Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden, Germany

Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

Date Issued: September 11, 2019

Product

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

Abbott is releasing a software update, Software Version 4.0, and associated hardware changes, and an updated Operations Manual (80000023-107). This release addresses issues identified for the Alinity hq and Alinity hs Software Version 3.0 and below, Alinity h-series Operations Manual (80000023-106, 2018-10-08), and select hardware.

Section A. While Software Version 4.0 addresses several issues that are detailed later within this letter (refer to Section B and Section C), we are informing you of 4 new issues, detailed below, which will require necessary actions to be performed even after the installation of Software Version 4.0.

	ISSUE	DESCRIPTION	System Impacted	Patient Results or Operator Safety Impact	Necessary Actions required even after SW 4.0 Mandatory Upgrade
1)	% Reticulated Platelets (%rP)	During the CBC+DIFF+RETIC test the %rP may be falsely elevated due to incorrect inclusion of WBC events under certain circumstances.	Alinity hq	There is the potential for incorrect patient results. The %rP can be falsely elevated.	For cases where the WBC results are greater than 10.0 x 10^9 cells/L and PLT results are less than 30.0 x 10^9 cells/L, please review the results per your laboratory procedures.
2)	Absolute Immature Granulocytes (IG) and % Immature Granulocytes(%IG)	The absolute and relative (%) concentration of IG may be falsely elevated in rare occasions due to abnormal signal saturation.	Alinity hq	There is the potential for incorrect patient results. The absolute IG and %IG can be falsely elevated.	If %IG results are greater than 2%, please review the results per your laboratory procedures. A manual smear review must be performed to confirm the results.

	ISSUE	DESCRIPTION	System Impacted	Patient Results or Operator Safety Impact	Necessary Actions required even after SW 4.0 Mandatory Upgrade
3)	Rack is Not Ejected After Exceeding 5 Cap Piercings #1	The cap pierce count for patient samples is reset when a module goes to idle. This could lead to possible coring.	Alinity hq, Alinity hs	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. If you are running any workflow that may require more than 5 piercings, ensure your sample vial cap is replaced after five piercings.
4)	Front Cover	The front cover will fall if released from a partially open position.	Alinity hq, Alinity hs	There is the potential for operator safety impact and physical injury if the front cover is not rested against the top of the analyzer, as the cover may fall from the open position.	When opening the instrument cover, ensure that the cover rests against the top of the instrument.

Section B. Software Version 4.0, Operation Manual (80000023-107) and hardware upgrades will address issues previously described in the Product Correction Letters listed below. The performance of actions described in these Product Correction Letters will no longer be necessary after your Alinity h-series has been updated with Software Version 4.0, hardware upgrades completed, and you've received and reviewed the latest copy of the Operations Manual (80000023-107).

	ISSUE	DESCRIPTION	System Impacted	Patient Results or Operator Safety Impact	Necessary Actions required until Mandatory Upgrade to SW 4.0 is Completed
1)	Product Correction Letter FA26OCT 2017, dated 26 October 2017	WBC reagent stain is being gradually degraded (adsorbed) by the analyzer's fluidic system (e.g. tubing) which reduces available stain and affects results for high WBC concentration specimens. Software Version 4.0 and new hardware tubing addresses this issue and allows for a reduction in the frequency of flushing.	Alinity hq	There is the potential for incorrect results. Patient samples with very high WBC counts could have a reduction of greater than 70%.	Software Version 3.0, 2.0.1 and 2.0 automatically flushes reagent through the tubing to reduce the risk of WBC reagent stain adsorption into the tubing.

	ISSUE	DESCRIPTION	System Impacted	Patient Results or Operator Safety Impact	Necessary Actions required until Mandatory Upgrade to SW 4.0 is Completed
2)	Product Correction Letter FA27AUG 2018, dated 27 August 2018	Mean Cell Volume (MCV) may be biased for MCV values above approximately 105 femtoliters (fL) and below approximately 70 fL. This can occur after one or more calibration events. The calculated parameters, Hematocrit (HCT) and Mean Corpuscular Hemoglobin Concentration (MCHC), may also be impacted. Software Version 4.0 will allow the user to calibrate MCV per the Alinity h-series Operations Manual Section 6: Calibration Methods (Alinity hq).	Alinity hq	There is the potential for incorrect results. Patient samples with MCV values greater than approximately 105 fL or less than 70 fL may show a bias of ≥5% or 4 fL whichever is greater. If MCV shows a bias, HCT and MCHC will also be impacted as these parameters are calculated using MCV.	Continue to follow Section 6: Calibration Methods (Alinity hq) until updates are completed.
3)	Product Correction Letter FA07FEB 2019, dated 07 February 2019	Patient sample results with an "MCHC Out of Range. Check Sample Integrity" flag on the Alinity hq analyzer may indicate that the patient sample contained a clot. If the analyzer is not halted by the user, the system will continue to process samples and subsequent results may be impacted but not flagged. For Software Version 3.0 and below, the user is instructed to check the sample for clots after the flag is triggered, run AutoClean if clot is confirmed, run background and QC and then retest samples run after the flag. Software 4.0 and a new hardware sensor will enable halt mode for this flag.	Alinity hq	There is the potential for incorrect results. CBC results that are generated following the aspiration of a clot may be incorrect (falsely decreased).	Continue to follow actions defined in the Product Correction Letter or Product Information Letter dated January 2019 until updates are completed.

