Abbott
1300 E. Touhy Ave.
Des Plaines, IL 60018

Abbott

Urgent Field Safety Notice
Molecular Diagnostics at Abbott
Product: Alinity m System
List Number: 08N53-002
All Instruments
Unique Device Identifier (UDI): 00884999048034

February 11, 2022

Dear Abbott Molecular Customer,

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

Background
During Abbott's execution of Technical Service Bulletin (TSB) 640-060, Procedure to Lower the Amp-Detect Clamp Height and Update the Amp-Detect Personality, in connection with Urgent Field Safety Notices / Field Correction Recalls FA-AM-DEC2021-262 and FA-AM-DEC2021-264 issued in December of 2021, Abbott identified an increase in customer complaints of Reaction Vessel (RV) transfer errors, also called shifting or popping, out of Amplification Detection Units (ADUs) inside the Alinity m System. On December 19, 2021, Abbott suspended implementation of TSB 640-060 to investigate the issue. Abbott has determined that lowering the clamp bar height, as performed in TSB 640-060, may result in an increase in RV transfer errors.

Potential Impact
RV shifting may result in RVs not being transferred by the pipettor into the amplified waste. By design, this unrecoverable RV transfer error causes the applicable ADU module to be automatically placed out of service during sample processing and causes the samples in the applicable ADU module to be sent to exception. Such samples in the applicable ADU module will get an error code, and results for such samples will not be reported, causing a delay in the generation of test results. In that case, the Alinity m System will continue processing at reduced capacity with one ADU module placed out of service, while the remaining ADU modules continue to process and provide results.

In rare cases, RV transfer errors could result in RV opening, which may lead to contamination. The potential for contamination is dependent upon, among other things, the status of the sample in the impacted RV(s) at the time of RV transfer error. In rare cases, such contamination may result in an incorrect test result for qualitative assays or a misquantitation for quantitative assays.

Abbott plans to implement a correction on all Alinity m instruments, slowing the Amp Detect clamp motion to mitigate the prevalence of RV transfer errors. An Abbott Molecular Representative will contact you to schedule the implementation of the correction at your site.

While there is potential impact to results in all Alinity m assays (SARS-CoV-2, Resp-4-Plex, HBV, HCV, HIV-1, STI, EBV, CMV, HPV) in the event of contamination due to a compromised RV seal, there is no impact or change to the assay reagents. There have been zero (0) reports received to-date of harm associated with this issue.

Abbott
1300 E. Touhy Ave.
Des Plaines, IL 60018

Abbott

Urgent Field Safety Notice
Molecular Diagnostics at Abbott
Product: Alinity m System
List Number: 08N53-002
All Instruments
Unique Device Identifier (UDI): 00884999048034

Necessary Actions
Please complete and return the Customer Reply form.

If Abbott has executed TSB 640-060 on your Alinity m System, please take note of instrument stoppage or observation of RVs that shifted out of an ADU module where the RV seal between the RV and cap may have been compromised. In most cases of RV transfer errors, the RV is left intact and can be disposed of with care following the guidance provided in Section 9, Maintenance and Diagnostics - Alinity m System cleaning requirements of the Alinity m System Operations Manual.

If, during maintenance, you observe an RV that shifted out of an ADU module with a compromised RV seal, Abbott recommends that you request service from an Abbott Field Service Engineer (FSE). If an ADU goes out of service and you observe a compromised RV seal, positive results generated on the applicable Alinity m System during the time period beginning on the date that the ADU went out of service and ending on the date that the FSE returns the ADU to service should be considered presumptive, and retesting should be considered. A reactive negative control following a RV transfer error may also indicate the presence of contamination; Abbott recommends that you request service from an Abbott FSE to address.

If Abbott has not executed TSB 640-060 on your Alinity m System, there is no action for you to take in response to this letter. An Abbott Molecular Representative will contact you to schedule the implementation of the corrections (lowering the Amp-Detect Clamp Height and updating the Amp-Detect Personality as indicated in the previous Urgent Field Safety Notices / Field Correction Recalls FA-AM-DEC2021-262 and FA-AM-DEC2021-264, and slowing the Amp Detect clamp motion as indicated in this communication) to mitigate the prevalence of this issue at your site.

This field action 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. This communication was reviewed with FDA.

Please review this information with laboratory personnel and retain this communication for future reference. If you have any questions regarding this communication or are unsure if Abbott has executed TSB 640-060 on your system, please contact your local Abbott representative. We apologize for any inconvenience this may have caused your laboratory.

Sincerely,

Ray Bastian 2-11-22

Ray Bastian
Senior Director, Quality Assurance
Molecular Diagnostics at Abbott