



Urgent Field Safety Notice
Product Correction
Immediate Action Required

Date Issued August 02, 2017

Product **Product Name:** Alinity hq Analyzer
List Number: 09P68-01
UDI Number: N/A
Serial Numbers:

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|---------|---------|---------|---------|---------|
| hq00102 | hq00103 | hq00105 | hq00106 | hq00107 |
|---------|---------|---------|---------|---------|

Explanation Abbott Hematology has become aware that the Alinity hq Analyzer at your facility has a tube handling robot that may experience an error or failure. Abbott's robot supplier has reported that a select number of robots may have internal wires/cables that were not properly routed and may wear prematurely due to normal mechanical movement.

The potential robot issue may result in the following message code and be unable to transport specimen tubes:

- 5850 – Gripper Error

If this or another message code occurs, troubleshooting is required in accordance with the Alinity h-series Operations Manual. If the reason for the message code or robot failure is related to this issue, the instrument will experience stoppage and require service (robot replacement) to continue.

Patient Impact There is no impact to patient results. Previously generated results are not impacted. However, there is a potential for delay in generation of patient results due to failure of the Alinity h-series robot.

- Necessary Actions**
- Your instrument may not be impacted; however, to reduce your risk of unscheduled downtime, an Abbott representative will be contacting you to schedule robot replacement on your instrument at no charge.
 - Ensure that you have a back-up instrument or the ability to send samples to another location for processing if the instrument stops working prior to robot replacement.
 - 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.