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

Urgent Field Safety Notice / Field Correction Recall
Molecular Diagnostics at Abbott
Product: Alinity m System
List Number: 08N53
Not Serial Specific
Unique Device Identifier: See table below

Dear Abbott Customer,

This letter contains important information regarding Alinity m System (List 08N53). 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 Molecular is implementing an improved design element to prevent leaks outside the footprint of the instrument. Abbott has identified that the System Solutions drawer enclosure design of the Alinity m System may allow liquid (liquid waste or system solution(s)) originating in the System Solutions drawer to flow beyond the footprint of the instrument and into the walking-path of the user.

An Alinity m System Liner will be installed to mitigate these leaks beyond the footprint of the instrument. An Abbott representative will contact you to schedule this installation. Availability of this liner is dependent upon obtaining local regulatory approval.

Potential Impact

If the leaked fluid (liquid waste or system solution(s)) accumulates within the System Solution drawer and potentially into the walking path of the user, the fluid could result in a physical hazard due to the potential for slip or fall. Additionally, leakage may introduce a potential for exposure to chemicals and potential biohazard exposure due to the presence of liquid waste originating from processed patient sample(s).

This issue has no impact on performance and clinical results generated. Furthermore, there have been zero occurrences of harm reported to date.

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Necessary Actions
In accordance with the Alinity m Operations Manual, users should always utilize Personal Protective Equipment when engaging with the instrument. In the event you observe a leak, please take appropriate precautions to prevent exposure and immediately contact your Abbott Molecular Representative for additional troubleshooting information.

Please complete and return the associated Customer Reply Form. If you have forwarded this product to any other laboratories, please also forward this letter and customer reply form to that laboratory.

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 created for your laboratory.

Sincerely,

March 19, 2025

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

Abbott

Customer Reply Form

Molecular Diagnostics at Abbott
Product: Alinity m System
List Number: 08N53
Not Serial Specific
Unique Device Identifier (UDI): See table in FA-AM-MAR2025-306
Urgent Field Safety Notice/Field Correction Recall Letter FA-AM-MAR2025-306
Dated 19 March 2025

Dear Abbott Customer,

Please complete the following information below acknowledging receipt of the **Urgent Field Safety Notice / Field Correction Recall FA-AM-MAR2025-306** and return it to us by Fax or by e-mail, **prior to April 7, 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 Urgent Field Safety Notice / Field Correction Recall Letter FA-AM-MAR2025-306 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 April 7, 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 Urgent Field Safety Notice / Field Correction Recall Letter; 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 Urgent Field Safety Notice / Field Correction Recall Letter FA-AM-MAR2025-306 was 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