

Single Registration Number (SRN): N/A



Urgent Field Safety Notice Product Correction

Urgent - Immediate Action Required

Date Issued

March 24, 2022

Product

Product Description	List Number	Lot Number	UDI
Alinity i Homocysteine Reagent Kit	09P2820	11406UP00	(01) 00380740153496 (17) 220804 (10) 11406UP00
Alinity i Homocysteine Reagent Kit	09P2820	11453UP00	(01) 00380740153496 (17) 220913 (10) 11453UP00
Alinity i Homocysteine Reagent Kit	09P2820	11466UP00	(01) 00380740153496 (17) 220913 (10) 11466UP00
Alinity i Homocysteine Reagent Kit	09P2820	11486UP00	(01) 00380740153496 (17) 221024 (10) 11486UP00
Alinity i Homocysteine Reagent Kit	09P2820	11485UP00	(01) 00380740153496 (17) 220913 (10) 11485UP00

Explanation

The purpose of this letter is to inform you of a Product Correction for the Alinity i Homocysteine Reagent Kits listed in the Product section above. Abbott has identified that some reagent kits produce suboptimal calibrations resulting in a downward shift of quality control results. If your laboratory has established statistically-based control limits at each clinically relevant control level, your controls will detect the shift out of range. If quality control results do not meet the acceptance criteria defined by your laboratory, sample results may be suspect and should not be reported.

Impact on Patient Results

There is a potential for falsely depressed results to occur following suboptimal calibration.

Necessary Actions to be Taken by Customer

- You may continue to use the reagent lot number(s) listed above if your laboratory has established statistically-based control limits at each clinically relevant control level.
- If your laboratory has not established statistically-based control limits at each clinically relevant control level, refer to the Instructions for Use (IFU).
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
- 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 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.
