



Field Advisory Notice/Product Correction Letter

Molecular Diagnostics at Abbott

Product: Alinity m System

List Number: 08N53-002

Serial Number: 00443

Unique Device Identifier (UDI):

(01)00884999048034(11)201116(21)00443(240)08N53-002

Dear Abbott Customer,

This letter contains important information regarding your Alinity m System List Number 08N53-002. Please review this information carefully.

Background

As part of a previous Service visit, Abbott had identified that an Integrated Reaction Unit (IRU) Elevator panel was missing on your Alinity m System. An Instrument Service Ticket was executed by a Field Service Engineer (FSE) on your Alinity m System and the configuration of your Alinity m System was corrected by your Abbott FSE on 10/10/2024.

Impact

The missing IRU Elevator panel may have caused a potential physical (mechanical) hazard if a user attempted to access the back of the instrument above the elevator while the IRU Handler robot was in motion. Per Alinity m System Operations Manual (R13), the potential for injury and bodily harm from moving mechanical components is present when system operation occurs.

The missing IRU Elevator panel may also have caused a potential hazard of Incorrect results (false positive/misquantitation high) or Delay in Results if the loaded IRUs were subjected to inappropriate handling due to the unrestricted access.

Refer to the Alinity m System Operations Manual (R13) Section 7 “Requirements for handling the accessories – Requirements for Use” and Section 8 “Mechanical Hazards” or contact Abbott technical support for more information regarding these hazards.

There have been no reports of physical harm received to date and/or allegations of incorrect results associated with this issue.

Necessary Actions

No further actions are required.

Please complete and return the associated Customer Reply Form.

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,

January 10, 2025

Pamela Yip
Divisional Vice President, Quality Assurance
Abbott Molecular Inc.



Customer Reply Form
Molecular Diagnostics at Abbott

Products: Alinity m System

List Number: 08N53

Serial Numbers:

See Appendix A of FA-AM-JAN2025-302

Unique Device Identifiers (UDIs):

See Appendix A of FA-AM-JAN2025-302

Field Advisory Notice/ Product Correction Letter FA-AM-JAN2025-302

Dated 10 January 2025

Dear Abbott Customer,

Please complete the following information below acknowledging receipt of the **Field Advisory Notice / Product Correction Letter FA-AM-JAN2025-302** and return it to us by Fax or by e-mail, **prior to January 27, 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 / Product Correction Letter FA-AM-JAN2025-302 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 January 27, 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 / Product Correction 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 Field Advisory Notice / Product Correction Letter FA-AM-JAN2025-302 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