Abbott Laboratories
1921 Hurd Drive
Irving, Texas 75038
USA

Single Registration Number (SRN): N/A

CORE DIAGNOSTICS

Urgent Field Safety Notice

Urgent Product Correction

Immediate Action Required

Date Issued February 3, 2022

Product

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

Explanation

Abbott has identified an error associated with the reagent probe (R1) wash cycle introduced in the Alinity s System software (SW) version 2.8.0. The wash cycle removes fluid that remains on the interior and exterior surfaces of the probe at the wash station. The R1 probe wash is utilizing 1 mL versus the intended 3 mL of wash buffer to wash the exterior of the R1 probe.

As a result of this error, while operating Alinity s System software version 2.8.0, LN 04U76-15, there is potential for false reactive Alinity s HIV Ag/Ab Combo test results when Alinity s HIV Ag/Ab Combo Reagent Kit, LN 06P0155, and the Alinity s Anti-HCV II Reagent Kit, LN 04W5655, are calibrated and run on the same processing lane.

Impact on Donor/Patient Results

There is potential for incorrect Alinity s HIV Ag/Ab Combo test results should the initial and retest results be falsely reactive. For other assays, although there is potential for incorrect test results should the initial and retest results be falsely reactive, there have been no reports of falsely reactive results associated with this event. There is no potential for incorrect nonreactive results.

Necessary Actions to be Taken by Customer

Please perform the necessary immediate actions, if utilizing the Alinity s HIV Ag/Ab Combo and Alinity s Anti-HCV II assays while operating on Alinity s System SW version 2.8.0, to continue to use the Alinity s System. These actions mitigate potential impact for false reactive results when using the Alinity s HIV Ag/Ab Combo Reagent kit.

Necessary Actions to be Taken by Customer continued

If utilizing Alinity s System SW version 2.8.0	Then…
The Alinity s HIV Ag/Ab Combo and Alinity s Anti-HCV II assays are not installed or do not run on the same Alinity s System.	No action is required.
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.
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.

If utilizing Alinity s System SW version 2.7.1 or prior, no further action is required.

Abbott is developing a software update and will communicate when it is available.

A complaint review and analysis of available data on the Alinity s System software version 2.8.0 was completed. There was no indication of incorrect test results attributable to the conversion from the Alinity s System software version 2.7.1 to version 2.8.0 for any assay other than Alinity s HIV Ag/Ab Combo.

Please review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported Alinity s HIV Ag/Ab Combo assay test results while operating on Alinity s System SW version 2.8.0.

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.