Abbott GmbH
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DIAGNOSTICS

Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

Date Issued July 20, 2020

Product

Product Name: Alinity hq Analyzer
List Number: 09P68-01
Serial Numbers: See Attachment A
UDI Number: Not applicable

Explanation

This Product Correction letter is to inform you of a potential issue with the Alinity hq Analyzer which may impact the classification of White Blood Cell (WBC) subpopulations.

It has been observed that Eosinophils (EOS) may be misclassified as Neutrophils (NEU) for some samples on impacted Alinity hq systems. This can be seen when comparing the Polarized Side Scatter (PSS)/Depolarized Side Scatter (DSS) scatterplot (Fig. 1 and Fig. 2 below).

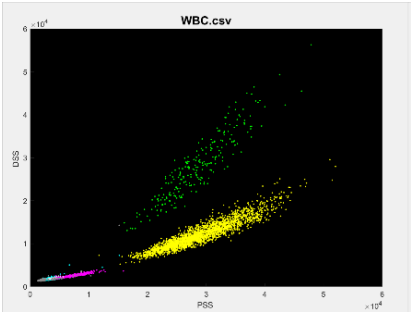

Fig 1. Expected NEU/EOS classification

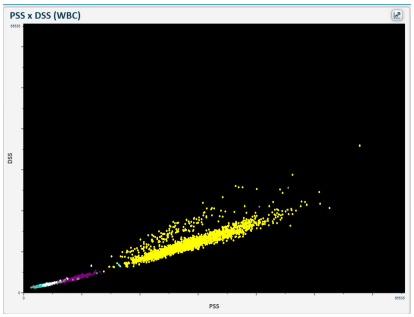

Fig 2. NEU/EOS misclassification

Patient Impact

There is potential impact to patient results. The absolute Eosinophil concentration (EOS) and Eosinophil percentage of WBCs may be underestimated and the absolute Neutrophil concentration (NEU) and Neutrophil percentage of WBCs may be overestimated by the same amount.

Necessary Actions	For cases where the reported eosinophil (EOS) concentration is below 0.140 $x10^9$/L, please review these results per your laboratory procedures and validate the result by another method if required. An Abbott representative will be contacting you to arrange an on-site service visit when replacement parts are available as they may be limited. If on-site verification confirms that your instrument is operating as expected, you can discontinue the review and validation of results as your laboratory procedures allow. Should verification testing indicate that your instrument is impacted, a replacement part will be required. Ensure that you have access to an alternate method of generating hematology patient results in the event that we are unable to immediately resolve the issue after on-site service verification. 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. Please retain this letter for your laboratory records.
Contact Information	If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Abbott 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 Abbott Customer Service.