CORE DIAGNOSTICS

Abbott Ireland
Diagnostics Division
Finisklin Business Park
Sligo, Ireland

Single Registration Number (SRN):
IE-MF-000009849

Urgent Field Safety Notice

Urgent Product Recall

Immediate Action Required

Date Issued August 26, 2024

Product

Product Description	List Number (LN)	Lot Number	UDI
Alinity i HBsAg Controls	08P0810	59044FZ00	(01) 00380740130152 (17) 250115 (10) 59044FZ00
ARCHITECT HBsAg Controls	6C36-10	60109FZ00	(01) 00380740009496 (17) 250115 (10) 60109FZ00
ARCHITECT HBsAg Controls	6C36-10	59039FZ00	(01) 00380740009496 (17) 250115 (10) 59039FZ00

Explanation

Abbott has identified that some positive control 2 vials of Alinity i HBsAg Control Kit, LN 08P0810 lot number 59044FZ00 and ARCHITECT HBsAg Control Kit, LN 6C36-10 lot numbers 60109FZ00 and 59039FZ00 may contain a fungal contaminant which could result in aspiration errors. We received complaints associated with this issue due to aspiration errors and/or material clogging the dispensing tip of the Positive Control 2 (PC2) vial, also with reports of visible material in the PC2 component only.

Abbott is investigating this event and will take the necessary actions to prevent recurrence in the future.

Impact on Patient Results

There is no impact to patient results.

Necessary Actions to be Taken by Customer

- Immediately discontinue use of and destroy all inventory of Alinity i HBsAg Control Kit, LN 08P0810 lot number 59044FZ00 and ARCHITECT HBsAg Control Kit, LN 6C36-10 lot numbers 60109FZ00 and 59039FZ00 according to your local procedures.
- Immediately contact Customer Support to order replacement material.
- If you have forwarded the products listed above 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

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.

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Customer Reply

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Core Diagnostics Product Recall letter dated August 26, 2024 – FA26AUG2024

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Instructions

Please provide a copy of the accompanying Product Recall letter to the laboratory manager, supervisor or health professional responsible for the impacted product. Please complete all sections and return this Customer Reply Form to the Abbott contact prior to **09SEP2024**. Even if you no longer have the instrument(s)/reagent(s), this form is required for the reconciliation of our records.

Abbott contact

E-mail: PMS@abbott.com (insert local e-mail address here)
Fax: 1-800-777-0051 (insert local number here)

Acknowledgement

By completing and signing this document I confirm that the Product Recall Letter was understood and that the necessary actions for the customer were completed. If not, please choose one of the options below.

☐ No, I would like to be contacted by an Abbott Representative.
☐ Not Applicable, Please Explain (e.g. no longer have the instrument):
_____

Product Replacement

Credit will be based upon the total number of kits/units destroyed:

List Number	Lot Number	Number of kits/units Destroyed
08P0810	59044FZ00	
6C36-10	60109FZ00	
6C36-10	59039FZ00	

Customer number		**Serial Number(s)**	
Facility Name(s)			
Address			
City		**State**	
Phone Number		**E-mail**	
Name (print)		**Title/Position**	
Signature		**Date**	