Abbott GmbH & Co. KG
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Germany

Abbott

Urgent Field Safety Notice

Product Recall

Urgent - Immediate Action Required

To The Medical Director/ Head of Laboratory

Date Issued September 28, 2018

Product

Product Description	List Number (LN)	Lot Number	UDI
ARCHITECT HAVAb-IgG Reagent Kit	6C29-22	90356LI00	(01)00380740115302 (17)190607(10)90356LI00
	6C29-27	90360LI00	(01)00380740115319 (17)190607(10)90360LI00
ARCHITECT HAVAb-IgM Reagent Kit	6C30-22	90228LI00	(01)00380740145231 (17)190107(10)90228LI00
	6C30-22	91012LI00	(01) 00380740145231 (17)190211(10)91012LI00
	6C30-27	90227LI00	(01)00380740145248 (17)190107(10)90227LI00
	6C30-27	91013LI00	(01) 00380740145248 (17)190211(10)91013LI00
Alinity i HAVAb IgG Reagent Kit	8P26-32	90385LI00	(01)00380740131340 (17)190607(10)90385LI00

Explanation

This letter is to inform you of a Product Recall for ARCHITECT HAVAb-IgM, ARCHITECT HAVAb-IgG and Alinity i HAVAb IgG reagent lots as listed in table above and provide instructions on the actions your laboratory must take.

Abbott has confirmed that a performance shift for the ARCHITECT HAVAb-IgM, ARCHITECT HAVAb-IgG and Alinity i HAVAb IgG reagent lots as listed in table above has the potential to generate falsely elevated control and patient sample results.

Preliminary investigation of this issue has identified a manufacturing error specific to the lots listed above. Additional information will be provided upon completion of the investigation to help quantify the magnitude of the shift in results.

Patient Impact

Samples tested using ARCHITECT HAVAb-IgM, ARCHITECT HAVAb-IgG and Alinity i HAVAb IgG assays may show falsely elevated results with lots mentioned in table above.

Necessary Actions	• **Immediately** discontinue use of, and destroy, any remaining inventory of these seven ARCHITECT HAVAb-IgM, ARCHITECT HAVAb-IgG and Alinity i HAVAb IgG reagent lots according to your laboratory procedure. • In the event you are currently using or have inventory of one of these seven lots, immediately contact Customer Support for replacement material. • 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. • If you have forwarded any of these seven lots to other laboratories, please inform them of this Product Recall 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	We sincerely regret any inconvenience this issue may cause. If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.