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 December 12, 2023

Product

Product Description	List Number	Lot Number	UDI
Alinity i HBsAg Reagent Kit	08P0852	51503FN00	(01) 380740130206 (17)240509 (10) 51503FN00

Explanation

Abbott has identified a few cartridges within Alinity i HBsAg Reagent Kit, list number 08P0852, lot 51503FN00 that may exhibit variability in relative light unit (RLU) response and concentration values which may result in controls out of range, and/or incorrect patient results.

Positive control out of range low results and/or negative control out of range high results could occur when using an impacted cartridge. Per the Instructions for Use (IFU), controls are required to be run once within each 24 hours of use.

A potential falsely decreased or falsely increased patient result may occur for any of the following scenarios:

1. An impacted cartridge was used without running controls.
2. An impacted cartridge was used following calibration with a non-impacted cartridge.
3. An impacted cartridge was successfully calibrated, and controls were within range but calibrator and/or control RLUs are low.

Impact on Patient Results

There is potential for incorrect patient results. Falsely decreased and/or falsely increased results may be observed when using the Alinity i HBsAg assay for the quantitative determination of hepatitis B surface antigen (HBsAg).

Necessary Actions to be Taken by Customer

- Immediately discontinue use of Alinity i HBsAg Reagent Kit, lot number 51503FN00.
- Destroy all inventory of lot number 51503FN00 received according to your local procedure.
- Immediately contact Customer Support to order replacement material.
- Please review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for review of previously reported patient results using lot number 51503FN00.
- 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 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 December 12, 2023 – FA21NOV2023 Revision 01

Product

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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 **26DEC2023**. 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
08P0852	51503FN00	

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