VQA HIV RNA Copy Control (200cp/mL) Implementation Plan

The Virology Quality Assessment (VQA) Program has completed their evaluation of the new VQA HIV RNA 200cp/mL control and is ready to initiate the use this control for HIV RNA run validation. **The control will be required on all HIV RNA assays performed using the Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 Test (RT, version 1 or 2) and the Abbott RealTime HIV-1 Test (AR) that includes samples for the VQA, ACTG, IMPAACT, or MTN.** Inclusion of this control in runs that do not contain specimens from the listed groups is optional. The inclusion of additional controls for internal quality control, including other levels of VQA controls is also optional. However, inclusion of the VQA HIV RNA 200cp/mL control is the only control that is required for run validation on Abbott RealTime and Roche TaqMan assays.

The use of other VQA HIV RNA copy controls (e.g. the 1,500cp/mL control) will still be used to validate Roche Amplicor HIV-1 Monitor assays. The 1,500cp/ml control will continue to be required for run validation of the UltraSensitive Roche Monitor assays.

The new VQA HIV RNA 200cp/mL copy control is currently available and can be ordered via HANC website (http://portal.hanc.info/lab/pages/VQAOrders.aspx). **Multiple lots of controls have been produced, but only use controls with lot numbers of 076** (10176**076**) **or later. Earlier lots were used for the initial evaluation.**

- A new LDMS (Laboratory Data Management System) version (version 5.8.4) is available, and laboratories should contact FSTRF to receive this update. They need to make sure they have the 200 cp/mL control from the VQA on-hand, including the appropriate range sheet for that control prior to downloading this version to your computer. The previous versions of the LDMS required the use of this control in any AR and RT run that includes ACTG/IMPAACT clinical trial or VQA proficiency panel specimens. **The new version 5.8.4 will now use the result for this control for run validation.**
- This VQA HIV RNA 200cp/mL control, in addition to the kit controls, will now be used to validate Abbott RealTime and Roche TaqMan assays. One control will be included with kit controls for every run (control requirements with respect to batch sizes vary by manufacturer). All VQA and kit control results must fall within the specified ranges for the HIV RNA run to be valid.
- The 200cp/mL control is ONLY to be used for the Abbott RealTime and Roche TaqMan assays. VQA HIV RNA controls must still be included in other HIV RNA assay platforms as previously defined by the VQA and/or clinical trials network/group for whom the laboratory does testing.

Timeline:

This new rule becomes effective 01 January 2011. Any new HIV RNA assay that is tested with RT or AR, includes samples for ACTG, IMPAACT, MTN or VQA, and is performed **on or after 01 January 2011** must include the VQA 200cp/mL control in the run, and the result will be used to validate the run. This new rule will not affect assays performed before 01 January 2011, even if the assay files are read into LDMS on or after 01January 2011.

Additional Information:

The VQA will establish the acceptable ranges for each lot of VQA HIV RNA 200cp/mL control. One range will be applied to both the Abbott RealTime and Roche TaqMan assay platforms. The VQA will determine the median value that will be used to generate the range for each lot of control. This median value will be determined by combining VQA internal validation data generated on Abbott RealTime, Roche TaqMan v1 and Roche TaqMan v2 assays. The VQA will utilize a total range that encompasses a +/- 0.5$\log_{10}$ RNA cp/mL – this equates to a $\log_{10}$ SD of 0.167. Initial review of data generated laboratories participating in the VQA HIV RNA proficiency testing program, which included results obtained on three separate lots of VQA 200cp/mL controls, showed that the failure rate for each established control range was < 0.25%. Interim data captures will continue to be done on a regular basis to monitor the new VQA HIV RNA 200 cp/mL control's performance.

Laboratories should already have controls available for testing. Additional controls may be ordered via the HANC website. Laboratories should only use controls with lot numbers of 076 (10176**076**) or higher for run validation. A copy of the current range sheet for lot numbers 76 (10176**076**) and 77 (10223**077**) are provided with this memo.