



Urgent Field Safety Notice Product Recall

Immediate Action Required

Date Issued

November 30, 2016

Product

Product Description	List Number	Lot Number	Expiration Date	UDI Number
ARCHITECT Active-B12 Reagent kit	3P24-25	10533UP00	29MAY2017	(01) 00380740006365 (17) 170529 (10) 10533UP00 (240) 3P2425
ARCHITECT Active-B12 Reagent Kit	3P24-35	10534UP00	29MAY2017	(01) 00380740006372 (17) 170529 (10) 10534UP00 (240) 3P2435

Explanation

The purpose of this letter is to inform you of a product recall for ARCHITECT Active-B12 (List Number (LN) 3P24) reagent lots listed above and to provide instructions on what action your laboratory must take.

Abbott has identified a lot specific stability issue with both reagent lots 10533UP00 and 10534UP00. As the reagent ages, Relative Light Unit (RLU) values for the calibration curve will decrease causing patient results calculated from this depressed curve to over-recover, potentially resulting in falsely elevated patient results. Controls may not reflect reagent instability as recalibration may result in control values within acceptable ranges.

Patient Impact

There is a potential for falsely elevated Active-B12 results to be generated when using ARCHITECT Active-B12 reagent lots 10533UP00 and 10534UP00.

Internal studies have determined the worst case magnitude of elevation to be up to 30% for Active-B12 concentrations close to 20 pmol/L and up to 20% for concentrations close to 30 pmol/L.

Necessary Actions

- Discontinue use and **immediately destroy any remaining inventory** of ARCHITECT Active-B12 reagent lots 10533UP00 and 10534UP00.
- Order replacement material.
- Please review this letter with your Medical Director to determine if a review of results previously generated with reagent lots 10533UP00 and 10534UP00 is required.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Recall and provide to them a copy of this letter.
- Please complete and return the Customer Reply Form.
- Please retain this letter for your laboratory records.

Contact Information

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