



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).

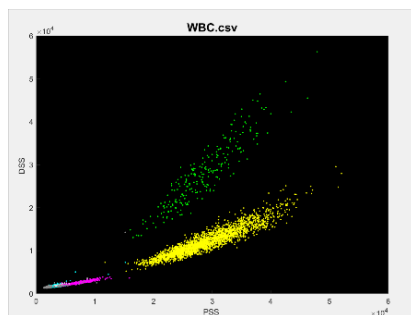


Fig 1. Expected NEU/EOS classification

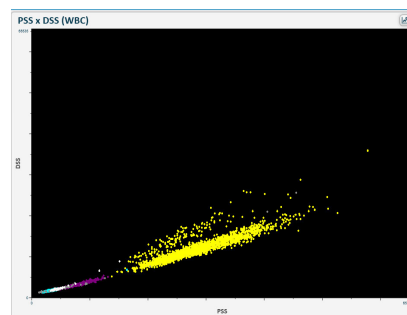


Fig 2. NEU/EOS misclassification

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 $0.140 \times 10^9/L$, 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.

Attachment A

hq00104	hq00115	hq00119	hq00126	hq00127	hq00130	hq00132	hq00145	hq00148
hq00157	hq00165	hq00168	hq00171	hq00191	hq00197	hq00202	hq00214	hq00232
hq00248	hq00254	hq00260	hq00263	hq00264	hq00276	hq00282	hq00301	hq00311
hq00322	hq00329	hq00334	hq00378	hq00379	hq00404	hq00412	hq00427	hq00440
hq00446	hq00458	hq00464	hq00477	hq00495	hq00519	hq00524	hq00527	hq00528
hq00530	hq00534	hq00535	hq00536	hq00537	hq00539	hq00540	hq00541	hq00543
hq00545	hq00546	hq00547	hq00548	hq00550	hq00551	hq00552	hq00553	hq00554
hq00557	hq00558	hq00561	hq00563	hq00565	hq00566	hq00567	hq00568	hq00569
hq00570	hq00571	hq00572	hq00573	hq00574	hq00575	hq00576	hq00577	hq00578
hq00579	hq00580	hq00581	hq00582	hq00583	hq00584	hq00651		