



Product Recall

Immediate Action Required

Date Issued

June 22, 2017

Product

Product Description	List Number	Lot Number	Expiration Date	UDI Number
ARCHITECT T-Uptake Reagent	2K48-20	36482UN16	31-MAY-2018	(01)00380740042523(17) 180531(10)36482UN16
	2K48-25	36481UN16	31-MAY-2018	(01)00380740003517(17) 180531(10)36481UN16
	2K48-25	43782UN17	31-JUL-2018	(01)00380740003517(17) 180731(10)43782UN17

Explanation

The purpose of this letter is to inform you of a Product Recall for ARCHITECT T-Uptake reagent lots **36481UN16, 36482UN16, and 43782UN17**, and to provide you with instructions on what actions your laboratory must take.

Abbott has identified a product formulation issue that may lead to calibration error code (EC) 1119, *Assay (T-Uptake) Number (271) Calibration Failure, curve validity check failed*, when using any of the three impacted reagent lots listed above, which prevents the generation of patient results. Abbott has confirmed that this issue does not generate incorrect patient results when a valid calibration curve is generated.

Patient Impact

There is no patient impact as a result of this issue.

Necessary Actions

- Immediately discontinue use of reagent lots **36481UN16, 36482UN16, and 43782UN17** and switch to an alternate reagent lot.
- **Destroy any remaining inventory** of reagent lots **36481UN16, 36482UN16, and 43782UN17** according to your laboratory procedures.
- If you have forwarded any of the products listed above to other laboratories, please inform them of this Product Recall and provide to them a copy of this letter.
- Complete and return the Customer Reply Form.
- 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.