



## 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  | 7K63-30         | All         | N/A         | 4 x 500 tests/kit |
| ARCHITECT Free T3 Reagent Kit  | 7K63-35         | All         | N/A         | 1 x 500 tests/kit |
| ARCHITECT Free T3 Reagent Kit  | 7K63-27         | All         | N/A         | 1 x 100 tests/kit |
| ARCHITECT Free T3 Reagent Kit  | 7K63-32         | All         | N/A         | 4 x 500 tests/kit |
| ARCHITECT Free T3 Reagent Kit  | 7K63-37         | All         | N/A         | 1 x 500 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 | 7K64-30         | All         | N/A         | 4 x 500 tests/kit |
| ARCHITECT Total T3 Reagent Kit | 7K64-35         | All         | N/A         | 1 x 500 tests/kit |
| ARCHITECT Total T3 Reagent Kit | 7K64-27         | All         | N/A         | 1 x 100 tests/kit |
| ARCHITECT Total T3 Reagent Kit | 7K64-32         | All         | N/A         | 4 x 500 tests/kit |
| ARCHITECT Total T3 Reagent Kit | 7K64-37         | All         | N/A         | 1 x 500 tests/kit |

\*Note: Some size codes are not available in all countries

\*\* Note: Size codes 7K63-27/32/37 and 7K64-27/32/37 are not available in the United States.

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**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 ARCHITECT 25-OH Vitamin D (LN5P02) assay on the i2000/i2000SR platform.

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.

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**Patient Impact**

Samples tested using ARCHITECT Free T3 or ARCHITECT Total T3 assay may show falsely depressed results when tested on board with the ARCHITECT 25-OH Vitamin D assay. Refer to Appendix 1 for additional data.

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**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 ARCHITECT 25-OH Vitamin D assay, by running these tests on different instruments.                            |
| you cannot use a separate instrument*                | Perform Daily Maintenance (Operations Manual, 6041 for i2000/i2000SR) 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.
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**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).

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## 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 i2000/i2000SR System, ARCHITECT 25-OH Vitamin D (5P02) is the only assay that may cause a negative bias with ARCHITECT Free T3 and ARCHITECT Total T3 assays.

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  $4.05 \times 10^6$  on-market Free T3 and Total T3 tests. Therefore, the occurrence of the bias observed in your laboratory may vary.

Table 2: Observed % bias of ARCHITECT Free T3 (7K63) or ARCHITECT Total T3 assay (7K64) when tested internally on board with ARCHITECT 25-OH Vitamin D (5P02) on the ARCHITECT **i2000SR** platform.

| Product Name       | List Number | Size Code   | Frequency of Occurrence | % Bias Observed |
|--------------------|-------------|-------------|-------------------------|-----------------|
| ARCHITECT Free T3  | 7K63        | 27/32/37    | 0.44%                   | -26%            |
| ARCHITECT Total T3 | 7K64        | 27/32/37    | 0.41%                   | -22%            |
| ARCHITECT Free T3  | 7K63        | 20/25/30/35 | 0.27%                   | -14%            |
| ARCHITECT Total T3 | 7K64        | 20/25/30/35 | 0.17%                   | -18%            |