



Product Correction

Urgent- Immediate Action Required

Date Issued September 14, 2018

Product

Product Name	List Number	Serial Number	UDI
Alinity i Processing Module	03R65	Ai01001 to Ai01336	Not Applicable

Explanation

Abbott has identified an issue with the Alinity i Bulk Solution Dispense Pumps (part number A-35001280-01) resulting in pump failures. The issue is linked to the design of an internal seal within the pump that allows a small amount of leakage of bulk solution(s) that eventually results in the pump failure.

The amount of the leakage does not impact the ability of the pump to accurately dispense bulk solutions, and the leakage is contained within the service-only area of the instrument. Therefore, this issue does not pose a risk of incorrect results nor a risk of physical exposure to the operator.

Patient Impact

The failure of this pump could result in unexpected instrument down time potentially causing a delay in generating results.

Necessary Action

Your Abbott representative will be contacting you to schedule the replacement of all bulk solution dispense pumps A-35001280-01 with a redesigned dispense pump A-35001280-02.

Please complete and return the attached Customer Reply form.

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 have caused 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.