



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 169 dated 21/8/23 Regarding NCMDR Field Safety Corrective Action of Alinity s Anti-HBc Reagent Kit from (mfr: Abbott).

Copy to:

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





Circular No. 169/ 2023

05 -02-1445 H

21 -08-2023

Field Safety Corrective Action of Alinity s Anti-HBc Reagent Kit from Abbott.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19639
Product	Alinity s Anti-HBc Reagent Kit.
Description	IVD.
Manufacturer	Abbott.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	List Number (LN): 06P0655 Lot Number: 40471BE00, 43073BE00, 45291BE00, 49212BE00, 50512BE00, and all future lots. UDI: (01) 00380740103002 (17) 230804 (10) 40471BE00, (01) 00380740103002 (17) 231014 (10) 43073BE00, (01) 00380740103002 (17) 231124 (10) 45291BE00, (01) 00380740103002 (17) 240405 (10) 49212BE00, (01) 00380740103002 (17) 240502 (10) 50512BE00
Reason	When the Alinity s Anti-HBc Reagent Kit (LN 06P0655) and the Alinity s Anti-HCV II Reagent Kit (LN 04W5655, 04W5656) are calibrated and run on the same processing lane, incorrect Anti-HBc test results (false positive) may occur.
Action	1. Please refer to "Necessary Actions to be Taken by Customer" in the attachment. Moreover, follow your laboratory protocol regarding the need for reviewing previously reported test results. 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: Med-device@moh.gov.om



CORE DIAGNOSTICS
Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden, Germany

Single Registration Number (SRN):
DE-MF-000009455

Urgent Product Correction

Immediate Action Required

Date Issued July 25, 2023

Product

Product Description	List Number (LN)	Lot Number	UDI
Alinity s Anti-HBc Reagent Kit	06P0655	40471BE00	(01) 00380740103002 (17) 230804 (10) 40471BE00
		43073BE00	(01) 00380740103002 (17) 231014 (10) 43073BE00
		45291BE00	(01) 00380740103002 (17) 231124 (10) 45291BE00
		49212BE00	(01) 00380740103002 (17) 240405 (10) 49212BE00
		50512BE00	(01) 00380740103002 (17) 240502 (10) 50512BE00

Note: This communication applies to Alinity s Anti-HBc Reagent Kit lots above and all future lots.

Explanation

When the Alinity s Anti-HBc Reagent Kit (LN 06P0655) and the Alinity s Anti-HCV II Reagent Kit (LN 04W5655, 04W5656) are calibrated and run on the same processing lane, incorrect Anti-HBc test results (false positive) may occur.

The Alinity s System software includes a feature to configure assays to calibrate on designated processing lanes when prescribed by the associated assay file. The Alinity s Anti-HCV II assay file has been updated to activate this feature for the Alinity s Anti-HBc Reagent Kit. Installation of the updated Alinity s Anti-HCV II assay file 260_008, (LN 04W56-1D), will automatically separate the Alinity s Anti-HBc and Alinity s Anti-HCV II assays by processing lane if both assays are installed on the same Alinity s System.

Impact on Donor/Patient Results

There is potential for incorrect Anti-HBc test results should the initial and retest results be falsely reactive.

**Necessary
Actions to be
Taken by
Customer**

If...	Then...
<p>The Alinity s Anti-HCV II assay and the Alinity s Anti-HBc assay are calibrated, and run, on the same processing lane.</p>	<p>The two assays must be calibrated, and run, on separate processing lanes.</p> <p>Necessary Action: Install the Alinity s Anti-HCV II assay file 260_008 (LN 04W56-1D) on your Alinity s System(s). Refer to the installation instructions below.</p>
<p>The Alinity s Anti-HCV II assay is not calibrated, and run, on the same processing lane as the Alinity s Anti-HBc assay.</p>	<p>Maintain the current configuration with the Anti-HCV II and Anti-HBc assays calibrated on separate processing lanes.</p> <p>Necessary Action: Install the Alinity s Anti-HCV II assay file 260_008 (LN 04W56-1D) on your Alinity s System(s). Refer to the installation instructions below.</p>
<p>The Alinity s Anti-HBc and / or Alinity s Anti-HCV II assays are not currently included in the active testing profile, or the two assays are not calibrated, and run, on the same Alinity s System.</p>	<p>Necessary Action: Install the Alinity s Anti-HCV II assay file 260_008 (LN 04W56-1D) on your Alinity s System(s). Refer to the installation instructions below.</p> <p>No additional necessary action will be required.</p>

Necessary Action

Three (3) Options for Installing the Alinity s Anti-HCV II assay file 260_008, (LN 04W56-1D)

1. From your work computer terminal, visit www.transfusion.abbott. Go to the CUSTOMER PORTAL LOGIN tab to access LABCENTRAL. From there, go to TECHNICAL LIBRARY. **Location:** Outside US. **Search Type:** Assay Files. **Product:** Alinity s. **List Number:** 04W56-1D. Click **SEARCH**. Follow the instructions to Select and Download to a USB.
or
2. **AbbottLink:** Using the Alinity s System User Interface (UI), on the *Abbott Mail Inbox screen* tap Request. Then, tap Request Assay on the *Manual File Request screen* to manually download the assay file to the Alinity s System.

For either option above, follow instructions found in the **Alinity s System Online Help** to update the assay file. Access the Operations Manual by clicking on the *System* tab to go to *Operations Manual (Help)*. From the *Contents* tab, select *Section 2, Installation procedures and special requirements > System configuration > Configure screen, Assay tab* and follow the *Install/Uninstall assays screen > Install assay files and Uninstall assay files screen.*

3. If you require additional support, please contact your local area customer service representative to install the Alinity s Anti-HCV II assay file 260_008 (LN 04W56-1D) on your Alinity s System(s).

**Necessary
Actions to be
Taken by
Customer
continued**

- Please review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported test results.
- If you have forwarded the Alinity s Anti-HBc product to other laboratories, please inform them of this Product Correction and provide 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 any 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.
