Abbott Ireland Diagnostics Division
Lisnamuck, Longford
Co. Longford, Ireland

Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

Date Issued October 12, 2018

Product

Product Name	List Number*/**	Lot Numbers	UDI Numbers	Kit Configuration
ARCHITECT Free T3 Reagent Kit	7K63-20	All	N/A	4 x 100 tests/kit
ARCHITECT Free T3 Reagent Kit	7K63-25	All	N/A	1 x 100 tests/kit
ARCHITECT Free T3 Reagent Kit	7K63-27	All	N/A	1 x 100 tests/kit
ARCHITECT Total T3 Reagent Kit	7K64-20	All	N/A	4 x 100 test/kit
ARCHITECT Total T3 Reagent Kit	7K64-25	All	N/A	1 x 100 tests/kit
ARCHITECT Total T3 Reagent Kit	7K64-27	All	N/A	1 x 100 tests/kit

*Note: Some size codes are not available in all countries
** Note: Size codes 7K63-27 and 7K64-27 are not available in the United States.

Explanation

This letter is to inform you of a Product Correction, which impacts ARCHITECT Free T3 and ARCHITECT Total T3 assays and provide instructions on the actions your laboratory must take. Samples tested using ARCHITECT Free T3 or ARCHITECT Total T3 assays may show depressed results due to reagent carryover when testing on board with the assays specified in table 1 below.

Table 1: List of assays that should not be tested while the ARCHITECT Free T3 (7K63-20/25/27) or Total T3 assay (7K64-20/25/27) is on the ARCHITECT **i1000SR** Platform.

Assay Name	List Number*	Assay File Number
ARCHITECT TSH	7K62	241
ARCHITECT T-Uptake	2K48	271
ARCHITECT HIV Ag/Ab Combo	4J27/2P36	639/877
ARCHITECT Cortisol	8D15	601
ARCHITECT LH	2P40	187
ARCHITECT ProGRP	1P45	527
ARCHITECT rHTLV-I/II	6L61	442
ARCHITECT Total PSA	7K70/6C06	211
ARCHITECT AFP	3P36	003
ARCHITECT Free PSA	7K71/6C07	221
ARCHITECT 25-OH Vitamin D	5P02	523 or 670

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

Explanation continued

Please refer to Appendix 1 for additional information.

The root cause for this issue is under investigation. Further corrective actions will be implemented and communicated upon completion of the investigation. Please refer to the Necessary Action section of this letter for recommendations on an interim mode of control to mitigate this issue.

Patient Impact

Samples tested using ARCHITECT Free T3 or ARCHITECT Total T3 assay may show falsely depressed results when tested on board with select ARCHITECT assays, as listed in Table 1. Refer to Appendix 1 for additional data.

Necessary Actions

In order to prevent the interaction described above:	
If….	**Then…**
you can use a separate instrument	Separate the ARCHITECT Free T3 and ARCHITECT Total T3 assays from the assays detailed in Table 1 above, by running these tests on different instruments
you cannot use a separate instrument*	Perform Maintenance Procedure (6445 Pipettor/WZ Probe Cleaning for i1000SR) in the i1000SR Operations on the instrument prior to performing batch testing for all ARCHITECT Free T3 or ARCHITECT Total T3 samples.

*It is suggested to run all Free T3/Total T3 samples immediately after this maintenance in order to minimize additional disruptions to laboratory workflow.

- 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.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction 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

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.

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 1

The frequency of this issue is determined by the order of pipetting driven by the instrument scheduler when potentially contaminating assays are run with Free T3 and Total T3 and not all controls and patient samples will be affected. Based on an assessment of product formulation and design of the ARCHITECT i1000SR system, ARCHITECT TSH (7K62) is representative for assays listed in Table 1.

Internal studies were designed to replicate the necessary event to evaluate the % bias at a concentration level of 3.1 pg/mL or 4.8 pmol/L for Free T3 and 0.86 ng/mL or 1.32 nmol/L for Total T3, and the frequency of occurrence was calculated through an assessment of 4.05×10^6 on-market Free T3 and Total T3 tests. Therefore, the occurrence of the bias observed in your laboratory may vary.

Please review this information with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported patient results.

Table 2: Observed % bias of ARCHITECT Free T3 (7K63) or ARCHITECT Total T3 assay (7K64) when tested internally on board with ARCHITECT TSH (7K62) on the ARCHITECT **i1000SR** platform.

Product Name	List Number	Size Code	Frequency of Occurrence	% Bias Observed
ARCHITECT Free T3	7K63	27	0.98%	-39%
ARCHITECT Total T3	7K64	27	1.88%	-21%
ARCHITECT Free T3	7K63	25/20	0.07%	-17%
ARCHITECT Total T3	7K64	25/20	0.13%	-23%