



Urgent Field Safety Notice
Product Recall
Urgent – Immediate Action Required

Date Issued

November 21, 2018

Product

See Appendix A for the list of impacted products.

Explanation

The purpose of this letter is to inform you of a product recall relating to the products listed in Appendix A and to provide instructions on the necessary actions your laboratory must take.

Abbott has become aware of a manufacturing issue that can result in damage to a bottle neck in some of the reagent cartridges found in the lots listed in Appendix A. If a bottle neck is damaged, it may cause a failure during the reagent loading process on the Alinity i instrument.

When the failure occurs, you will observe one or more of the following error codes:

- 5818 Reagent transport error
- 5819 Reagent cartridge load error at reagent carousel position (0).
- 5794 Reagent carousel load error.

The reagent cartridge will remain on the reagent positioner and will not be returned to the reagent and sample manager. The bottle susceptible to the damaged described above is the first bottle located next to the cartridge tab when the product is orientated with cartridge labelling facing outward (See Appendix B, Figure 1).

The root cause for this issue is under investigation and actions have been taken to prevent recurrence. Only the lot numbers listed in Appendix A are potentially impacted by this issue.

Patient Impact

There is no impact to generated patient results. There may be a potential delay in generating results because of the failure to load error.

**Necessary
Actions**

If you have the impacted lots, please follow the necessary actions below:

1. Pending completion of the manual inspection detailed below, use an alternate lot of the product, if available.
2. Manually inspect each reagent cartridge in inventory before use, refer to Appendix B Figure 2 for detailed inspection instructions.
Note: As a priority, manually inspect STAT assays, Alinity i STAT High Sensitive Troponin-I and Alinity i Total β -hCG, first to ensure no delay to testing these assays.
 - If the bottle moves freely, proceed to load and use the cartridge.
 - If the bottle does not move freely, discard the cartridge.
3. Complete and Return the Customer Reply Form
4. Reagent lots received subsequent to receipt of this letter, including the product lots listed in Appendix A, have been pre-inspected by Abbott and are acceptable for use on the Alinity i instrument.
5. 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.
6. Please retain this letter for your laboratory records.

**Contact
Information**

We sincerely regret the inconvenience this situation is causing you. 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).

Appendix A

Product Description	List Number*	Lot Number	UDI
Alinity i TSH Reagent Kit	07P4830	90061UI00	(01)00380740131159 (17)190710(10)90061UI00
		91526UI00	(01)00380740131159 (17)190827(10)91526UI00
		92291UI00	(01)00380740131159 (17)190924(10)92291UI00
Alinity i Free T4 Reagent Kit	07P7030	90111UI00	(01)00380740121822 (17)190727(10)90111UI00
		92388UI00	(01)00380740121822 (17)190911(10)92388UI00
Alinity i Free T3 Reagent Kit	07P6930	90334UI00	(01)00380740131111 (17)190701(10)90334UI00
		92029UI00	(01)00380740131111 (17)190715(10)92029UI00
Alinity i Total T3 Reagent Kit	07P9420	88183UI00	(01)00380740130558 (17)190710(10)88183UI00
Alinity i Total β -hCG Reagent Kit	07P5120	89203UI00	(01)00380740121501 (17)190609(10)89203UI00
	07P5121	92056UI00	(01)00380740160616 (17)190807(10)92056UI00
Alinity i Estradiol Reagent Kit	07P5020	90193UI00	(01)00380740131159 (17)190317(10)90193UI00
	07P5030	90198UI00	(01)00380740129927 (17)190317(10)90198UI00
Alinity i Progesterone Reagent Kit	08P3620	91254UI00	(01)00380740121877 (17)190503(10)91254UI00
		92360UI00	(01)00380740121877 (17)190618(10)92360UI00
Alinity i B12 Reagent Kit	07P6722	91129UI00	(01)00380740131401 (17)190714(10)91129UI00
		91343UI00	(01)00380740131401 (17)190727(10)91343UI00
	07P6732	91342UI00	(01)00380740131418 (17)190727(10)91342UI00
		92225UI00	(01)00380740131418 (17)190827(10)92225UI00
Alinity i Folate Reagent Kit	08P1422	88316UI00	(01)00380740130893 (17)191109(10)88316UI00

