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Abbott

Urgent Field Safety Notice
Product Recall

Urgent - Immediate Action Required

Date Issued October 17, 2018

Product

Table 1: Reagent lots of initial Field Action FA28SEP2018

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

Table 2: Reagent lots of extended Field Action FA28SEP2018

Product Description	List Number (LN)	Lot Number	UDI
ARCHITECT HAVAb-IgG Reagent Kit	6C29-22	87316LI00	(01)00380740115302 (17)190404(10)87316LI00
	6C29-27	87317LI00	(01)00380740115319 (17)190404(10)87317LI00
ARCHITECT HAVAb-IgM Reagent Kit	6C30-22	87006LI00	(01) 00380740145231 (17)181001(10)87006LI00
	6C30-22	87306LI00	(01) 00380740145231 (17)181103(10)87306LI00
	6C30-22	89081LI00	(01) 00380740145231 (17)181208(10)89081LI00
	6C30-27	87007LI00	(01)00380740145248 (17)181001(10)87007LI00
	6C30-27	89082LI00	(01)00380740145248 (17)181208(10)89082LI00
	6C30-27	89248LI00	(01)00380740145248 (17)181225(10)89248LI00
Alinity i HAVAb IgG Reagent Kit	8P26-22	87322LI00	(01)00380740131333 (17)190404(10)87322LI00
	8P26-32	88245LI00	(01)00380740131340 (17)190404(10)88245LI00

Explanation

You may have received the initial Product Recall Letter for ARCHITECT HAVAb-IgM, ARCHITECT HAVAb-IgG and Alinity i HAVAb IgG reagent lots (FA28SEP2018) issued on 28-Sep-2018 as you received one or more lots listed in Table 1.

This letter is an extension to Product Recall FA28SEP2018 issued on 28-Sep-2018. While investigating to root cause, another 10 ARCHITECT HAVAb-IgM, ARCHITECT HAVAb-IgG and Alinity i HAVAb IgG reagent lots have been identified as being also impacted by a performance shift (see Table 2). Evaluation of all lots has been completed and no additional impacted lots have been identified.

The investigation identified a manufacturing error specific to the lots listed in Tables 1 and 2. A mode of detection and additional manufacturing instructions will be implemented to prevent reoccurence of this issue.

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 Tables 1 and 2, has the potential to generate falsely elevated control and patient sample results.

An internal study with anti-HAV negative patient samples has been performed and has determined the following impacted S/CO ranges for:

- ARCHITECT HAVAb-IgG: 1.00 – 2.13 S/CO
- ARCHITECT HAVAb-IgM: 1.00 – 1.26 S/CO
- Alinity i HAVAb IgG: 1.00 – 2.59 S/CO

Patient Impact

Samples tested using ARCHITECT HAVAb-IgM, ARCHITECT HAVAb-IgG and Alinity i HAVAb IgG assays may show falsely elevated results with lots referenced in Tables 1 and 2.

Necessary Actions

- **Immediately** discontinue use of, and destroy, any remaining inventory of these 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 lots, immediately contact Order Entry 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 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.