



Product Information

Date Issued March 18, 2014

Product

Description	List Number
ARCHITECT Intact PTH	8K25

Reason

This letter is to provide an update on the investigation regarding the performance shift of the ARCHITECT Intact PTH assay that has the potential to generate falsely elevated patient results. The issue was originally communicated per Product Recall Letter FA12FEB2014.

Current Status

The investigation to date has identified the following:

- Instability of the ARCHITECT Intact PTH calibrators is a major contributor to the observed increase in patient sample values.
- ARCHITECT product release testing was not able to detect the issue because the effect of calibrator instability on patient sample values does not occur until several months after the calibrators are manufactured.
- The bias is not due to a shift in standardization as the assay continues to recover the WHO (World Health Organization) first International standard consistently since launch when calibrating with the ARCHITECT Intact PTH frozen reference calibrators.
- If ARCHITECT Intact PTH calibrators and controls with similar expiration dates are used at the same time, the controls may continue to generate values within established ranges because ARCHITECT Intact PTH calibrators and controls have the same formulation and exhibit a similar instability.
- Because of the instability over time, the extent each customer saw the bias depended on the age of the calibrators and controls.

In an effort to return ARCHITECT Intact PTH assay to your laboratory as soon as possible, we are evaluating the expiration dating (shelf life) of calibrators and controls as a potential short-term solution. Specific information regarding product availability will be communicated in upcoming weeks. A long term solution will be determined upon the completion of the investigation.

Action

Please retain this letter for your laboratory records.

Contact

Abbott is committed to providing you with high 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.

Please refer to the Product Information control number PI18MAR2014.



Product Information

Date Issued **May 7, 2014**

Product

Description	List Number (LN):	Lot Number:
ARCHITECT Intact PTH Calibrators	8K25-01	Starting with 03214C000
ARCHITECT Intact PTH Controls	8K25-10	Starting with 03114C000
ARCHITECT Intact PTH Reagents	8K25-20, 8K25-25	All lots

Reason

Based on our on-going investigation, we would like to inform you of initial actions which will address the performance shift of the ARCHITECT Intact PTH assay, originally communicated per Product Recall Letter FA12FEB2014.

Abbott has identified that a major contributor to the observed increase in patient sample values is the instability of the ARCHITECT Intact PTH Calibrators. ARCHITECT Intact PTH Controls are manufactured from the same matrix material as the Calibrators. Therefore, ARCHITECT Intact PTH Calibrators and Controls will initially have a reduced expiration date (shelf life) to address the calibrator instability.

Current Status

ARCHITECT Intact PTH Calibrators, Controls, and Reagents are now available for ordering.

- Implementation of ARCHITECT Intact PTH Calibrators and Controls with reduced expiration date (shelf life) will return the product performance to Package Insert claims. Please refer to the Supporting Data Section of this letter.
 - The new expiration date will provide you with approximately 1 to 2 months of laboratory usage dating.

Action

Please review the Supporting Data section below.

To ensure a smooth transition in your laboratory:

- Previous ARCHITECT Intact PTH Calibrator and Control lots **MUST NOT** be used as they should have been destroyed per Product Recall FA12FEB2014.
- After each use of ARCHITECT Intact PTH Calibrators and Controls, tightly close the caps and return to 2-8°C storage per the Package Insert instructions (56-7528/R2 Calibrators and 56-7520/R2 Controls).
- It is acceptable to use third party controls as an independent evaluation of the ARCHITECT Intact PTH assay.

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- Upon receipt of Calibrator and Control lots with new expiration dating:
 - You MUST calibrate. Stored calibration curves MUST NOT be used.
 - Once an ARCHITECT Intact PTH calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
 - A reagent kit with a new lot number is used.
 - Controls are out of range.
 - You should re-establish ranges for expected values. Based on your laboratory's evaluation, you may want to communicate the findings with your physicians and other health care providers.
 - As a reminder, the PTH analyte is relatively unstable requiring optimization of pre-analytical conditions including specimen type, sampling time and storage (Clin Chem Lab Med 2013; 51(10): 1925-1941), it is important that a normal range be established using samples from your laboratory.
 - Retain a copy of this communication for your records.
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Contact

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

Please refer to Product Information control number: PI07MAY2014.

