



Urgent Field Safety Notice
Product Correction
Immediate Action Required

Date Issued

October 5, 2017

Product

Product Name: Alinity hq Analyzer
List Number: 09P68-01
UDI Number: Not applicable
Serial Numbers: hq00102, hq00103, hq00105, hq00106, hq00107

Explanation

Abbott Hematology has identified the following potential issue with the Alinity hq Analyzer:

- White blood cell (WBC) counts may be over-estimated and nucleated red blood cells (NRBC) under-estimated in the presence of very high NRBC concentrations with very low WBC concentrations. This was identified on a specimen from a neonatal patient. The result was accompanied by variant lymphocyte and blast flags, together with a data invalidation flag for monocytes.
- Preliminary investigations indicate that this may have occurred due to the analyzer algorithm using WBC populations to determine the position of the NRBC population. In this case, the WBC concentration was very low and the analyzer misclassified both NRBC and WBC populations.

The cause for these performance issue is being further investigated.

Patient Impact

- Patient management could be impacted if WBC or NRBC counts are not validated prior to being reported to a healthcare provider. However, these types of specimens are expected to generate differential flags or data invalidations indicating an issue with the specimen prompting further review.

Necessary Actions

- While preliminary information suggests that these events may occur infrequently, our priority is to assure you of the integrity of your patient results. As such, the following actions are necessary:
 - Results for specimens that have WBC-related flags (e.g. VAR LYM or Blast

flags) or an invalidation flag for MONO should be validated by another method, including microscopic examination before any of the results are released to the healthcare provider.

- Ensure slides for neonatal patients upon first test are prepared in accordance with International Society for Laboratory Hematology recommendations.
- 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.
