



Product Correction

Immediate Action Required

Date Issued

June 25, 2018

Product

Product Name: Alinity hq Analyzer

List Number: 09P68-01

UDI Number: Not applicable

Serial Numbers: See Attachment A

Explanation

Abbott Hematology has identified a potential issue with the Alinity hq Analyzer. Reagent bottles are pierced by a needle assembly connected to an air line (tubing) that serves to vent reagents so that reagents will feed into their respective reagent supply lines. It was determined that liquid from a reagent bottle could leak through the check valve of the air line, which is connected to a common air tubing that is shared by other reagent air lines. This can result in cross-contamination of reagents and will impact the ability to process samples.

This issue is detected by Alinity hq Analyzer quality controls (QC). Therefore, patient results will not be impacted. If this issue occurs, one or more of the following will be observed: (a) background counts may fail for parameters such as hemoglobin and platelet; halting the system; (b) commercial control materials may recover out of range preventing use of system; and/or (c) parameters such as WBC will be consistently invalidated on test reports.

An improved venting system will be installed to prevent this issue.

Patient Impact

There is no impact to patient results. There is a potential for delay in generation of patient results due to failure of the venting system.

Necessary Actions

- Your Abbott representative will be contacting you to replace the vent system starting in July 2018.
- Until the improved vent system is installed on your Analyzer, continue to confirm that quality control results are within the acceptable limits before patient samples are run. If you experience the described issue, contact customer service for support.
- Ensure that you have a back-up instrument or an alternative method of generating hematology patient results should the instrument become inoperable.
- If you have forwarded the product listed above to other laboratories, please inform them of this product information and provide to them a copy of this letter.
- Please return the Reply Form and 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.