	ISSUE	DESCRIPTION	System Impacted	Patient Results or Operator Safety Impact	Necessary Actions required until Mandatory Upgrade to SW 4.0 is Completed
4)	Product Correction Letter FA28FEB 2019, dated 28 February 2019	The safety interlock covering the septum piercing probes may not deploy when a 1-liter bottle is removed from the Alinity hq and Alinity hs instruments. The septum piercing probe could cut or puncture the user's hand. A new CAUTION: Sharp Element label will be applied to the reagent drawers by Abbott Service. The CAUTION: Sharp Element label has also been added in the Alinity h-series Operations Manual (80000023-107).	Alinity hq, Alinity hs	There is the potential for operator safety impact, physical injury and chemical exposure if the septum piercing probes cut or puncture the user's hand. As there may be residual bulk solution in the area, this could expose the user's unprotected skin to the bulk solution.	Continue to follow the instructions provided in the Alinity h-series Operations Manual when replacing bulk solutions. Your Abbott representative will be contacting you to schedule the placement of a new safety hazard label CAUTION: Sharp Element.
5)	Product Correction Letter FA29MAR 2019, dated 29 March 2019	The Alinity hq Analyzer incubation paddle may cause "Step Loss on Axis" errors (Error Code 5874) and foaming of the reagent in the incubation cup. Software Version 4.0 will improve the acceleration of the paddle to reduce the number of step loss errors.	Alinity hq	There is a potential for delay in the generation of patient results due to the increase in step loss on axis errors. There is potential impact to patient results due to the foaming of the reagent in the incubation cup.	Abbott continues to monitor and replace the paddles until the new paddle design is released.

Section C. The following additional issues were identified in Software Version 3.0 and will be corrected in Software Version 4.0, Operations Manual (80000023-107) and hardware upgrades.

	ISSUE	DESCRIPTION	System Impacted	Patient Results or Operator Safety Impact	Necessary Actions required until Mandatory Upgrade to SW 4.0 is Completed
1)	Rack Transport During Servicing	When there are two or more Alinity hq analyzers in an integrated system, if one analyzer is processing routine samples while another analyzer is undergoing sample processing for precision, carryover or Abbott servicing procedures, **and** the Specimen ID (SID) of the tubes in the rack matches the Order ID on the analyzer being serviced, the rack with patient samples can be transported and processed on the analyzer being serviced.	Alinity hq	There is the potential for incorrect results. Patient sample tubes are transported and processed on an analyzer that has not been verified to release results. There is also a potential for delay in generation of patient results.	If running precision, carryover or undergoing Abbott servicing, ensure the SID numbers used for these procedures are unique.
2)	Incorrect Calibration Factor	During whole blood calibration, if the user views dilution factor runs (changes the screen), the calibration factors are calculated incorrectly using the dilution factors instead of the current calibration factors.	Alinity hq	There is the potential for incorrect results. Quality Control (QC) results as well as patient sample results could shift.	While setting the calibration factors, do not view the dilution factors until calibration is completed.
3)	No Halt Condition Triggered	During closed-tube processing, if QC samples are processed and there is a communication loss between the Alinity hq Analyzer and the System Command Center (SCC), a halt condition may not be triggered for a QC limit or Westgard violation.	Alinity hq	There is the potential for incorrect results. Patient results may be processed prior to the QC results being reviewed.	Confirm that QC results are within the acceptable limits before patient results are reported as described in Section 11 Guidelines for Control Use (Alinity hq) of the Alinity h-series Operations Manual.
4)	Rack is Not Ejected After Exceeding 5 Cap Piercings #2	The cumulative cap pierce count is not tracked when a sample is transported from one module to another module and a new order is added after the transport has begun. This could lead to possible coring.	Alinity hq, Alinity hs	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. If you are running any workflow that may require more than 5 piercings, ensure your sample vial cap is replaced after five piercings.