Supporting Data

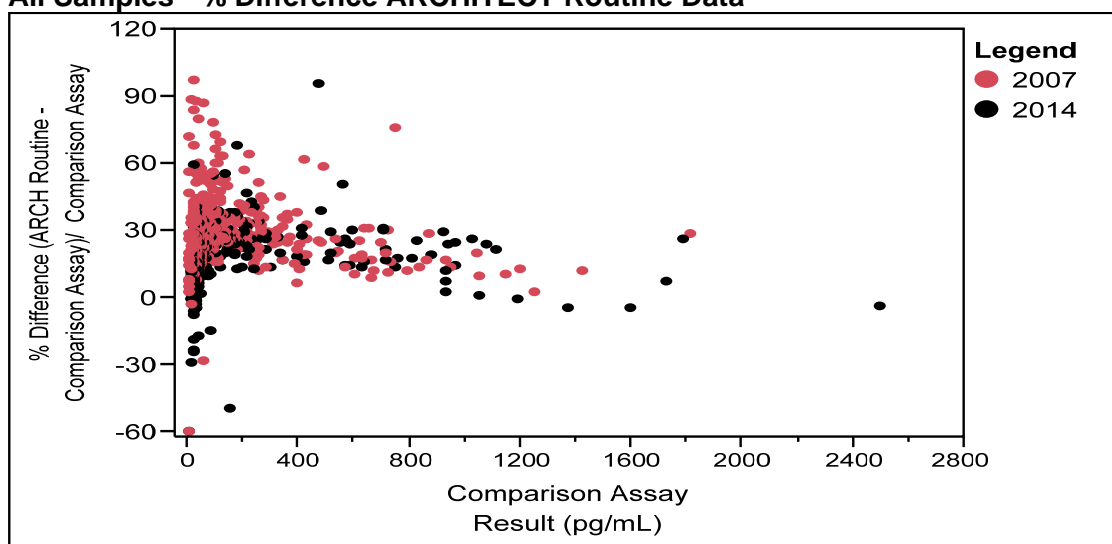
The data below supports the return of product performance to product claims.

A study performed in April 2014 using Abbott Intact PTH Calibrators with reduced dating demonstrates similar overall performance to a comparison assay. In the graphs below, the individual patient % bias from the 2007 study is shown in red and the individual patient % bias from an April 2014 study is shown in black. The study analysis includes tables and graphs for the overall population as well as a subset that are samples from patients with renal disease.

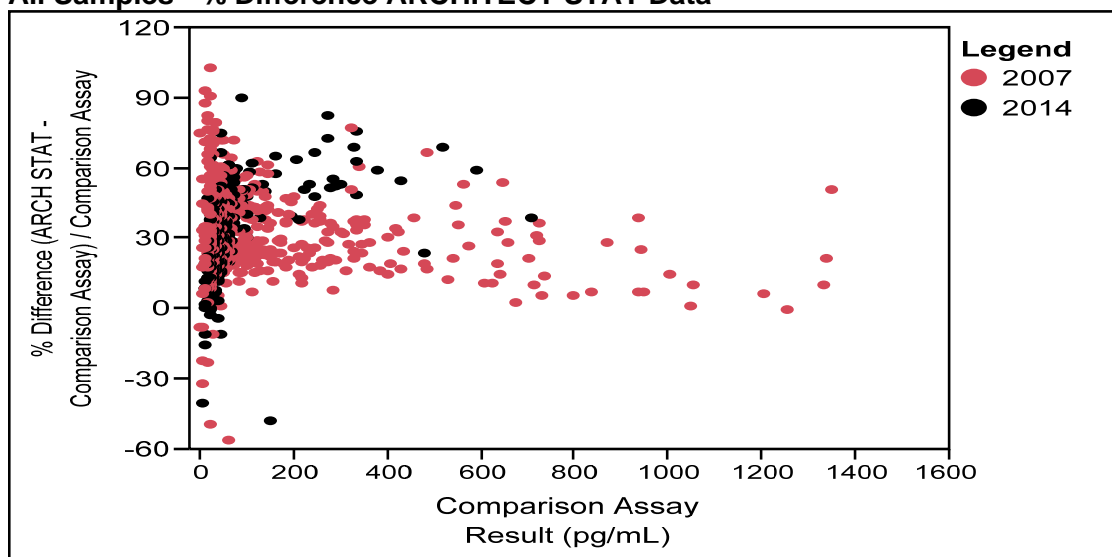
Representative performance data are shown. Variables such as differences in sampling size and sample population may impact the correlation of the assay; therefore, results obtained at individual laboratories may vary from these data.

