

**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**.

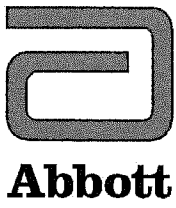
Necessary Actions

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.



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1300 E. Touhy Ave.
Des Plaines, IL 60018

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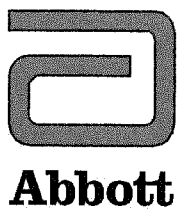
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Please review this information with laboratory personnel and retain this communication for future reference. If you have any questions regarding this communication, please contact your local Abbott representative. We apologize for any inconvenience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

Sincerely,

A handwritten signature in black ink that reads 'Ray Bastian' followed by the date '12/9/22'.

Ray Bastian
Divisional Vice President Quality Molecular
Diagnostics at Abbott



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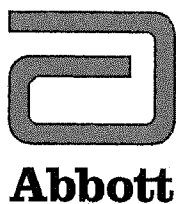
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Appendix A

| Alinity m System | | | |
|------------------|---|--|---|
| | Issue | Hazards and Impact | Available Actions Until Mandatory Service is Complete |
| 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">1. Suspected incorrect results2. A high frequency of errors <p>Contact Abbott technical support if you have concerns about the performance of your instrument or your results.</p> |



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| | Issue | Hazards and Impact | Available Actions Until Mandatory Service is Complete |
|-----------|---|--|--|
| 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 |