Product Description	List Number*	Lot Number	UDI
Alinity i Ferritin Reagent Kit	07P6530	91532UI00	(01)00380740131487 (17)190730(10)91532UI00
		93238UI00	(01)00380740131487 (17)190905(10)93238UI00
Alinity i 25-OH Vitamin D Reagent Kit	08P4532	92313UI00	(01)00380740121952 (17)191011(10)92313UI00
		92484UI00	(01)00380740121952 (17)190831(10)92484UI00
Alinity i STAT High Sensitive Troponin- I Reagent Kit	08P1322	91288UI00	(01)00380740130732 (17)190206(10) 91288UI00
		92019UI00	(01)00380740130732 (17)190222(10) 92019UI00
		92469UI00	(01)00380740130732 (17)190318(10) 92469UI00
	08P1332	91291UI00	(01)00380740130749 (17)190206(10) 91291UI00
		90434UI00	(01)00380740130749 (17)190109(10) 90434UI00
		92010UI00	(01)00380740130749 (17)190222(10) 92010UI00

*Note: Some list numbers are not available in all countries

Appendix B



Figure 1: Location of Impacted Bottle.

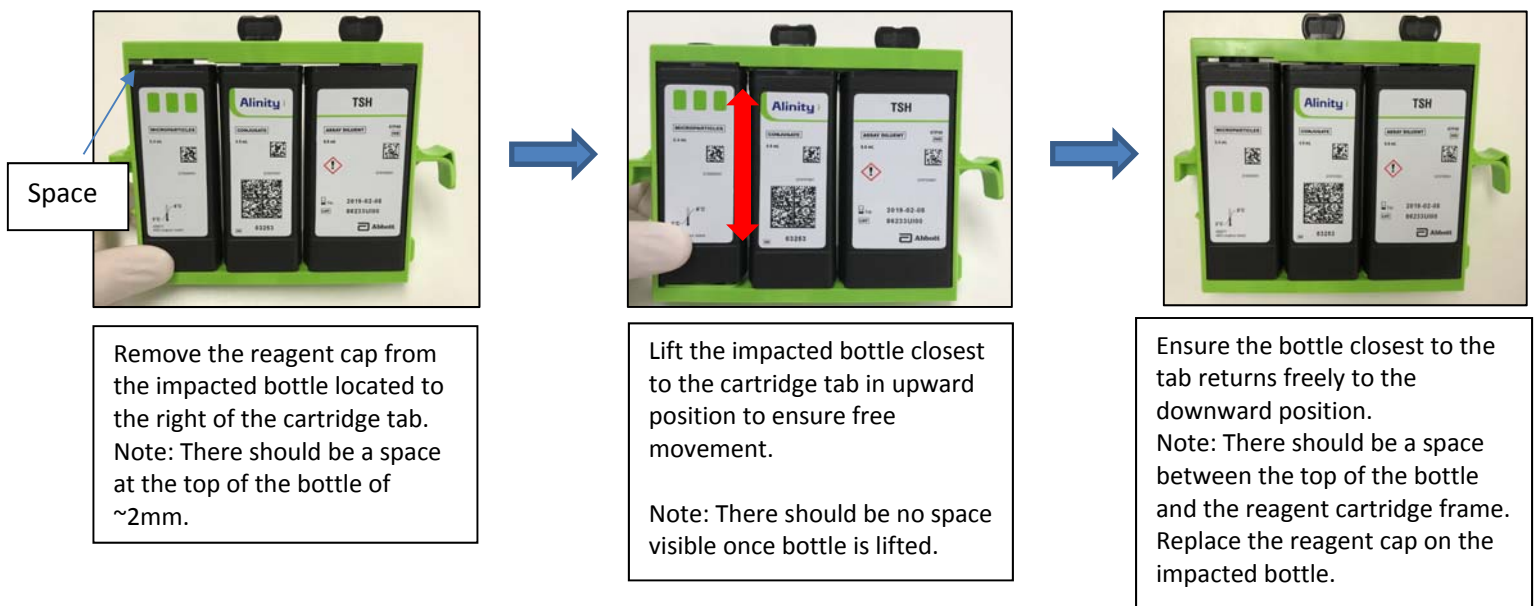


Figure 2: Inspection process

Note: If the bottle does not move freely up or down, the bottle neck is damaged and the reagent cartridge should not be used.