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

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

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 Inc. has received two customer reports of Alinity m Resp-4-Plex false positive results and two customer reports of Alinity m STI false positive results due to abnormal amplification curves. Preliminary investigation has identified that the expansion and contraction of air in the Alinity m System Reaction Vessel (RV) during thermal cycling in front of the fluorescent detection window can potentially create air bubbles that interfere with fluorescent readout, resulting in abnormal (non-sigmoidal) amplification curves. Refer to Appendix A for examples of normal and abnormal amplification curves.

Abnormal curves are typically detected by validity checks with assay-specific parameters and are reported as invalids. In rare cases, when an error code is not generated related to the abnormal curve, a false positive result due to abnormal curves may be observed at the following rates: 0.0006% - 0.0012% for the Alinity m Resp-4-Plex assay and 0.00026% for the Alinity m STI assay.

Potential Impact
This issue is only observed in results for Alinity m Resp-4-Plex and Alinity m STI. No reports of false positives related to abnormal curves have been reported in Alinity m SARS-CoV-2, HBV, HCV, HIV-1, EBV, CMV, or HPV.

Abnormal curves are mitigated in the Alinity m Resp-4-Plex and Alinity m STI assays by adjusting the clamp bar parameters in the Alinity m System. Lowering the clamp bar increases pressure on the RV cap which reduces the motion of air bubbles within the fluorescent detection window leading to less optical noise. This aids in the control of any potential abnormal curves that may lead to invalids and/or false positives for Alinity m Resp-4-Plex and/or Alinity m STI.

There is no impact or change to the Alinity m Resp-4-Plex or Alinity m STI AMP Kit reagents. The clamp bar adjustment will be implemented on all Alinity m Systems.

Necessary Actions
Please complete and return the Customer Reply form.

As an interim action until your Alinity m System(s) are updated, if a false positive result is suspected including results that have an associated error flag, evaluate the PCR curve generated for the result. Please see Appendix A for examples. If the amplification curve is abnormal (non-sigmoidal), retest the sample. Additionally, repeat tests when two or more analytes (e.g., SARS-

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CoV-2, Flu A, Flu B, RSV for Alinity m Resp-4-Plex, or Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), Mycoplasma genitalium (MG) or Trichomonas vaginalis (TV) for Alinity m STI) are positive in the same sample.

Please review this information with your Medical Director or physicians as appropriate and retain this communication for future reference. For handling previous positive results generated with the Alinity m Resp-4-Plex and/or Alinity m STI assays, follow your laboratory's standard operating procedures to investigate the potential for false positive results.

A Molecular Diagnostics Abbott Representative will be contacting you regarding clamp bar adjustments 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.

If you have any questions regarding this communication, please contact your local Molecular Diagnostics Abbott representative. We apologize for any inconvenience this may have caused your laboratory.

Sincerely,

Ray Bastian 06 Dec 21

Ray Bastian
Senior Director, Quality Assurance
Molecular Diagnostics at Abbott

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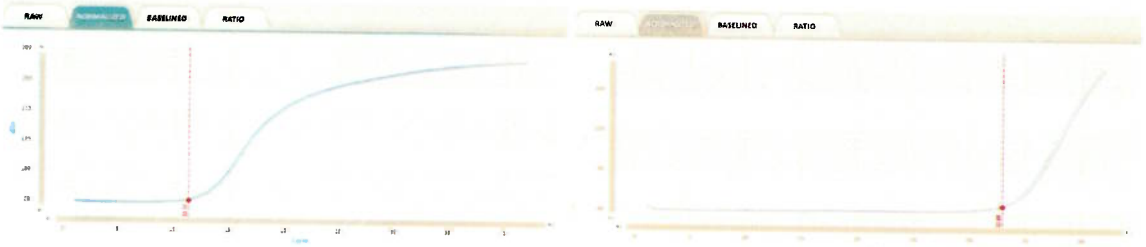
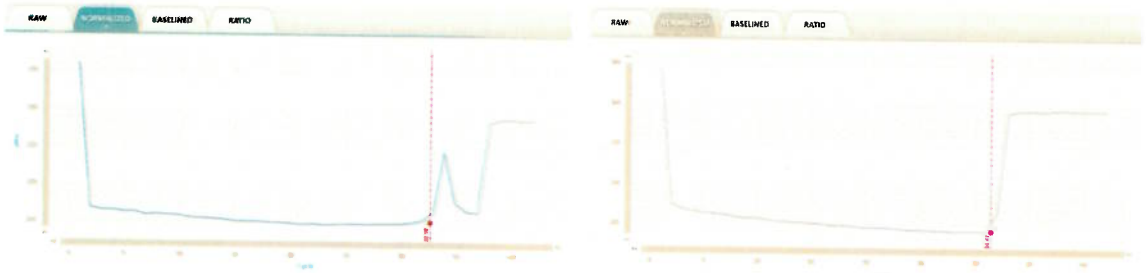
Appendix A

