Abbott GmbH
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CORE DIAGNOSTICS

Urgent Field Safety Notice

Urgent Product Correction

Immediate Action Required

Date Issued May 5, 2022

Product

Product Description	List Number	Serial Number	US/EU UDI
Alinty hq Analyzer	09P68-01	See Attachment 1	
Alinity hs Slide Maker Stainer Module	09P69-01		

Explanation

Abbott Hematology is releasing new software version 5.0 for the Alinity h-series.

Issues in previous Product Correction Letters (see Table 1) or Product Information Letter (1035-2020), for software versions 4.3 and below that will be addressed with software version 5.0:

- % Reticulated Platelets (%rP)
- Absolute Immature Granulocytes (IG) and % Immature Granulocytes (%IG)
- Message Codes

The front cover safety issue previously specified in the Product Correction Letters (see Table 1) or Product Information Letter (1035-2020) is not associated with the software version 5. 0 upgrade. It will be addressed through a hardware update.

The Moving Average Programs Setup previously specified in a Product Correction Letter (see Table 1) or Product Information letter (1035-2020) is not associated with the software version 5.0 upgrade. Please continue to follow the instructions in the Necessary Actions to be Taken by the Customer.

Table 1

Issue	Product Correction Letter
% Reticulated Platelets (%rP)	FA11SEP2019
Absolute Immature Granulocytes (IG) and % Immature Granulocytes (%IG)	FA11SEP2019
Message Codes	FA04OCT2019
Front Cover	FA11SEP2019
Moving Average Programs Setup	FA11OCT2018 Revision 01

Impact on Patient Results

% Reticulated Platelets (%rP) – There is the potential for incorrect patient results. The %rP can be falsely elevated.

Absolute Immature Granulocytes (IG) and % Immature Granulocytes (%IG) – There is potential for incorrect patient results. The absolute IG and %IG can be falsely elevated.

Message Codes – There is no hazard or impact to patient results due to this issue

Impact on Patient Results - continued

Front Cover – 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.

Moving Average Programs Setup – There is a potential for delay in the generation of patient results due to the need for unplanned service.

Necessary Actions to be Taken by Customer

The performance of actions described in this letter for the above issues will no longer be necessary after your Alinity h-series has been updated with Software Version 5.0 except the Front Cover and Moving Average Program Setup issues.

The Front Cover issue will be addressed by a hardware update.

Software Version 5.0 does not address the Moving Average Program Setup therefore, actions for the Moving Average Programs Setup will need to be continued**.**

% Reticulated Platelets (%rP)

In software versions 4.3 or below, for samples 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 %rP results per your laboratory procedures.

In software version 5.0, samples with WBC results greater than 10.0 x 10^9 cells/L and PLT results less than 30.0 x 10^9 cells/L, will no longer require additional review outside of your normal laboratory procedures.

Absolute Immature Granulocytes (IG) and % Immature Granulocytes (%IG)

In software versions 4.3 or below, 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.

In software version 5.0, a new flag detects signal saturation that may cause elevated %IG results. Samples with %IG results greater than 2% that are not flagged will no longer require additional review outside of your normal laboratory procedures.

Message Codes

In software versions 4.3 or below, when Alinity h-series instruments are connected to a Laboratory Automation System (LAS), please follow the corrective actions below for the associated Analyzer Initiated Message (AIM) codes:

AIM Code and Corrective Action	
8078	Restart the System Control Center (SCC) and LAS.
8080	Restart the SCC.
8083	Restart the SCC.
8084	Restart the SCC and LAS.
8085	Restart the SCC and LAS.
8086	Restart the SCC.
8087	Restart the LAS.

Necessary Actions to be Taken by Customer – continued

For all message codes, if the error persists, please contact Customer Service and be prepared to provide information about the operation that was attempted when the error occurred. Should a loss of communication occur between the LAS and the Alinity h-series while samples are being transported from the LAS, samples can be manually transferred from the LAS to the Alinity h-series instrument for processing until the system has recovered.

Once the software version 5.0 update has been installed on your system, the following notifications instructions on how to resolve the issue are available in the Alinity h-series Operations Manual, or accessible via the online help (OLH):

AIM Code and Displayed Text	
8078	LAS communication error. Improper message acknowledgment.
8080	LAS communication error. LAS rejected the transmitted message.
8083	LAS internal communication error.
8084	LAS communication error. LAS receiver channel is unable to establish connection.
8085	LAS communication error. LAS sender channel is unable to establish connection.
8086	LAS message time-out error.
8087	LAS communication error. Unknown error occurred when the system transmitted data.

Front Cover
When opening the instrument cover, ensure that the cover rests against the top of the instrument. Please refer to Section 9 for additional precautions and hazard statements in the Alinity h-series Operations Manual (80000023-107).

Moving Average Programs Setup
The optical Moving Average Programs continuously monitor system performance. It is important that you do not adjust the Abbott Service Representative's setup. This setup allows for the detection of laser performance issues prior to the system becoming inoperable. If you receive message code 1801, you may continue to safely operate the Alinity hq analyzer but should contact your local Abbott Service Representative as soon as possible to schedule a maintenance visit.

An Abbott representative will be contacting you to schedule a software update when Software Version 5.0 or the Front Cover hardware update is available.

Please complete and return the 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.

Please 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.