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

December 6, 2021

Dear Abbott Customer,

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

Background

Abbott Molecular has been notified of a software issue in the Mechanica! and Thermal Test System used in the manufacturing of the Alinity m System that can cause the Amplification Detection clamp CLEAN position to be incorrectly set too high. This may lead to Reaction Vessels (RVs) that pop out of RV wells in Amplification Detection Units (ADUs) inside the Alinity m System. This may result in these RVs not being able to be retrieved by the pipettor for delivery into the amplified waste thus causing pipettor errors or the potential for liquid to escape the RV.

Potential Impact

This pipettor error may cause a potential delay in the generation of results. The RV popping may result in an unrecoverable error, placing the ADU out of service or stopping the process oftransferring RVs for waste disposal and sending samples to exception.

The potential for liquid to escape the RV may lead to contamination causing a potential for an incorrect result.

The correction will be made on all instruments. While there is potential impact to results in all Alinitym assays (SARS-CoV-2, Resp-4-Plex, HBV, HCV, HIV-1, STI, EBV, CMV, HPV), there is no impact or change to the assay reagents. There have been zero (o) reports received to-date of harm associated with this issue.

Necessary Actions

Please complete and return the Customer Reply form.

An Abbott Molecular Representative will contact you regarding clamp bar adjustments at your site. In the interim, be aware of instrument stoppage or observation of RVs that popped out of RV wells where the RV seal between the RV and cap may have been compromised and allowed liquid to escape. Positive results generated on such runs should be considered presumptive and retesting considered.

The clamp bar adjustment includes changes that correct the height of the Amplification Detection clamp CLEAN position when there are RVs present inside in the Amp-Detect module, thus eliminating RV popping. There is no impact to overall patient sample processing time.

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.

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Please 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 Molecular representative. We apologize for any inconvenience this may have caused your laboratory.

Sincerely,

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Molecular Diagnostics at Abbott