Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden, Germany

DIAGNOSTICS

Urgent Field Safety Notice
Product Recall

Urgent - Immediate Action Required

cc Chairman Medical Board and relevant Head of Departments

Date Issued May 22, 2019

Product

Product Name	List Number (LN)	Lot Number	Expiration Date	UDI Number
Hemoglobin A1c Calibrators	4P52-01	54582UQ02	24FEB2020	[redacted]

Explanation

The purpose of this letter is to inform you of a product recall for the Hemoglobin A1c Calibrators lot number listed above and to provide instructions on what actions your laboratory must take. Abbott has identified that the calibrator level 2 bottle may have been manufactured incorrectly for a portion of the lot.

Although this lot may generate an active calibration curve, a shift to QC and patient results may occur. We have observed that between the HbA1c concentration range of 5.33% to 6.87%, there is no impact to assay performance. However, outside of this range, a bias of greater than 3% may be seen with patient results.

Patient Impact

There is a potential for incorrect patient results.

Necessary Actions

- **Immediately** discontinue use of the calibrator lot number listed above and switch to the alternate calibrator lot.
- **Destroy any remaining inventory** of impacted material according to your laboratory procedures.
- Please review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported patient results.
- Complete and return the Abbott Customer Reply Form. Please contact your local Abbott representative for assistance with replacement product.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Recall and provide them with 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, 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 either 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.