Abbott GmbH
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Germany

Single Registration Number (SRN): N/A

DIAGNOSTICS

Urgent Field Safety Notice
Product Recall

Urgent - Immediate Action Required

Date Issued February 9, 2021

Product

Product Description	List Number	Lot Number	US UDI	EU UDI
Alinity i HIV Ag/Ab Combo Calibrator	08P0701	21292BE00	N/A	N/A

Explanation

This letter is to inform you of a Product Recall for the Alinity i HIV Ag/Ab Combo Calibrator lot number 21292BE00 and to provide instructions on the actions your laboratory must take.

Abbott identified internally a manufacturing issue where individual vials of the Alinity i HAVAb IgG Calibrator were mislabeled as Alinity i HIV Ag/Ab Combo Calibrator lot number 21292BE00.

Impacted vials can cause invalid calibrations due to low RLU (Relative Light Units) calibrator signals. When calibrating using an impacted vial you will observe either:

- Message code: 1400: Calibration failed for assay (HIV Ag/Ab) number (396). (CV too large for Cal 1).
- Or, if a calibration passes, the quality control values will be out of specification high and the calibrations are invalid.

The effect of these low calibrator RLU values was observed internally after lot release testing was completed. The root cause for this issue is under investigation.

Patient Result Impact

There is no impact to patient results. However, invalid calibrations may cause a delay of results. Non-impacted calibrator vials will perform as expected.

Necessary Actions

If…	Then…
You **HAVE an alternate calibrator lot available** in inventory	• Immediately discontinue use of the calibrator lot number 21292BE00 and switch to the alternate calibrator lot. • Destroy any remaining inventory of impacted material according to your laboratory procedures.
You do **NOT have an alternate calibrator lot available** in inventory **AND** you have **generated a valid calibration**	• Immediately contact Customer Support to order a replacement calibrator lot. • You may continue to use the calibrator lot number 21292BE00 while following your current laboratory procedures, as well as the recommended calibration and quality control procedures provided in the Instructions for Use. • Once you receive the replacement calibrator lot, destroy any remaining inventory of impacted material according to your laboratory procedures.

- Complete and return the Customer Reply Form.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Recall and provide to them a copy of this letter.
- Please retain this letter for your laboratory records.

Contact Information

If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.

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.