



Urgent Field Safety Notice Product Recall

Immediate Action Required

Date Issued

September 11, 2014

Product

ARCHITECT Total T3 Reagent Kit, LN 7K64-20/-25
Lot Numbers 38901UI00, 38901UI01
Expiry 29 January 2015

Explanation

The purpose of this letter is to inform you of a product recall for the ARCHITECT Total T3 Reagent lots listed above, and to provide instructions on the actions your laboratory must take.

We have determined that 17% of the two reagent lots above may exhibit lower Relative Light Units (RLUs) than expected, which in turn may result in controls out of range or patient results higher than expected.

Patient Impact

In the event that Controls do not identify the issue, patient results may show a positive bias of up to 38%.

As described in the ARCHITECT Total T3 reagent insert, it is recommended that, for diagnostic purposes, the ARCHITECT Total T3 results should be used in conjunction with other data; e.g., symptoms, results of other thyroid tests, clinical impressions etc.

Necessary Actions

Please follow the necessary actions below:

If...	Then...
You are currently using or have inventory of reagent lots 38901UI00 or 38901UI01	Discontinue use of and destroy any remaining inventory according to your laboratory procedures

- Follow your laboratory protocol regarding the need for review of previously reported patient results.
- Replacement material is available. For ordering, please order through your normal ordering process.
- If you have forwarded any of the affected lots to another laboratory, please provide them with a copy of this communication.

Please retain a copy of this communication for your records.

**Contact
Information**

We sincerely apologize for any inconvenience this may have caused. Abbott is committed to providing you with the highest quality diagnostic products and support services to meet the needs of your laboratory and the providers and patients you serve.

If you or any of the health care providers you serve have any questions regarding this information, U.S. customers should call Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local Customer Service representative.
