NIAID Virology Quality Assurance Program
Memo Regarding a Change in VQA HIV NAT Control Requirements

To: Laboratories that perform qualitative or quantitative HIV-1 nucleic acid testing (NAT) for VQA proficiency testing or NIAID clinical trials

From: Virology Quality Assurance (VQA) Program

Cc: The VQA Advisory Board (VQAAB)
ACTG/IMPAACT Laboratory Technologist Committee
ACTG Network Laboratory Center
IMPAACT Network Laboratory Center

Date: 22 November 2016

Subject: A Change in VQA Qualitative or Quantitative HIV NAT Control Requirements

Attachment: VQA HIV DNA/TNA SOP for HIV NAT

Effective 01 December 2016, laboratories are no longer required to use VQA HIV DNA/TNA Copy Controls (for example, controls that include 0, 5, 10, or 20 copies of proviral HIV DNA per aliquot) when performing qualitative or quantitative HIV-1 nucleic acid testing (NAT) for VQA proficiency testing or NIAID clinical trials. Additionally, laboratories are now asked to make sure they are using VQA HIV DNA/TNA blinded extraction controls that have the same matrix as the clinical samples being tested. If multiple sample matrices are included in a single assay, then a minimum of one blinded control for each different matrix must be included in the assay.

Please find attached the updated VQA HIV DNA/TNA Control SOP for HIV NAT that has been approved by the VQA Advisory Board.

Laboratories that use the Laboratory Data Management System (LDMS) to report Roche COBAS TaqMan HIV-1 Qual Test, v2 data will receive a separate message from Frontier Science with instructions about how to download and install LDMS version 12.4. This new version of LDMS will support these control changes and will no longer require VQA copy controls on runs with an assay date on or after 01 December 2016.

As a reminder, laboratories that do not use the LDMS must continue to verify the performance of the VQA blinded extraction control via email (vqa.blind@fstrf.org, **Note: this is a new email group**) using the template outlined in the SOP. Qualitative or quantitative HIV nucleic acid tests that only include plasma samples do not require the use of blinded extraction controls; in this case, the VQA200 control is used to verify run performance.

Please contact the VQA Data Management group at vqa.dmg@fstrf.org if you have any questions regarding this change in VQA HIV NAT control requirements.