



Urgent Field Safety Notice Product Correction

Urgent - Immediate Action Required

Date Issued September 6, 2019

Product

Product Description	List Number (LN)	Lot number	UDI
Alinity i STAT Myoglobin Reagent Kit	04V3720	04436FN00	(01)00380740174903 (17)200225(10)04436FN00

Explanation

The purpose of this letter is to inform you of a product correction for Alinity i STAT Myoglobin Reagent Kit, LN 04V3720, lot 04436FN00, and to provide instructions on necessary actions your laboratory must take.

Abbott has identified that a small quantity of reagent lot 04436FN00 was distributed with pre-launch vial labels instead of on market labels.



The correct solution is contained within the bottles and will function appropriately. The barcodes are correct and function correctly. There is no impact to product functionality or to the ability to utilize the product as intended. You may continue to use the kit.

The root cause for this situation is under investigation.

Patient Impact There is no impact to patient results.

- Necessary Actions**
1. You may continue to use the kit.
 2. Complete and return the Customer Reply Form.
 3. 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.
 4. Please retain this letter for your laboratory records.
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Contact Information We regret the inconvenience this situation may have caused. If you or any of the health care providers you serve have any questions regarding this information, please contact your local Abbott representative.

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.
