IRISH MEDICINES BOARD

Notice Information: - Advisory
21 February 2014

Part 1. Product Information

a)	Title:	ARCHITECT Intact PTH Assay Reagents, Calibrators and Controls
b)	Product Name/Type:	ARCHITECT Intact PTH Assay Reagents, Calibrators and Controls
c)	Reference:	SN2014(05)
d)	Manufacturer/Supplier:	Abbott Laboratories

Part 2. Target Audience

a) Target Audience:	Hospital Managers / CEOs Laboratory Managers Chief Medical Scientists Risk Managers Clinical Directors Nursing Managers Nursing staff Endocrinology units Endocrinology Consultants Purchasing Managers Supplies Managers Hospital personnel Private Medical Practitioners General Practitioners Hospital Pharmacists All wards

Part 3. Problem/Issue

a) Problem/Issue:	Abbott has confirmed that a performance shift in the ARCHITECT Intact Parathyroid (PTH) assay has the potential to generate falsely elevated results on patient samples. This issue affects ARCHITECT Intact PTH Assay List Number 8K25, Reagents (8K25-20, 8K25-25, 8K25-27*), Calibrators (8K25-01) and Controls (8K25-10). Refer to attached Field Safety Notice (FSN). The scope of the issue affects devices manufactured between May 2012 and November 2013. *Note: This list number is not CE-marked and is distributed to USA and Puerto Rico only.

Part 4. Background Information

a)	Background Information:	Results generated with impacted lots may demonstrate a positive shift relative to those generated with previous reagent and/or calibrator lots. The issue may also impact your established ARCHITECT Intact PTH reference ranges. Abbott ARCHITECT Intact PTH Controls do not detect the shift. All current reagent, calibrator and control inventory is impacted. In a study completed in January 2014, using current in-date reagent and calibrator lots, patient results demonstrated a magnitude of shift averaging approximately 13% to 45% when compared to a study completed in August 2012. The shift was observed across the full analytical range of the assay.

Part 5. Action to be taken

a)	Action to be taken:	Abbott has launched a product recall for affected lots of ARCHITECT Intact PTH assay reagents, calibrators and controls and has issued a FSN to provide instructions on what actions your laboratory must take (as follows): - Immediately discontinue use of, and destroy, any remaining inventory of ARCHITECT Intact PTH assay according to your laboratory procedures. - To continue Intact PTH testing at your laboratory, Abbott recommends that you identify an alternate method for testing patient samples. If further guidance is needed, please contact your Abbott sales representative. - This letter should be reviewed with the treating physician or healthcare provider to ensure they are aware of the issue and can determine whether re-evaluation of the patient is necessary. - If you have forwarded any product to other laboratories, please inform them of this FSN. The IMB recommends that results with the ARCHITECT Intact PTH assay are reviewed as appropriate to determine whether re-evaluation of the patient is necessary. Please forward this safety notice to all those who need to be aware of this action within your organisation and to maintain awareness over this safety notice for an appropriate time period.

Part 6. Enquiries

a)	All enquiries should be made to:	All adverse incidents relating to a medical device should be reported to: Irish Medicines Board Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2 Telephone: +353-1-6764971 Fax: +353-1-6344033 E-mail: vigilance@imb.ie Website: www.imb.ie Please quote IMB reference number V20026 for any queries in relation to this action. Enquiries on the issue should be addressed to: Abbott Customer Service Ireland Telephone: + 353 1 4691568 and +353 1 4691563 Fax: +353 1 4691565 E-mail: abbottcareirl@abbott.com Please click here to view the field safety notice Please click here to view a PDF version of this Safety Notice

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