upgraded to Alinity s System software v2.8.1 and the Anti-HCV II assay file 260_007 is installed.

If Operating with Alinity s System software v2.7.1 or v2.8.0…	Then…
The Alinity s Anti-HCV II assay is not calibrated and run on the same processing lane as the Alinity s HIV Ag/Ab Combo assay.	Maintain the current assay configuration and ensure the Alinity s HIV Ag/Ab Combo assay is not run on the same processing lane as the Alinity s Anti-HCV II assay. Install v2.8.1 Alinity s System software and Anti-HCV II assay file 260_007 when country approval to install has been obtained.
The Alinity s Anti-HCV II assay and the Alinity s HIV Ag/Ab Combo assay are calibrated and run on the same processing lane.	Contact your local area customer service representative to assess the configuration and uninstall/reinstall the assays to run on separate processing lanes or instruments. Install v2.8.1 Alinity s System software and Anti-HCV II assay file 260_007 when country approval to install has been obtained.

Abbott is releasing the Alternate Wash Delivery System (AWDS) hardware upgrade for the Alinity s System that will be installed based on the assay menu to mitigate the need for lane separation.

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, please contact your local area Customer Service.

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.