



Product Recall

Immediate Action Required

Date Issued March 02, 2016

Product

Product Description	List Number	Lot Number	Expiration Date	UDI Number
ARCHITECT T-Uptake Calibrators	2K48-01	614719	31JUL2016	N/A
	2K48-01	650124	31OCT2016	N/A
	2K48-01	697989	31DEC2016	N/A

Explanation

The purpose of this letter is to inform you of a product recall for ARCHITECT T-Uptake Calibrator lots **614719**, **650124**, **697989**, and to provide you with instructions on what actions your laboratory must take.

Abbott has identified a stability issue that may lead to controls out of range. The calibrator lot may not be able to be used due to this issue.

Patient Impact

There is no impact to patient results. When using any of the three impacted Calibrator lots listed above, you may experience controls out of range.

Necessary Actions

For CALIBRATOR lots 614719 and 650124

Immediately **destroy any remaining inventory** and order replacement material.

For CALIBRATOR lots 697989

If....	Then...
You HAVE an alternate Calibrator lot available in inventory (other than Calibrator lots 614719 or 650124)	Immediately discontinue use of Calibrator lot 697989 and switch to the alternate calibrator lot. Destroy any remaining inventory of Calibrator lot 697989 according to your laboratory procedures.
You do NOT have an alternate Calibrator lot available in inventory	Immediately order a replacement Calibrator lot. You may continue to use Calibrator lot 697989 while following your current laboratory QC procedures. Once you receive the replacement Calibrator lot, destroy any remaining inventory of Calibrator lot 697989 according to your laboratory procedures.

**Necessary
Actions
Continued**

For Quality Controls	
If....	Then...
You established control ranges using one of the three impacted calibrator lots	You must re-establish ranges using an alternate calibrator lot.

- Complete and return the Customer Reply Form. Your local Customer Support will provide you with replacement product and/or credit.
- 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.

Abbott has not yet identified a root cause and corrective action for this issue.

To prevent reoccurrence:

- New Calibrator lots will have shortened expiration (exp) dating.
- Since Controls are manufactured from similar material as the Calibrators, new Control lots will also have shortened expiration dating.
- The new expiration dating will provide you with approximately 2 to 3 months of laboratory usage dating.

In-date Calibrator lots 572984 (exp date 31MAY2016), 723113 (exp date 28FEB2017) and 745516 (exp date 31MAR2017) and Control lot 769294 (exp date 31MAY2017) will remain at 18 months dating as there is no indication that these lots are impacted by this issue.

**Contact
Information**

We sincerely regret any inconvenience this issue may cause. 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.
