Abbott GmbH
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DIAGNOSTICS

Abbott

Urgent Field Safety Notice
Product Recall

Urgent - Immediate Action Required

Date Issued November 12, 2020

Product

Product Description	List Number	Lot Number	US UDI	EU UDI
Alinity i Active-B12 (Holotranscobalamin) Reagent	09P2625	11093UP00	N/A	N/A
Alinity i Active-B12 (Holotranscobalamin) Reagent	09P2635	11095UP00	N/A	N/A
Alinity i Active-B12 (Holotranscobalamin) Calibrators	09P2602	11096UP00	N/A	N/A
Alinity i Active-B12 (Holotranscobalamin) Controls	09P2611	11094UP00	N/A	N/A

Explanation

The purpose of this letter is to inform you of a product recall for the reformulated Alinity i Active-B12 product.

The reformulated Active-B12 product was launched in August 2020. Initial customer data for the reformulated product indicates a higher bias to the previous formulation than was observed during pre-launch method comparison testing.

This product recall for the reformulated product is being issued as a precautionary measure while a technical investigation is performed at Abbott. The previous formulation of Active-B12 continues to be available for order.

Patient Results Impact

There is a potential for incorrect results. Preliminary data has shown a potential for both positive and negative bias to the previous formulation results. The positive bias has been observed near the low end of the measuring range, below 40 pmol/L.

Necessary Actions

- Immediately discontinue use of, and destroy, any remaining inventory of the lot numbers listed above according to your local guidelines and your laboratory procedures.
- In the event you are currently using or have inventory of the lots listed in the table above, immediately contact Customer Support to order replacement lots of the previous formulation Alinity i Active-B12 (Holotranscobalamin) Reagent 09P2620, 09P2630, Alinity i Active-B12 (Holotranscobalamin) Calibrators 09P2601, and Alinity i Active-B12 (Holotranscobalamin) Controls 09P2610 and use assay file 214 Version 5.

Necessary Actions continued

- If you need to revert from assay file 214 Version 8 to assay file 214 Version 5 please contact Customer Service.
- Please review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported patient results.
- Complete and return the Customer Reply Form.

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 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.

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.