	ISSUE	DESCRIPTION	System Impacted	Patient Results or Operator Safety Impact	Necessary Actions required until Mandatory Upgrade to SW 4.0 is Completed
5)	No Manual Background After Maintenance	When there are two or more Alinity hq analyzers in an integrated system, if a sample is sent from one analyzer for retest to another analyzer that is near the end of maintenance, the user is unable to perform a manual background before the retest is processed.	Alinity hq	There is the potential for incorrect results. Patient results may be processed prior to checking the background level; therefore, background events could impact patient sample results.	Ensure that background runs are completed after maintenance and prior to running patient results as described in Section 9 Maintenance Procedures of the Alinity h-series Operations Manual.
6)	Retest	Retest orders are not processed as STAT when the original order is STAT or routine.	Alinity hq	There is a potential for delay in generation of patient results for the retest as it is processed with no priority.	Retest is only handled as Routine and not handled as STAT.
7)	“INVALID DATA” on Result Details Screen for Results Outside the AMR	When a result is outside the AMR (Analytical Measurement Range), it is appropriately flagged with an asterisk; however, the system will incorrectly display "INVALID DATA" in red text on the "Result Details" screen.	Alinity hq	No patient results or operator safety impact.	Refer to descriptions of display status flags for numerical results outside the AMR described in Section 3, Calculation and Display Status Flags (Alinity hq) of the Alinity h-series Operations Manual. Results outside of the AMR are transmitted to the LIS/Middleware when the transmission of "Alerted Patient Results" is enabled.
8)	Unable to Print QC Results	If a QC file is created using the "SAVE/NEXT" button in the "CREATE QC FILE" flyout, the Print Option or the Print to File Option is not available in the QC results screen for that QC file.	Alinity hq	No patient results or operator safety impact.	View the QC file or export the QC file if a hardcopy is needed. Export the QC results to a .csv file and print.
9)	Barcode Exceeding 9 Characters	If a non 2D format barcode is applied to the calibrator vial, the handheld barcode scanner will only populate the lot number field with first 9 characters from the barcode.	Alinity hq	No patient results or operator safety impact.	Ensure that the lot number for the calibrator does not contain more than 9 characters.
10)	Missing Corrective Action Text	In the Alinity h-series Operations Manual, Message Code 3312 “Vacuum pressure timeout” incorrectly states “No corrective action is required”.	Alinity hq, Alinity hs	No patient results or operator safety impact.	When you receive Message Code 3312, “Vacuum pressure timeout”, cycle power to the module (page 334). If the error continues, contact Customer Service. Provide information about the operation that was attempted when the error occurred.

	ISSUE	DESCRIPTION	System Impacted	Patient Results or Operator Safety Impact	Necessary Actions required until Mandatory Upgrade to SW 4.0 is Completed
11)	Prioritization of Reflex Tests	The Reflex sampling priority is not prioritized as a high priority equivalent to a STAT test.	Alinity hs	No patient results or operator safety impact.	Reflex is only handled as Routine and not prioritized as STAT.
12)	Missing Explanation of "+" Character	On the Alinity hs analyzer, if the Specimen ID (SID) exceeds the printable space on the slide, the SID is truncated and appends a "+" character to indicate that the field was truncated.	Alinity hs	No patient results or operator safety impact.	Ensure that the number of characters for the SID does not exceed the printable space.
13)	Incorrect Diluent Cubitainer On-line Help (OLH) Replacement Sequence	The sequence of steps in the On-line Help (OLH) for replacing the Diluent Cubitainer is incorrect.	Alinity hq	No patient results or operator safety impact.	Perform Steps 10-12 in the following order: · Step 12 · Step 11 · Step 10 Do not perform Step 13.
14)	Scheduled Maintenance Not Completed	In the On-Line Help (OLH), Message Code 2508: Maintenance overdue probable cause states "Scheduled maintenance not completed within one minute past the scheduled time" when it should state: "Scheduled maintenance not completed within five hours past the scheduled time".	Alinity hq, Alinity hs	No patient results or operator safety impact.	If you receive message code 2508: Maintenance overdue, ensure that the weekly maintenance is performed at the earliest convenience.

Necessary Actions

- Your Abbott representative will begin scheduling mandatory software, hardware, and Operations Manual upgrades starting in September 2019. Refer to the tables above for necessary actions until upgrades are completed on your system(s).
- When you receive the mandatory software upgrade, it may be necessary to download the Alinity h-series Operations Manual (80000023-107) for Software Version 4.0 onto a USB drive for use until the upgraded on-line help is installed. The Operations Manual is available by accessing the Technical Library through the Abbott Customer Portal.
- 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 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.