Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

CORE DIAGNOSTICS

Single Registration Number (SRN): N/A

Urgent Field Safety Notice

Urgent Product Recall

Immediate Action Required

Date Issued March 8, 2022

Product

Product Description	List Number	Lot Number	US/EU UDI
ARCHITECT STAT Myoglobin Calibrators	2K43-01	166000	(01)00380740003272 (17)220531(10)166000

Explanation

The purpose of this letter is to inform you of a Product Recall for ARCHITECT STAT Myoglobin Calibrators, LN 2K43-01, lot number 166000. We have identified that this calibrator lot did not meet acceptance criteria during ongoing stability testing. When a calibration is performed with this lot, controls may exceed the specified range in the Instructions for Use (IFU).

Impact on Patient Results

- There is a potential for delay of patient results due to inability to generate a valid calibration curve.
- There is no impact on patient results when calibration is successful, and controls are within range. Per the ARCHITECT STAT Myoglobin Reagent IFU, a single sample of each control level must be tested to evaluate the assay calibration.

Necessary Actions to be Taken by Customer

- Immediately contact Customer Support to order a replacement lot.
- Discontinue use of and destroy any remaining inventory of lot 166000 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 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.