



## Product Correction

Immediate Action Required

**Date Issued**

February 11, 2011

**Product**

Product Name	List Number	Lot Number
ARCHITECT 25-OH Vitamin D Reagent	3L52-25	01110L000

**Explanation**

Abbott has become aware of an error in the maximum on-board stability time displayed on the ARCHITECT for the 100-test kit size of ARCHITECT 25-OH Vitamin D List 3L52-25 lot 01110L000.

The barcode error eliminates the ability of the instrument to prevent the use of reagents that are on board the instrument greater than 7 days (168 hours).

Once the kit has been installed onto the ARCHITECT and the barcode is scanned, the kit displays an incorrect on board stability of 1680 hours, which would equal 70 days. The correct on board stability time is 7 days or 168 hours. The reagent package insert (commodity 49-2152/R1) states in the Storage Instructions section, "The ARCHITECT 25-OH Vitamin D 100-test Reagent Kit may be stored on board the ARCHITECT *i* System for a maximum of **7 days**."

The cause of this issue was a human error that occurred during the barcode generation process. Actions have been taken to prevent additional occurrences.

**Patient Impact**

There is no patient impact as a result of this issue.

**Necessary Actions**

In order to ensure the ARCHITECT 25-OH Vitamin D product is performing per package insert claims, you will need to take additional action to track on board storage time.

**Please perform the following action:**

Please manually track on board storage time of reagent lot 01110L000 whether you leave the kit on board continuously or remove the kit each day after testing. Discard the reagent kit after 168 hours of testing time has elapsed on board the ARCHITECT.

**Contact Information**

We sincerely regret the disruption this will cause your laboratory. 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, please contact your local Customer Service representative.