Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-6081

Urgent Field Safety Notice
Product Recall
Immediate Action Required

Date Issued

February 12, 2014

Product

ARCHITECT Intact PTH Assay List Number 8K25 (see attached for impacted lots) Reagents (8K25-20, 8K25-25, 8K25-27), Calibrators (8K25-01) and Controls (8K25-10)

Explanation

- The purpose of this letter is to inform you of a product recall for ARCHITECT Intact PTH assay and to provide instructions on what actions your laboratory must take.
- Abbott has confirmed that a performance shift in the ARCHITECT Intact PTH assay has the potential to generate falsely elevated results on patient samples.
- 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.
- We are working diligently to determine the root cause of this issue and will provide the information as soon as it becomes available.

Patient Impact

Falsely elevated patient results are generated when using the ARCHITECT Intact PTH assay.

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.

Necessary Actions

- **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. Abbott has included a physician letter that you can use to notify your ordering physicians of this issue. Follow your laboratory procedures for further guidance.
- If you have forwarded any product to other laboratories, please inform them of this Product Recall and provide a copy of the recall letter, customer reply, and physician letter to them.
- Complete the Customer Reply.
- Please retain this letter for your laboratory records.

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Contact Information

We recognize the significant disruption this will cause and sincerely apologize for the inconvenience. 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.

Product Name	List Number	Lot Number	Expiration Date on Product Labeling
ARCHITECT Intact PTH	8K25-01 Calibrator	00613I000	05 SEP 2014
		01913C000	14 MAR 2014
		01913K000	12 NOV 2014
		02413E000	09 MAY 2014
		01312K000	12 NOV 2013
		00813A000	08 JAN 2014
		01412H000	16 AUG 2013
		00912F000	30 MAY 2013
	8K25-10 Control	00713I000	05 SEP 2014
		01813C000	14 MAR 2014
		01813K000	12 NOV 2014
		02613E000	09 MAY 2014
		01412K000	12 NOV 2013
		00713A000	08 JAN 2014
		01012F000	30 MAY 2013
	8K25-20 Reagent	00913F000	23 NOV 2014
		01313C000	21 AUG 2014
		01512K000	25 APR 2014
		01712H000	23 FEB 2014
		01813I000	13 MAR 2015
		02213K000	08 MAY 2015
		01312G000	13 JAN 2014
		00512H000	13 JAN 2014
	8K25-25 Reagent	00112K000	25 APR 2014
		01113C000	21 AUG 2014
		01313G000	05 JAN 2015
		01612H000	23 FEB 2014
		01913I000	02 FEB 2015
		02213D000	05 OCT 2014
		00113K000	11 APR 2015
		01212G000	13 JAN 2014
		00412H000	13 JAN 2014
	8K25-27 Reagent	00212K000	25 APR 2014
		01213C000	21 AUG 2014
		01413G000	05 JAN 2015
		01812H000	23 FEB 2014
		02013I000	02 FEB 2015
		02313D000	05 OCT 2014
		00213K000	11 APR 2015
		01412G000	13 JAN 2014
		00612H000	13 JAN 2014