



Urgent Field Safety Notice
Abbott Molecular Inc.
Product: Abbott RealTime HIV-1 Qualitative
List Number: 04N66-90
Lot Numbers: ALL

August 8, 2017

Dear Abbott Molecular Customer,

This letter contains important information regarding all lot numbers of the Abbott RealTime HIV-1 Qualitative, List 04N66-90. Please review this information carefully.

Background

For plasma samples, Abbott RealTime HIV-1 Qualitative may exhibit false "Not Detected" results for HIV samples between 110 Copies/mL (Limit of Detection) and 336 Copies/mL.

For Dried Blood Spot (DBS) samples, Abbott RealTime HIV-1 Qualitative performs in accordance with the detection rate within the RealTime HIV-1 Qualitative package insert for DBS sample types. No action is required for DBS samples.

Potential Impact for Plasma Samples

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.

Necessary Actions for Plasma Samples

1. Immediately discontinue use of and discard all remaining inventory of Abbott RealTime HIV-1 Qualitative lots for plasma samples.
2. A previously reported "Not Detected" result should be interpreted as less than 336 Copies/mL (95% CI from 271 - 489 Copies/mL) as compared to the current package insert claim of less than 110 Copies/mL (95% CI from 65 - 118 Copies/mL).

Consider this information at the discretion of healthcare providers in the field and may be modified based on other laboratory values, if available, and the clinical status of each patient.

Consider this information in regards to retesting a non-detected HIV-1 qualitative result.

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,



Joe Hutson
Quality Assurance
Abbott Molecular Inc.