



Urgent Field Safety Notice Product Correction

Immediate Action Required

Date Issued

August 31, 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 become aware that the Alinity hq Analyzer at your facility has a laser optics bench that may experience a laser power transmission loss. The cause for this gradual reduction in laser power transmission is being investigated. There are three potential issues associated with the laser power transmission loss if it continues without action:

1. Falsely decreased Mean Corpuscular Volume (MCV), Red Cell Distribution Width (RDW) and Hematocrit (HCT) parameters, and falsely increased Mean Cellular Hemoglobin Concentration (MCHC).
2. An unplanned service call for laboratory quality controls (e.g., laboratory established control values, moving averages) not staying within limits for impacted parameters could be required.
3. Alinity hq Analyzer could become inoperable requiring laser optics bench replacement.

As a result, laser power adjustments or laser optics bench replacement are required for maintaining optimal performance of the system.

Patient Impact

Internal data indicates that the laser power transmission from an optics bench may gradually decrease up to 2% per month with corresponding MCV, RDW, and HCT decreases of approximately 1.6%, 2.0% and 2.0% respectively, as well as MCHC increase of approximately 2.2%. Data indicates that no other parameters are impacted when there is up to a 5% decrease in laser power transmission. In addition, there is a potential for delay in generation of patient results due to the laser optics bench requiring unplanned service. Based on available information, previously generated patient results are not impacted.

**Necessary
Actions**

- As part of routine laboratory practices, use laboratory quality controls including laboratory established parameter ranges and moving averages to monitor system performance.
- Abbott will monitor your system's performance through Abbott Link and schedule planned service events to inspect, adjust or replace the laser optics bench before power transmission decreases approximately 3% or as you request.
- Ensure your laboratory has a back-up instrument or the ability to send samples to another location for processing if the Analyzer stops working prior to actions being taken.
- A software revision which will automatically monitor and compensate for the gradual reduction in laser power transmission is planned to be available in October 2017.
- 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.
