



Urgent Field Safety Notice
Product Recall
 Urgent - Immediate Action Required



Date Issued October 29, 2019

Product

Product Name	List Number (LN)	Serial Number	UDI
Alinity ci Level Sensor, Bulk Solution	04S68-03	All	N/A

Explanation

Abbott has identified that the Alinity ci Level Sensor, Bulk Solution (LN 04S68-03), can allow air to enter from the joint between the level sensor cap and the inlet or outlet tubes. The introduction of air may result in either a failure to dispense or an incomplete dispense of the bulk solution on Alinity i and Alinity c.

Alinity i	Alinity c
<p>A reduced dispense volume of Trigger Solution or Pre-Trigger Solution will cause an unexpectedly low RLU (relative light unit) reading, resulting in lower than expected values for direct assays (upward slope calibration curves), or higher than expected values in indirect assays (downward slope calibration curves).</p> <p>These events may be accompanied by result exception message codes 1043, 1044, 1072, 1402 or 1403 and potentially impact patient results.</p> <p>Air in the Concentrated Wash Buffer line will not impact patient results as the system will detect the change in solution conductivity and prevent testing.</p>	<p>A failure to dispense Acid Wash or Alkaline Wash may lead to inadequate washing of the cuvettes. This may cause carryover which could impact patient results. These events may be accompanied by message codes 3687 or 3689. These message codes retained in the Alinity ci-series system logs.</p> <p>ICT Results are not impacted by this issue.</p>

Patient Impact

Air in the bulk solution lines (Trigger Solution, Pre-Trigger Solution, Acid Wash or Alkaline Wash) due to this issue have the potential to impact patient results on the Alinity c and the Alinity i.

**Necessary
Actions**

If you have received Alinity ci Level Sensor, Bulk Solution (LN 04S68-03), please discard and contact your Abbott representative. If the level sensor is installed on your Alinity system, please replace with a level sensor 04S68-02 before producing further test results.

**Contact
Information**

If you or any of the health care providers you serve have any questions regarding this information, U.S. Customers please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program via online (<http://www.fda.gov/MedWatch/report.htm>), by mail (<http://www.fda.gov/MedWatch/getforms.htm>), by phone (1-800-332-1088), or by fax (1-800-FDA-0178).

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.
