



## Urgent Field Safety Notice Product Correction

Immediate Action Required

### Date Issued

April 17, 2018

### Product

Product Name	List Number (LN)	Lot Number	UDI Number
Alinity i HBsAg Calibrators	08P0801	83313FN00	(01)00380740130145(17)180719 (10)83313FN00(240)08P0801

### Explanation

The individual Alinity i HBsAg Calibrator bottles were labelled with an incorrect lot number and barcode. The Alinity i HBsAg Calibrator kit (box) lot is correctly labelled as **83313FN00** whereas the bottles are incorrectly labelled with **83133FN00A** to **83133FN00F**.

If this lot is used with the automated calibration ordering feature the mismatch in the lot numbers will result in an error and an unsuccessful calibration.

### Patient Impact

There is no impact to patient results as automated calibration ordering will result in a calibration error and testing cannot be performed. However, there may be a delay of results due to the inability to order a calibration automatically.

### Necessary Actions

- Do not use automated calibration ordering with Alinity i HBsAg Calibrator kit lot 83313FN00.
- **Create a manual calibration order with Alinity i HBsAg Calibrator lot 83313FN00.**
- Disregard the lot number listed on the individually labelled calibrator bottles, the correct lot number 83313FN00 is referenced on the kit label and can be verified on the technical library (<https://www.corelaboratory.abbott>) using the Certificate of Analysis.
- Guidance on performing a successful manual calibration order can be found in the Alinity ci-series Operations Manual (Section 5) or by contacting your local area Customer Service.
- In the event, you do not wish to perform a manual calibration order for the Alinity i HBsAg Calibrator lot 83313FN00, please contact your local area Customer Service for replacement material.
- Abbott recommends discussing the content of this letter with your laboratory management.
- 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 issue may cause. An investigation is underway to determine the cause of this issue. If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.