



## 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, and 476951

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

All lots 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 Dried Blood Spot (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 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 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 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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**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 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, appearing to read 'Joe Hutson', is positioned above the printed name.

Joe Hutson  
Quality Assurance  
Abbott Molecular Inc.