Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden, Germany

Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

Date Issued June 18, 2020

Product

Product Name: Alinity h-series (Alinity hq Analyzer and Alinity hs Slide Maker Stainer Module)
List Numbers: 09P68-01 and 09P69-01
Serial Numbers: All
UDI Number: Not applicable

Abbott has identified the following issues in Software Version 4.2 and below, which will be corrected in Software Version 4.3 which is scheduled to be released in September 2020.

	ISSUE	DESCRIPTION	Patient Results or Operator Safety Impact	Necessary Actions required until Mandatory Upgrade to SW 4.3 is Completed
1	Halt Mode	On the Alinity hq, software versions 4.0, 4.1 and 4.2, if a sample is being processed at the same time as a halt mode condition is triggered, the System Message "Sample was Processed in Halt Mode" is generated. Along with this message, "INVALID DATA" is displayed on the "Reportable" tab of the results on the SCC, however the system does not invalidate any numerical results and will transfer the results to the LIS with a flag indicating the "Sample was processed in halt mode".	There is the potential for incorrect results for samples processed in halt mode associated with specific halt triggers. These triggers are MCHC out of range, three consecutive short samples and two consecutive probe obstructions. Samples with potentially incorrect results may not be identified if their results are reviewed only on middleware or LIS.	Samples with the "Sample processed in halt mode" system message or flag for the reasons described should be rerun. Reruns can be programmed as a rule in the middleware or LIS (if used). In Software Version 4.3, samples with potentially incorrect results due to being processed in halt mode for the specific triggers will have their numerical results invalidated and should be rerun.

	ISSUE	DESCRIPTION	Patient Results or Operator Safety Impact	Necessary Actions required until Mandatory Upgrade to SW 4.3 is Completed
2	Falsely Elevated nRBC Results	On the Alinity hq, software versions 4.2 and below, when a sample with a high absolute Lymphocyte count (>30.0 x 10e9/L) is processed, it may result in a falsely elevated nRBC count in the subsequent two samples. Such samples are not currently identified by the existing "WBC carryover" alert.	There is the potential for incorrect results. Falsely elevated nRBC results may be generated for up to two samples following the testing of a specimen with a high absolute Lymphocyte count (>30.0 x 10e9/L).	Continue following your internal procedures for reviewing nRBC results. Examine any nRBC result that is > 0.0 x 10e9/L and identify the two samples that immediately preceded the sample. If any of these samples have an absolute Lymphocyte count of >30.0 x 10e9/L, the nRBC results should not be reported, and the sample should be rerun. In Software Version 4.3, impacted samples as described above will be flagged with the "WBC carryover" alert and the nRBC results will be invalidated. The flagged samples should be rerun. Reruns can be programmed as a rule in the middleware or LIS (if used).

Software Version 4.3 will address the following issue previously described in Product Correction Letter FA11SEP2019 or PI-P 80002948-101. The performance of actions described in these letters for this issue will no longer be necessary after your Alinity h-series has been updated with Software Version 4.3.

	ISSUE	DESCRIPTION	Patient Results or Operator Safety Impact	Necessary Actions required until Mandatory Upgrade to SW 4.3 is Completed
3	Rack is Not Ejected After Exceeding 5 Cap Piercings	On the Alinity h-series, the cap pierce count is reset when a module goes to idle. This could lead to possible coring. This issue could lead to incorrect results	There is the potential for incorrect patient results. Should a cap be pierced more than 5 times, cap fragmentation (coring) can potentially lead to incomplete or partial aspiration as the cores may obstruct the sample probe.	During typical workflows, the cap is not expected to be pierced more than 5 times. However, if you are running a workflow where samples may need to be pierced more than 5 times, ensure the sample vial cap is replaced after the fifth piercing.

Necessary Actions	• Please complete the included Abbott Customer Reply Form. • 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. • An Abbott representative will be contacting you to schedule a software update. • Please retain this letter for your laboratory records.
Contact Information	We sincerely regret any inconvenience this may cause your laboratory. If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service. If you have experienced any patient or user injury associated with the Field Action, please immediately report the event to your local area Customer Service.