



## Urgent Field Safety Notice Product Correction

Immediate Action Required

### Date Issued

February 23, 2018

### Product

**Product Name:** Alinity hq Analyzer

**List Number:** 09P68-01

**UDI Number:** Not applicable

**Serial Numbers:**

|         |         |         |         |
|---------|---------|---------|---------|
| HQ00102 | HQ00121 | HQ00137 | HQ00162 |
| HQ00103 | HQ00122 | HQ00138 | HQ00165 |
| HQ00105 | HQ00126 | HQ00140 | HQ00166 |
| HQ00106 | HQ00127 | HQ00144 | HQ00167 |
| HQ00107 | HQ00128 | HQ00146 | HQ00168 |
| HQ00113 | HQ00130 | HQ00147 | HQ00169 |
| HQ00115 | HQ00132 | HQ00148 | HQ00171 |
| HQ00116 | HQ00133 | HQ00150 | HQ00172 |
| HQ00118 | HQ00134 | HQ00151 | HQ00173 |
| HQ00119 | HQ00135 | HQ00153 | HQ00181 |
| HQ00120 | HQ00136 | HQ00154 | HQ00182 |

### Explanation

Abbott Hematology has identified the following issue with Alinity hq Analyzer Software Version 1.0 and 2.0 when creating an open tube test order via the System Command Center (SCC) or through the Abbott Middleware System (AMS):

For open-tube processing only, the system will default to “Unspecified” gender (instead of using male or female) and apply the limits that the user may have established for the “Unspecified” gender type. If the user did not establish limits, there will not be annotations/flags for the “Unspecified” gender type, as the system defaults to the factory-established limits.

Results are generated correctly and data invalidation and morphological flagging are not impacted.

Software Version 2.0.1 will correct this issue.

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**Patient Impact**

Patient results are not impacted and there is no delay in patient results. This issue may result in the lack of flagging for gender-specific limits and could result in the incorrect interpretation of results.

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**Necessary  
Actions**

- Your Abbott representative will begin scheduling software upgrades (Software Version 2.0.1) starting in February 2018.
  - Until the software version 2.0.1 is installed on your system, review all open tube results as your established limits for the “unspecified” gender type may not meet your needs.
  - 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 retain this letter for your laboratory records.
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**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.

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