



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 248 dated 29/12/2022 Regarding NCMDR Field Safety Corrective Action of Alinity m System 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. 248/2022

نقدم بثقة  
Moving Forward  
with Confidence



05 -06-1444 H

29 -12-2022

### Field Safety Corrective Action of Alinity m System from Abbott.

Source	NCMDR - National Center Medical Device Reporting- SFDA. <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=18378">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=18378</a>
Product	Alinity m System
Description	IVD.
Manufacturer	Abbott.
Local agent	Waleed Pharmacy & Stores LLC.
The affected products	Product: Alinity m System List Number: 08N53-002 Not Serial Specific Unique Device Identifier (UDI): 00884999048034.
Reason	Abbott has identified three potential issues which may have impacted the Amplification Detection Unit(s) (ADU) installed on Alinity m System (see details in Appendix A) in the attached FSN.
Action	1. An assessment of your Alinity m System associated with the listed potential issues will be completed remotely if your system is currently connected to AbbottLink or alternatively via onsite inspection by an Abbott representative. If necessary, an Abbott representative will schedule time to correct the affected ADU(s) on your Alinity m. System(s). In the interim, please continue to follow your laboratory protocols for any suspected incorrect results. Following the assessment and any necessary service, an additional communication will follow. If it is determined that your instrument was impacted, please assess the impact to your laboratory in reviewing previously generated 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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

Director General



**PADDC**  
المديرية العامة للصيدلة والرقابة الدوائية  
Directorate General of Pharmaceutical  
Affairs & Drug Control

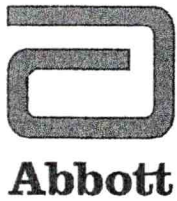


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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

dgpa\_dc Email: [dg-padc@moh.gov.om](mailto:dg-padc@moh.gov.om)





**Urgent Field Safety Notice  
Molecular Diagnostics at Abbott**

**Product:** Alinity m System

**List Number:** 08N53-002

**Not Serial Specific**

**Unique Device Identifier (UDI):** 00884999048034

December 9, 2022

Dear Abbott Customer,

This letter contains important information regarding your Alinity m System which is the subject of this field correction; specifically, the Amplification Detection Unit(s) (ADU) installed on your Alinity m System. Please review this information carefully.

**Background**

Abbott has identified three potential issues which may have impacted the Amplification Detection Unit(s) (ADU) installed on your Alinity m System (see details in **Appendix A**).

1. Systems which had their ADUs serviced may have an incorrect board value (calibration data file) referenced causing a misconfiguration of the calibration.
2. Inability of Maintenance and Diagnostics 2300 (Amp Detect Optical Calibrations) to recognize error handling and thermal hold errors during the calibration process, potentially leading to a misconfiguration of the calibration.
3. Under specific conditions during the ADU manufacturing process, an incorrect calibration may potentially have been configured.

There have been zero (0) reports received to-date of harm associated with these issues.

**Potential Impact**

Refer to **Appendix A**.

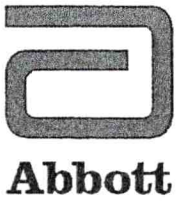
**Necessary Actions**

Please complete and return the Customer Reply Form.

An assessment of your Alinity m System associated with the above listed potential issues will be completed remotely if your system is currently connected to AbbottLink or alternatively via onsite inspection by an Abbott representative. If necessary, an Abbott representative will schedule time to correct the affected ADU(s) on your Alinity m System(s). In the interim, please continue to follow your laboratory protocols for any suspected incorrect results. Following the assessment and any necessary service, an additional communication will follow.

If it is determined that your instrument was impacted, please assess the impact to your laboratory in reviewing previously generated test results.

This correction is to be carried out at the user/customer level. If this product has been further distributed by your facility, please notify any additional impacted customers.



Abbott  
1300 E. Touhy Ave.  
Des Plaines, IL 60018

**Urgent Field Safety Notice  
Molecular Diagnostics at Abbott**

**Product:** Alinity m System

**List Number:** 08N53-002

**Not Serial Specific**

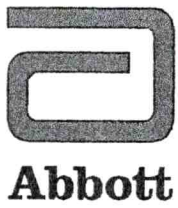
**Unique Device Identifier (UDI):** 00884999048034

Please review this information with laboratory personnel and retain this communication for future reference. If you have any questions regarding this communication, please contact your local Abbott representative. We apologize for any inconvenience this may have caused your laboratory.

Sincerely,

*Ray Bastian 12/9/22*

Ray Bastian  
Divisional Vice President Quality Molecular  
Diagnostics at Abbott



**Urgent Field Safety Notice  
Molecular Diagnostics at Abbott**

**Product:** Alinity m System

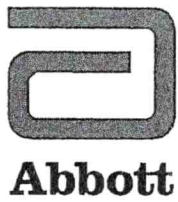
**List Number:** 08N53-002

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**Unique Device Identifier (UDI):** 00884999048034

**Appendix A**

Alinity m System			Available Actions Until Mandatory Service is Complete
	Issue	Hazards and Impact	
1.	When replacing a previous ADU if a backup boardvalue (calibration data file) exists on the system that was from another ADU and that file was not properly restored onto the previous ADU, the new ADU being installed may have that backup file restored in which the calibration values do not match that new ADU. The process of installing a new ADU does not consider the uniqueness of the ADU (e.g., hardware MAC address) when restoring boardvalues.	<p>There is the potential for incorrect results if this scenario occurs and the internal control (IC), Cellular Controls (CC), or routine process controls does not invalidate the test and/or run.</p> <p>There is the potential for delay of results if one of these scenarios occur and the samples or runs are flagged due to invalid IC, CC, or routine process controls.</p>	<p>Place an ADU out of service until mandatory service is complete if it is associated with any of the following:</p> <ol style="list-style-type: none"> <li>1. Suspected incorrect results</li> <li>2. A high frequency of errors</li> </ol> <p>Contact Abbott technical support if you have concerns about the performance of your instrument or your results.</p>



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	<b>Issue</b>	<b>Hazards and Impact</b>	<b>Available Actions Until Mandatory Service is Complete</b>
2.	There is a possible M&D 2300 Optical Calibration vulnerability when an ADU thermal error occurs, or an instrument error occurs during optical calibration that can lead to non-optimized calibration parameters for the ADU being calibrated.	<p>There is the potential for Incorrect Results if this scenario occurs and the internal control (IC), Cellular Controls (CC), or routine process controls does not invalidate the test and/or run.</p> <p>There is the potential for Delay of Results if this scenario occurs and the samples or runs are flagged due to invalid IC, CC, or routine process controls.</p>	Same as above
3.	Specific scenarios of using an incorrect optical calibration completed during manufacturing or using a dye with extraneous fluorescent material, or incorrect board value (optical calibration file), in the ADUs may have occurred resulting in an incorrect crosstalk or optical calibration.	<p>There is the potential for incorrect results. Incorrect crosstalk or optical calibration can cause signal compensation that may boost or suppress signal generating incorrect results.</p> <p>There is a potential for Delay in Results if the instrument flags test results with data reduction errors invalidating the sample.</p>	Same as above