September 1, 2017

Dear Abbott Molecular Customer,

This is a follow-up to Urgent Field Safety Notice FA-AM-AUG2017-225 that you received regarding Abbott RealTime HIV-1 Qualitative, List 04N66-90.

**Background**
You recently received an Urgent Field Safety Notice FA-AM-AUG2017-225 from Abbott Molecular. In the Field Safety Notice, we shared that Abbott RealTime HIV-1 Qualitative may exhibit false "Not Detected" results for HIV plasma samples between 110 Copies/mL (Limit of Detection) and 336 Copies/mL.

Investigation results identified that the issue described above is due to a change implemented to the Version 2.00 plasma application specification file contained on the Abbott RealTime HIV-1 Qualitative m2000 System ROW Combined Application CD-ROM, list number 04N66-002.

- Version 1.00 of the plasma and Dried Blood Spot (DBS) application specification files (CD-ROM list number 04N66-01) are not impacted for both plasma and DBS sample types. You can continue to use the Version 1.00 application specification files for both sample types.

- Version 2.00 of the DBS application specification file (CD-ROM list number 04N66-002) is not impacted for the DBS sample type and can continue to be used for DBS testing.

- However, Version 2.00 of the plasma application specification file (CD-ROM list number 04N66-002) for plasma sample type is impacted. Use of Version 2.00 plasma application specification file may exhibit false "Not Detected" results for HIV-1 plasma samples between 110 Copies/mL and 336 Copies/mL.

**Necessary Actions for Version 2.00 Application Specification with Plasma Samples**
1. Immediately discontinue use of the Version 2.00 application specification for the plasma sample type (Refer to Appendix A to identify the version of the application specification file installed in your m2000system).

2. If you have Version 2.00, an Abbott Molecular Technical representative or your distributor will be in contact to install Version 1.00 for plasma sample type.

3. It is recommended that you review this information with your medical director or treating physician.

Please review this information within your organization and with any organization/individual that should be aware of this communication. Retain this communication for future reference.

If you have any questions regarding this communication, please contact your Abbott Molecular Technical Services representative. We apologize for any inconvenience this may have created for your laboratory.

Sincerely,

[Signature]

Julio Salwen
Quality Assurance
Abbott Molecular Inc.
APPENDIX A

The Version application specification file that you are using is visible on the Application Management screen (Refer to Illustration 1 below):

Illustration 1. Application Management screen - Version application specification file

The changes from Version 1.00 to Version 2.00 for the plasma protocol were:

- Adjusted a timer setting on the m2000sp to prevent timer warning errors with certain batch sizes.
- Updated the minimum volume specification during the volume verification step at the sample/lysis removal and the volume of lysis pipette tip pre-wetting prior to lysis pipetting to improve liquid handling.

Additionally, the following change below impacted the plasma protocol as described in this Field Safety Notice (this change was not implemented in the DBS protocol):

- Adjusted the Detect Liquid Level command prior to sample tube aspiration.