Per the Alinity m System Operations Manual (09N33-017 (54-605001/R10) Section 6 page 420, on the Results Graphs screen, the operator can view the graphical representations of the results detail data. The shape of PCR amplification curves can be visualized by selecting "Normalized" tab from the graph selections on the monitor. Below are examples of normal (sigmoidal) and abnormal (non-sigmoidal) PCR curves. These are typical normal and abnormal examples and are not inclusive of all curves that may be observed.

Normal (sigmoidal) PCR curve examples



Abnormal (non-sigmoidal) PCR curve examples



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Dear Abbott Customer,

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

Background

A software issue has been identified with the Alinity m System Software (Version 1.5.0 and greater) associated with the ability to properly complete a Field Service Engineer (FSE) executable-only Maintenance and Diagnostics procedure for the Amplification Detection Unit (Amp Detect or ADU) on the Alinity m System.

Specifically, when an Abbott FSE is utilizing the Maintenance and Diagnostics procedure 2303 (Amp Detect Optical Adjustment), there is potential that the procedure may improperly restore Amp Detect board values to an incorrect ADU. This only occurs if the FSE cancels this specific Maintenance and Diagnostic procedure, or if the Maintenance and Diagnostics procedure generates an error and the FSE selects the option to restore the Amp Detect board values.

Potential Impact

Incorrect ADU values may have been restored on your Alinity m System, which may have potentially led to the following:

1. Incorrect results for qualitative assays or a misquantitation for quantitative assays which have not been invalidated by the Internal Control (IC), Cellular Control (CC) or routine process controls.

2. Invalid results would be flagged for quantitative assays and for qualitative negative samples where the assay's IC, CC, or routine process control is used.

In a review of available log data for active instruments, Abbott identified 13 potentially impacted customer Alinity m Instrument Systems. The log review identified 4 incorrect results out of 436,895 samples (0.001%) tested for Alinity m SARS-CoV-2, Resp-4-Plex, HBV, HCV, HIV-1, STI, EBV, CMV, and HPV assays potentially related to this issue. The 4 incorrect results potentially related to this issue were generated for the Alinity m SARS-CoV-2 (4 out of 312,741 (0.001%) SARS-CoV-2 results). No false positives were identified for Alinity m Resp-4-Plex, HBV, HCV, HIV-1, STI, EBV, CMV, or HPV assays.

The correction will be made on all instruments. 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), there is no impact or change to the assay reagents.

Necessary Actions

Please complete and return the Customer Reply form.

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An Abbott representative will be in contact with you to schedule an assessmentof your Alinity m System, and if necessary, correct the Amp Detect board values on your Alinity m system. The assessment and correction of the board values can be completed during an on-site visit or via remote screensharing using AbbottLink (for AbbottLink-connected instruments only). In the interim, please continue to follow your laboratory protocols for suspected false positive results.

If it is determined that your instrument was impacted, please assess the impact to your laboratory.

This recall 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.

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 Molecular Diagnostics at Abbott representative. We apologize for any inconvenience this may have caused your laboratory.

Sincerely,

06 Dec 21

Ray Bastian
Senior Director, Quality Assurance
Molecular Diagnostics at Abbott

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Dear Abbott Customer,

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Background
Abbott Molecular has been notified of a software issue in the Mechanical 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 of transferring 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 Alinity m 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 (0) 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.

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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,

Ray Bastian 06 Dec 21

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Senior Director, Quality Assurance
Molecular Diagnostics at Abbott