



**Urgent Field Safety Notice
Abbott Molecular Inc.**

Product: Abbott RealTime HIV-1 assay

List Number: 02G31-010

Lot Numbers: 473470, 474215, 474890, 475025, 475532, 475694, 476172, 476356, 476736, 476951 and 476139

August 8, 2017

Dear Abbott Molecular Customer,

This letter contains important information regarding the lots listed above for the Abbott RealTime HIV-1 assay, List 02G31-010. Please review this information carefully.

Background

For Lot 476139, please see Table 1.

For all other lots listed above, please see Table 2.

Table 1

Lot 476139

Background

It has been identified that Lot 476139 may exhibit a higher than expected rate of error codes, misquantitation, and the potential to not detect HIV samples.

Potential Impact

Error Code Generation

Lot 476139 may experience error codes (4439, 4440, 4441, 4442, 4457) due to controls out of range or internal control failures.

HIV Results

Lot 476139 may exhibit misquantitation and false 'Not Detected' results for HIV samples.

Necessary Actions

1. Immediately discontinue use of and discard all remaining inventory of Lot 476139.
2. Consider retest of all patient samples. This information should be considered 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.
3. It is recommended that you review the information contained within this communication with your medical director or treating physician.



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Table 2

Lots 473470, 474215, 474890, 475025, 475532, 475694, 476172, 476356, 476736 and 476951

Background

All lots listed in this table may exhibit a higher than expected rate of error codes.

For plasma samples, all lots have the potential to exhibit false "Not Detected" results for HIV samples less than 120 Copies/mL when using 0.6 mL assay application.

For DBS samples when using a 1-Spot protocol associated with the RealTime HIV-1 Package Insert 51-608282, all lots are performing in accordance with the detection rate within the RealTime HIV-1 package insert for DBS sample types.

Potential Impact for Plasma Samples

Error Code Generation for Plasma Samples

All lots listed in this table may experience error codes (4439, 4440, 4441, 4442, 4457) due to controls out of range or internal control failures.

HIV Results for Plasma Samples

All lots listed in this table may exhibit a false "Not Detected" for HIV samples with less than 120 Copies/mL when using a 0.6 mL assay application. At 120 Copies/mL and above when using a 0.6 mL assay application, the percent detection is in accordance with the RealTime HIV-1 package insert.

All lots listed in this table are performing in accordance with the RealTime HIV-1 claim of 95% quantitation accuracy within +/- 0.50 log Copies/mL within the RealTime HIV-1 package insert.

Necessary Actions for Plasma Samples

1. Immediately discontinue use of and discard all remaining inventory of all the RealTime HIV-1 Quantitative lots listed above.
2. The following information should be considered 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 the guidance below in regards to retesting the HIV-1 viral load of potentially impacted HIV patients.

| Clinical Decision Point | If the result is... | Then... |
|-------------------------|---------------------|---|
| 50 Copies/mL or less | Not Detected | consider retest |
| 200 Copies/mL | Not Detected | consider retest if using the 0.2 mL assay application only |
| | | should not affect the clinical interpretation if using the 0.6 mL or the 1.0 mL assay application |
| 1000 Copies/mL | Not Detected | should not affect the clinical interpretation |

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



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Table 2 continued

Potential Impact for DBS Samples (when using a 1-Spot protocol associated with the RealTime HIV-1 Package Insert 51-608282)

Error Code Generation for DBS Samples

All lots listed in this table may experience error codes (4439, 4440, 4441, 4442, 4457) due to controls out of range or internal control failures.

HIV Results for DBS Samples

All lots are performing in accordance with the detection rate contained within the RealTime HIV-1 package insert information.

Please contact your local Abbott Molecular representative to coordinate replacement inventory, as needed.

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,

A handwritten signature in black ink that reads "Joe Hutson".

Joe Hutson
Quality Assurance
Abbott Molecular Inc.