



**Field Advisory Notice**  
**Molecular Diagnostics at Abbott**  
**Product:** Alinity m System  
**List Number:** 08N53-002  
**Serial Number:** Not Serial Specific  
**Unique Device Identifier (UDI):** (01)00884999048034

Dear Abbott Customer,

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

**Background**

Abbott has identified that an Integrated Reaction Unit (IRU) Elevator panel is missing on your Alinity m System. A Technical Service Bulletin (TSB) was executed by a Field Service Engineer (FSE) on your Alinity m System, specifically, TSB 640-057A (Alinity m Missing Elevator Panel Inspection and Installation).

**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. This could have potentially resulted in a pinch or impact due to exposure to moving parts.

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 contamination.

Refer to the Alinity m System Operations Manual (R13) pg 452 and pg 434 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 contamination associated with this issue.

**Necessary Actions**

It was identified through inspection that your Alinity m System was impacted by this issue and the configuration of your Alinity m System has been or will be corrected by your Abbott FSE. If correction is still required, service will schedule a follow up visit.

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,

Ray Bastian  
Divisional Vice President, Quality Assurance  
Molecular Diagnostics at Abbott