



Urgent Field Safety Notice Product Recall

Urgent - Immediate Action Required

Date Issued April 4, 2019

Product

Product Name	List Number	Lot Number	UDI
Technopath Multichem S Plus (Assayed) Level 1	5P78-10	18004181	(01)05391523440011(240)05P78-10(17)201031(10)18004181
Technopath Multichem S Plus (Assayed) Level 2	5P78-11	18005182	(01)05391523440028(240)05P78-11(17)201031(10)18005182
ARCHITECT HbA1c Calibrators	4P72-01	902920500	(01)00380740007812 (17)190726(10)902920500
ARCHITECT Intact PTH Controls	8K25-12	01018I000	N/A
ARCHITECT Intact PTH Calibrators	8K25-04	01018H000	N/A
ARCHITECT STAT High Sensitive Troponin-I Controls	3P25-11	94347UI00	N/A
ARCHITECT STAT High Sensitive Troponin-I Calibrators	3P25-02	93284UI00	N/A
ARCHITECT Sirolimus Calibrators	1L76-01	46K15718	(01)00380740001339 (17)200303(10)46K15718
Alinity i Anti-TPO Calibrators	09P3501	84347UN18	(01)00380740150594 (17)190408(10)84347UN18

Explanation

This Field Action is for Latvia only as Abbott has identified one shipment from a Latvian distributor to multiple customers in Latvia on January 17, 2019 was delivered without dry ice, as re-icing by the distributor was not performed. As a result, the shipments to these customers were not delivered at the correct storage condition and likely thawed during shipment.

Patient Impact

Product	Patient Impact
ARCHITECT Intact PTH	Patient results may be falsely elevated or depressed
ARCHITECT HbA1c	Patient results may be falsely depressed
Technopath Multichem S Plus (Assayed)	Delay in results
Alinity i Anti-TPO ARCHITECT STAT High Sensitive Troponin-I ARCHITECT Sirolimus	No patient impact

**Necessary
Actions**

- Determine if you have any remaining inventory of the above lots delivered to your laboratory on January 17, 2019.
- If replacement material is available, discontinue use of the impacted material and destroy any remaining inventory according to your laboratory procedures.
- If replacement material is not available, immediately order replacement material. You may continue to use the impacted material as long as controls are within range. Destroy impacted material once replacement material is available.
- 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.
- Contact Abbott Customer Service for assistance if needed.
- Complete and return the Customer Reply.
- 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.
