



## Urgent Field Safety Notice Product Correction

Immediate Action Required

**Date Issued** February 17, 2012

**Product** AxSYM Free T4 Standard Calibrators, LN 7K51-01,  
Lot Number 96238JN00, **Expiry 05 January 2012**

AxSYM Free T4 Controls, LN 7K51-10,  
Lot Number 96197JN00, **Expiry 22 January 2012**

**Explanation** As you may already be aware from previous communications, Abbott is conducting an investigation into the performance of the AxSYM Free T4 Standard Calibrator and Control lots listed above. Although both lots have now expired, the Irish Medicines Board has advised Abbott that they consider the following information to be still relevant post-expiration. The purpose of this communication is to provide/re-iterate information that your laboratory must be aware of, regarding the aforementioned products, per a request from the Irish Medicines Board.

- Usage of either AxSYM Free T4 Standard Calibrator lot 96238JN00 **or** AxSYM Free T4 Control lot 96197JN00 on their own may have resulted in an observation of controls out of range.
- Usage of both AxSYM Free T4 Standard Calibrator lot 96238JN00 **and** AxSYM Free T4 Control lot 96197JN00 together may have resulted in a valid calibration and depressed patient results may have been observed.
- Through investigation it has been shown that the AxSYM Free T4 reagent is not impacted. In addition, no other lots of AxSYM Free T4 Standard Calibrators or Controls are impacted.

**Patient Impact** Usage of AxSYM Free T4 Standard Calibrator lot 96238JN00 and AxSYM Free T4 Control lot 96197JN00 together may have resulted in a valid calibration curve and patient results may have been depressed by up to 24%. This could have occurred between 01 October 2011 and 05 January 2012.

As described in the AxSYM Free T4 reagent insert, it is recommended that, for diagnostic purposes, the AxSYM Free T4 results should be used in conjunction with other data; e.g., symptoms, results of other thyroid tests (e.g. second generation hTSH test), clinical impressions etc.

**Necessary Actions** Abbott would like to advise you to be vigilant when performing comparative analysis of Free T4 results if you had obtained a successful calibration with AxSYM Free T4 Standard Calibrator lot 96238JN00 and AxSYM Free T4 Control lot 96197JN00 during the time period between 01 October 2011 and 05 January 2012.

Although both lots have now expired, the Irish Medicines Board has advised Abbott that they consider this information to be still relevant post-expiration.

**Contact  
Information**

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We sincerely apologise for any inconvenience this may have caused you.

If you or any of the health care providers you serve have any questions regarding this information, please contact your local Customer Service Representative.

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