

VQA HIV RNA Copy Control (200 copies/mL) Change in Control Range

The Virology Quality Assurance (VQA) Program circulated a memo dated 16 May 2011 which documented a change in the VQA200 control range. At that time, the VQA implemented two separate ranges for the VQA200 control: a range of 98 – 985 cp/mL was used to evaluate the Roche COBAS AmpliPrep / COBAS TaqMan HIV-1 RNA Test (RT), and a range of 64 – 642 cp/mL was used to evaluate the Abbott RealTime HIV-1 RNA Test (AR). These ranges were created using field-generated data from three production lots of VQA200 controls. Briefly, a mean value of 203 cp/mL (2.31log₁₀) was estimated using AR-generated data; and a mean of 311 cp/mL (2.49 log₁₀) was estimated using RT data. While the manufacturer's claims for precision varied for each assay, the standard deviation of 0.167 was determined to be within the capability of both assays and would result in a range of +/- 0.5 log₁₀ RNA cp/mL for a 3 SD range. Therefore, while the assay-specific ranges employed separate mean values, both ranges utilized the same expectations for precision.

In January 2014, the VQA began to observe a shift in log₁₀ recovery for proficiency testing (PT) data generated with the RT assay that appeared to be kit lot related. Ongoing surveillance showed a trend that affected multiple laboratories and included multiple kit lots. An investigation by Roche Molecular Systems, Inc identified a change in Calibration Standard that was used for kit production that correlated with the shift in log₁₀ recovery and affected kit lots produced after July 2013 with lot numbers of S02574 or greater. The VQA has been monitoring this shift for the last 18 months and data show that a leveling off of the log₁₀ recovery has occurred, which would be expected as the kit lots that were produced using the previous Calibration Standard were being replaced by the newer kit lots.

As a result of these analyses, the VQA is proposing to change the control range for the VQA200 control so that one range will be used to evaluate both the RT and AR assays. Re-analysis of VQA200 control performance for the past five years including kit lots from both Calibration Standards provide the evidence that this proposed change in the control range is warranted. Applying the mean value of 311 cp/ml to data generated with RT using kit lots produced with the new Calibration Standard resulted in a shift in log₁₀ recovery from -0.004 to -0.192 with relatively stable precision (SD=0.148). If the data generated with the new kits lots were applied to the AR-specific range, then the performance shifted back toward nominal (-0.007, SD = 0.148) suggesting the AR-specific range could be used for evaluating either the AR or RT assays.

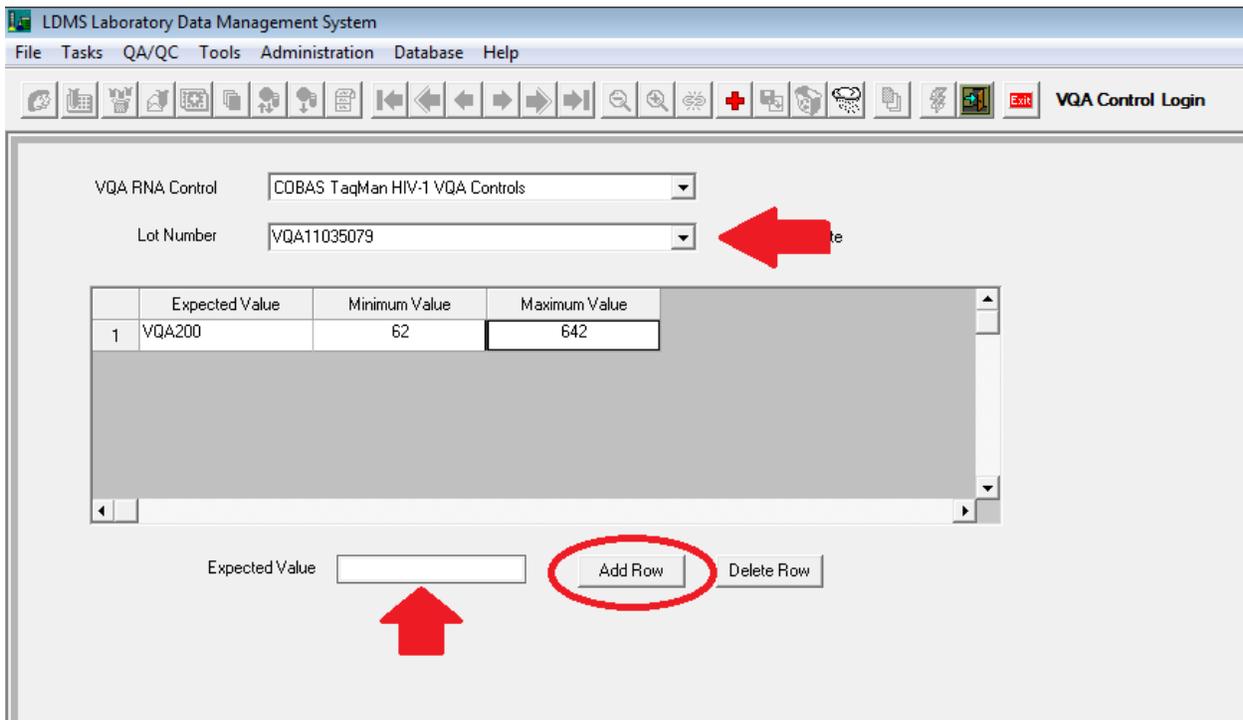
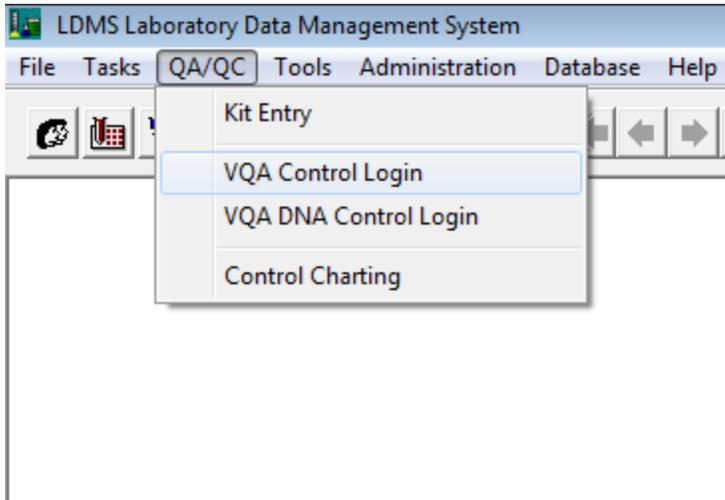
Therefore, **effective 01 April 2015**, laboratories using the VQA200 control will use one range to evaluate run performance for both the RT and AR assays; that range (**64 – 642 cp/mL**) is based on the mean value of 203 cp/mL (2.31) +/- 3SD where 1 log₁₀ SD = 0.167.

