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

**Urgent Field Safety Notice**
**Molecular Diagnostics at Abbott**
**Product:** Alinity m BKV AMP Kit
**List Number**: 09N85-090
**Lot:** 391674
**Unique Device Identifier (UDI):**
(01)00884999050693(10)391674(17)240809(240)09N85-090

November 17, 2023

Dear Abbott Customer,

This letter contains important information regarding Alinity m BKV AMP Kit, List Number 09N85-090 Lot Number 391674 (the "Identified Lot"), utilized with the Alinity m System. Please review this information carefully.

**Background:**
Abbott has discovered that the Identified Lot of Alinity m BKV AMP Kit may have decreased PCR efficiency when stored onboard the Alinity m System for multiple days and before reaching the maximum storage time onboard the Alinity m System. Per Alinity m BKV AMP Kit Package Insert (PI) List 53-608288 Revision 3, the maximum storage time onboard the Alinity m System is 15 days (not to exceed expiration date). This decrease in PCR efficiency may manifest as suppressed or delayed signal, potentially impacting calibrators, controls, and samples on test.

**Potential Impact:**
There is a potential of delay in results when using the Identified Lot of Alinity m BKV AMP Kit. Specifically, calibrator or control results may be flagged and invalidated by the Alinity m System, resulting in a potential delay of specimen results, as valid results for the calibrators and all control levels must be obtained before specimen results are reported.

There is also a potential of incorrect results when using the Identified Lot of Alinity m BKV AMP Kit. Specifically, if a signal is suppressed below the established threshold in a patient sample, the Alinity m software may consider the signal "not detected," causing an incorrect, false "not detected" result. If a signal is detected, but the cycle number is delayed in a patient sample due to this issue, it may lead to an under-quantitation result outside of the established precision claims.

**Necessary Actions:**
- Discard all units of Alinity m BKV AMP Kit, List Number 09N85-090 Lot Number 391674 currently in your possession.
- A lookback is recommended for results generated with units from the Identified Lot of Alinity m BKV AMP Kit. Please follow your laboratory procedures for any suspect results.
- Complete and return the Customer Reply Form. Abbott will issue a credit for the purchase price of any unused kits from the Identified Lot of Alinity m BKV AMP Kit that are discarded in response to this Urgent Field Safety Notice.
- If you have forwarded any kits from the Identified Lot of Alinity m BKV AMP Kit to other laboratories, please inform them of this Urgent Field Safety Notice, provide a copy of this letter to them, and have them take the necessary actions listed here.

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Retain this letter for your laboratory records. 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 representative. We apologize for any inconvenience this may have caused your laboratory.

Sincerely,

Julie Strom
Global Director of Compliance
Molecular Diagnostics at Abbott