



نتقدم بثقة
Moving Forward
with Confidence



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 133 dated 26/9/2024 Regarding SFDA Field Safety Corrective Action of Alinity i HBsAg Controls and ARCHITECT HBsAg Controls from (mfr: Abbott Ireland Diagnostics Division).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



DSC
مركز سلامة الدواء
Drug Safety Center



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

☒ @DSCPHO Email: dscpho@moh.gov.om



Circular No. 133/2024

22-03-1446 H
26-09-2024

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FSCA of Alinity i HBsAg Controls and ARCHITECT HBsAg Controls from Abbott Ireland Diagnostics Division.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/88
Product	Alinity i HBsAg Controls and ARCHITECT HBsAg Controls.
Manufacturer	Abbott Ireland Diagnostics Division.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Alinity i HBsAg Controls List Number (LN): 08P0810 Lot Number: 59044FZ00 UDI: (01) 00380740130152 (17) 250115 (10) 59044FZ00 ARCHITECT HBsAg Controls List Number (LN): 6C36-10 Lot Number: 60109FZ00 (UDI: (01) 00380740009496 (17) 250115 (10) 60109FZ00 Lot Number: 59039FZ00 (UDI: (01) 00380740009496 (17) 250115 (10) 59039FZ00
Reason	Some positive control 2 vials of the devices mentioned above may contain a fungal contaminant, which could result in aspiration errors.
Action	1. Immediately discontinue use of and destroy all affected lots, refer to the attachment for more details. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General





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.



Customer Reply

Immediate Action Required

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

Product	Product Description	List Number	Lot Number	UDI												
	Alinity i HBsAg Controls	08P0810	59044FZ00	(01) 00380740130152 (17) 250115 (10) 59044FZ00												
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	ARCHITECT HBsAg Controls	6C36-10	59039FZ00	(01) 00380740009496 (17) 250115 (10) 59039FZ00												
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. <input type="checkbox"/> No, I would like to be contacted by an Abbott Representative. <input type="checkbox"/> Not Applicable, Please Explain (e.g. no longer have the instrument): <hr style="width: 20%; margin-left: 10%;"/>															
Product Replacement	Credit will be based upon the total number of kits/units destroyed:															
	<table border="1"> <thead> <tr> <th>List Number</th> <th>Lot Number</th> <th>Number of kits/units Destroyed</th> </tr> </thead> <tbody> <tr> <td>08P0810</td> <td>59044FZ00</td> <td></td> </tr> <tr> <td>6C36-10</td> <td>60109FZ00</td> <td></td> </tr> <tr> <td>6C36-10</td> <td>59039FZ00</td> <td></td> </tr> </tbody> </table>				List Number	Lot Number	Number of kits/units Destroyed	08P0810	59044FZ00		6C36-10	60109FZ00		6C36-10	59039FZ00	
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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	