



Urgent Field Safety Notice Product Correction

Urgent - Immediate Action Required

Date Issued October 17, 2018

Product

Product Name	List Number	Lot Numbers	UDI Number	Kit Configuration
Alinity i Free T3 Reagent Kit	07P6920	All	N/A	2 x 100 tests/kit
Alinity i Free T3 Reagent Kit	07P6930	All	N/A	2 x 600 tests/kit
Alinity i Total T3 Reagent Kit	07P9420	All	N/A	2 x 100 tests/kit
Alinity i Total T3 Reagent Kit	07P9430	All	N/A	2 x 600 tests/kit

Explanation

This letter is to inform you of a Product Correction, which impacts Alinity i Free T3 and Alinity i Total T3 assays, and provide instructions on the actions your laboratory must take.

Samples tested using Alinity i Free T3 and Alinity i Total T3 assays may show depressed results due to reagent carryover when testing on board with the Alinity i 25-OH Vitamin D (LN 08P45). 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 Alinity i Free T3 or Alinity i Total T3 assay may show falsely depressed results when tested on board with the Alinity i 25-OH Vitamin D assay. Refer to Appendix 1 for additional data.

Necessary Actions

In order to prevent the interaction described above:	
If...	Then...
you can use separate instruments	Separate the Alinity i Free T3 and Alinity i Total T3 assays from the Alinity i 25-OH Vitamin D assay by running these tests on different systems.
you cannot use separate instruments*	Perform daily maintenance procedure 2500 Daily Maintenance (i-series) found in section 10 of the Alinity ci-series Operations Manual prior to performing batch testing for all Free T3 or Total T3 samples.

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

**Necessary
Actions
continued**

- 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, please contact your local area Customer Service.

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 Alinity i System, Alinity i 25-OH Vitamin D (08P45) is the only assay that may cause a negative bias with Alinity i Free T3 or Alinity i Total T3 assays.

Internal studies were designed to replicate the necessary event to evaluate the % bias at a concentration 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 4.1×10^4 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 1: Observed % bias of Alinity i Free T3 (07P69) or Alinity i Total T3 assay (07P94) when tested internally on board with Alinity i 25-OH Vitamin D (08P45) on the Alinity i.

Product Name	List Number	Size Code	Frequency of Occurrence	% Bias Observed
Alinity i Free T3	07P69	20/30	0.341%	-20%
Alinity i Total T3	07P94	20/30	0.036%	-22%