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

Abbott

URGENT: MEDICAL DEVICE FIELD CORRECTION COMMUNICATIONS

December 6, 2021

Dear Abbott Customer,

You are receiving the four (4) following field corrections. Abbott is grouping instrument related issues which have the potential for incorrect results on the Alinity m System.

The Field Actions are as follows:

1. Field Action 1: (FA-AM-DEC2021-262) Reaction Vessel (RV) popping
2. Field Action 2: (FA-AM-DEC2021-263) Maintenance & Diagnostics procedure 2303
3. Field Action 3: (FA-AM-DEC2021-264) Clamp Bar Height Adjustment
4. Field Action 4: (FA-AM-JUL2021-257v3) Incorrect Camera Settings

One customer reply form is required to be returned attesting receipt and understanding of the above four communications. Please return the reply form as soon as possible.

Please note that FA-AM-JUL2021-257v3 is a follow up communication to the assessment and correction, where required, which was completed by your Abbott Field Service Engineer in the July/August 2021 timeframe.

Please review all communications carefully. If you have any questions, please contact your Molecular Diagnostics Abbott representative.

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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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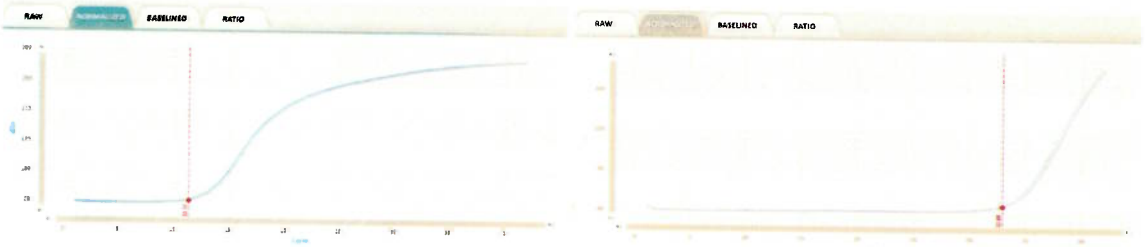
Appendix A

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