Study Year	ARCHITECT Method	Population	ARCHITECT Intact PTH versus Comparison PTH Assay	
			n	% Bias Mean (95% CI)
2014	STAT	All samples	309	29.4 (-6.7 to 65.5)
2014	Routine	All samples	300	16.8 (-13.9 to 47.4)
2007	STAT	All samples	467	32.0 (-8.7 to 72.7)
2007	Routine	All samples	442	30.1 (-1.8 to 61.9)

All Samples - % Difference ARCHITECT Routine Data

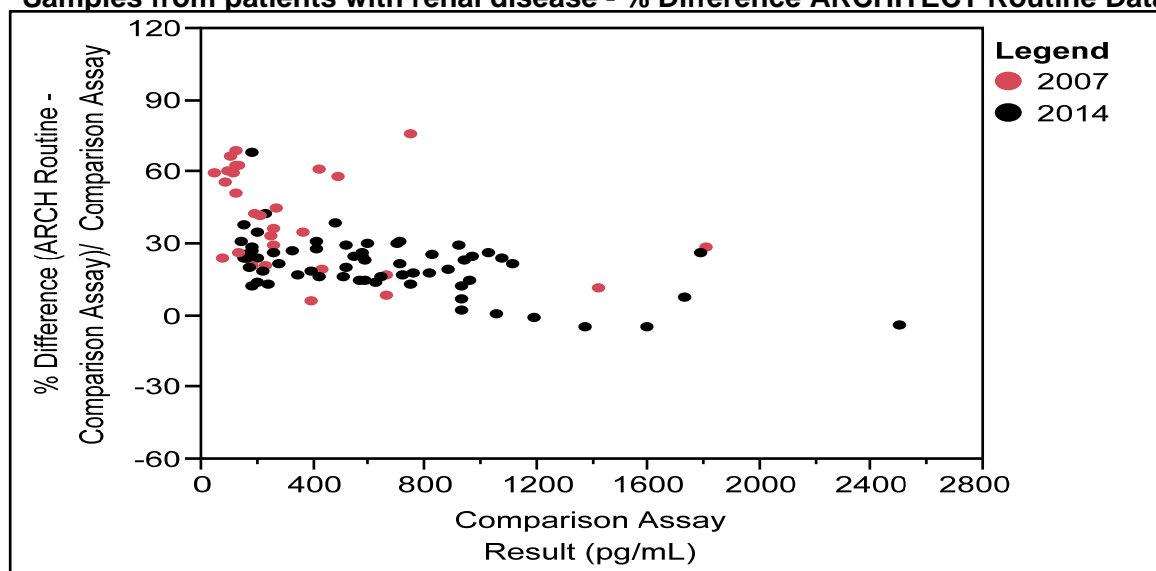


All Samples - % Difference ARCHITECT STAT Data



Study Year	ARCHITECT Method	Population	ARCHITECT Intact PTH versus Comparison PTH Assay	
			n	% Bias Mean (95% CI)
2014	STAT	Samples from patients with renal disease	33	51.1 (24.7 to 77.5)
2014	Routine	Samples from patients with renal disease	64	20.9 (-2.6 to 44.5)
2007	STAT	Samples from patients with renal disease	64	41.3 (11.6 to 70.9)
2007	Routine	Samples from patients with renal disease	29	40.9 (0.0 to 81.7)

Samples from patients with renal disease - % Difference ARCHITECT Routine Data



Samples from patients with renal disease - % Difference ARCHITECT STAT Data