LDMS Instructions

If a laboratory is using the LDMS, they must log in a new name for their existing controls and apply the new range. They should use VQAnnnnnnnn Control Lot Numbers in LDMS, where nnnnnnnn represents the control's numeric lot number. For example, if the laboratory was using lot 11035079 with a previous range of 98 – 985 cp/mL, they would now call the control VQA11035079 and apply a new range of 64-642 cp/mL.

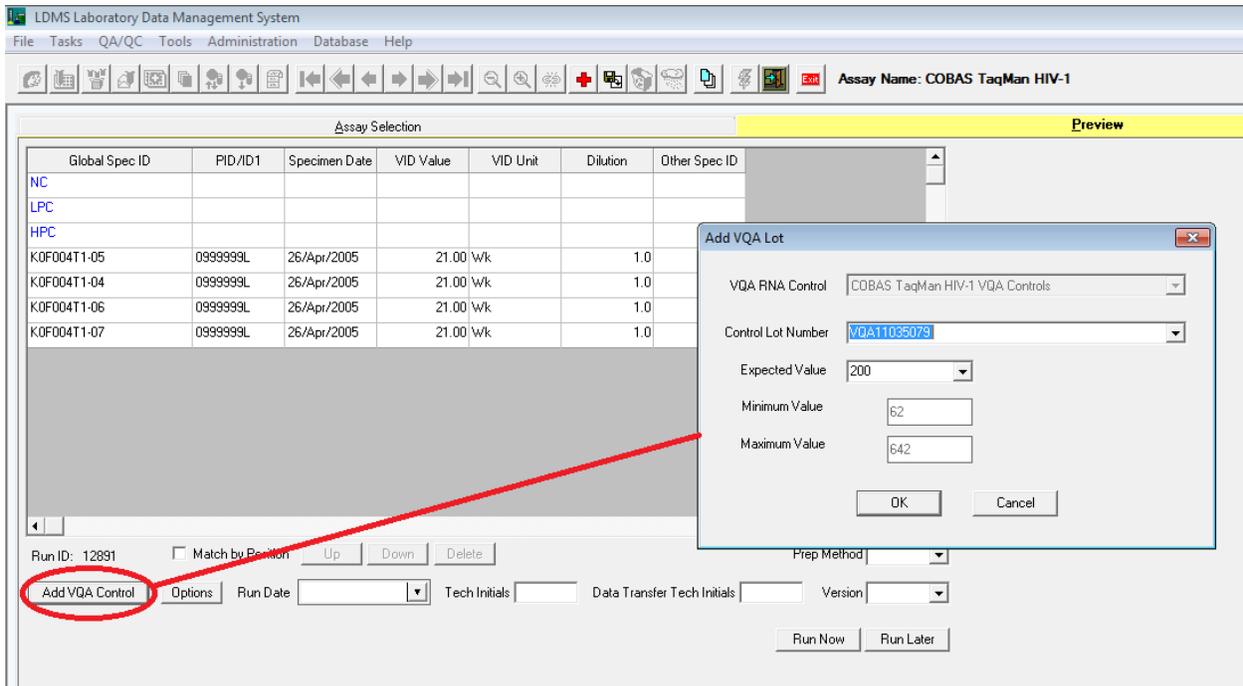
There are two ways to add a new VQA200 lot into the LDMS:

1. VQA Control Login module
 - a. Access the VQA Control Login module from the QA/QC menu on the LDMS home screen.
 - b. Select the Assay you will be using in the drop down menu
 - c. Enter the new lot number in the Lot Number field
 - d. Enter '200' in the Expected Value field and click Add Row
 - e. In the new row, enter '64' for Minimum Value and '642' for Maximum Value
 - f. Click the Save (diskette) icon



2. In the Assay Module

- a. Click Add VQA Control
- b. In the blank Lot Number field, enter the new VQA200 lot number
- c. Enter '200' in the Expected Value field
- d. Enter '64' for Minimum Value and '642' for Maximum Value
- e. Click OK



Please contact the VQA (vqa.dmg@fstrf.org) if you have any questions regarding the new control ranges for the VQA 200 copies/mL control.