Molecular Diagnostics at Abbott
1300 E. Touhy Ave.
Des Plaines, IL 60018

Field Advisory Notice
Molecular Diagnostics at Abbott
Product: Alinity m System
List Number: 08N53
Not Serial Specific
Unique Device Identifiers (UDIs): See table below

February 27, 2025

Dear Abbott Customer,

This letter contains important information regarding the Alinity m System; specifically, Alinity m System Software version v1.8.1 or lower installed on your Alinity m System(s). Please review this information carefully.

PRODUCT	LIST NUMBER	UNIQUE DEVICE IDENTIFIER (UDI)
Alinity m System	08N53-01	(01)00884999047389
Alinity m System	08N53-02	(01)00884999048034
Alinity m System Refurbished	08N53-32	(01)00884999047587

Background

Abbott has identified three potential performance issues for the Alinity m System Software and will release a mandatory Alinity m System Software update (version v1.9.0) to correct these issues (see details in Appendix A).

1. The Sample Input Camera may falsely recognize primary tubes as secondary tubes if the user places labels or markings near the top of the tubes. This may result in aspiration errors due to incorrect aspiration parameters being applied.
2. Integrated Reaction Units (IRUs) may become double stacked during processing if an IRU was moved out of position when Sample Processing Unit Processor (SPUP) initialization occurred. This may cause a stoppage of the instrument.
3. In the scenario where a user manually creates an order with a Sample ID (SID) that exceeds the twenty (20) character maximum as described in the Operations Manual and then repeatedly attempts to onboard the order, it may cause a lack of tracking of expiration for reagents, calibrators, controls, and specimens.

Potential Impact

Refer to Appendix A for details concerning any hazards identified due to the issues found in the Alinity m System Software.

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Necessary Actions
Please refer to Appendix A for actions until your Alinity m System receives the software upgrade. Please review this information with laboratory personnel and retain this communication for future reference.

Your Abbott representative will schedule a mandatory upgrade of your Alinity m System software. Software upgrade will be available upon specific local country regulatory approval.

Please complete and return the Customer Reply Form.

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,

Feb 27, 2025

Pamela Yip
Divisional Vice President, Quality Assurance
Molecular Diagnostics at Abbott

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Appendix A

	Issue	Hazards and Impact	Actions Until Mandatory Upgrade is Complete
1.	The Sample Input Camera may falsely recognize primary tubes as secondary tubes if the user places labels or markings near the top of the tubes. This may result in aspiration errors due to incorrect aspiration parameters being applied.	There is the potential for incorrect results for the scenario where the Sample Input Camera falsely recognizes primary tubes as secondary tubes.	Refer to the Alinity m Operations Manual Addendum on the Diagnostics Portal for Sample tube specifications and requirements. To reduce the risk of falsely identifying primary tubes as secondary tubes, avoid markings and labeling in the keep-out zone for sample tubes. The keep-out zone is the area where the sample tube label cannot contain colors other than white and black. The keep out zone is above a maximum of 85 mm from the bottom of a round-bottom sample tube or above a maximum of 70 mm from the bottom of a flat-bottom sample tube.
2.	Integrated Reaction Units (IRUs) may become double stacked during processing if an IRU was moved out of position when Sample Processing Unit Processor (SPUP) initialization occurred. This may cause a stoppage of the instrument.	If IRUs become double stacked, there may be a potential delay in results.	If an IRU double stacking occurs, place the impacted APU out of service using the Maintenance and Diagnostic procedure 2752 in the Alinity m Service Manual. If you experience further issues, please contact your Abbott representative for further guidance and support.
3.	In the scenario where a user manually creates an order with a Sample ID (SID) that exceeds the twenty (20) character maximum as described in the Operations Manual and then repeatedly attempts to onboard the order, it may cause a lack of tracking of expiration for reagents, calibrators, controls, and specimens.	There is the potential for incorrect results if using a Sample ID length greater than 20 characters and attempting repeatedly to onboard the order may cause a lack of tracking of expiration for reagents, calibrators, controls, and specimens. This may lead to tests being run with expired calibrators, controls, reagents, or specimens that have expired.	Avoid using a SID that exceeds 20 characters. If orders are incorrectly updated to the ONBOARD status without a rack being onboard the system, shutdown and restart the instrument as explained in the Operations Manual.

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Customer Reply Form
Molecular Diagnostics at Abbott
Product: Alinity m System
List Number: 08N53
Not Serial Specific
Unique Device Identifiers (UDIs): See FA-AM-FEB2025-305
Field Advisory Notice FA-AM-FEB2025-305
Dated February 27, 2025

Dear Abbott Customer,

Please complete the following information below acknowledging receipt of the **Field Advisory Notice FA-AM-FEB2025-305** and return it to us by Fax or by e-mail, **prior to March 14, 2025,** to:

Molecular Diagnostics at Abbott
Attention: AM Field Quality
Fax #: 847-775-6728 or E-mail: AM_FieldQuality@abbott.com

Instructions:
1. Please provide a copy of the accompanying Field Advisory Notice FA-AM-FEB2025-305 to the laboratory manager, supervisor, or health professional responsible for the impacted product.
2. Please complete all sections and return this Customer Reply Form to the above Abbott contact prior to March 14, 2025. If you no longer have the instrument(s)/reagents(s), this form is still required to be completed and returned for the reconciliation of our records.
3. If you have forwarded any impacted product to other laboratories, please inform them of this Field Advisory Notice; provide a copy of the letter and reply form to them; and have them take the necessary actions listed here.

Please record the following information:

Customer Number		Name of Institution	
Address		City	
Country		Postal Code	
Name		Title / Position	
Phone Number		Email Address or Other Contact Information	

Customer Acknowledgement

By completing and signing this document, I confirm that the Field Advisory Notice FA-AM-FEB2025-305 disseminated to all users, understood, and implemented, and that the necessary actions for the customer were completed.

__ Yes, I confirm.

If not, please choose one of the options below:

__ No, I would like to be contacted by an Abbott Representative.
__ Not Applicable. Please explain on the line below (e.g., no longer have the instrument):
_____

_____ _____
Signature Date

_____
Printed Name