VQA RNA Proficiency Testing Program
Laboratory Recertification and "B" Panel Testing

The VQA Laboratory implemented a new HIV RNA proficiency testing program in 2001 whereby batch testing of QA samples was replaced with real-time testing. In the current program, a new laboratory first needs to pass a 20-member certification panel by obtaining a score of C based on the scoring criteria defined in the "Scoring Criteria for the New HIV RNA real-time Proficiency Testing Program" located on the ACTG website at https://www.hanc.info/labs/labresources/vqaResources/ptProgram/Pages/participationDocs.aspx. Briefly, 20-member panels are scored for intra-assay precision, assay sensitivity, assay specificity and accuracy. Once the certification process is completed, ongoing proficiency must be demonstrated to achieve approval for protocol testing. A laboratory must obtain a score of C on two real-time RNA panels (5 samples per panel submitted every 2 months) before they are approved for protocol testing. If problems occur after certification, then this process may take more than two real-time panels to achieve.

During the real-time testing phase of the program, problems may arise that require a laboratory to repeat a given five-member panel. Since problems that affect one five-member panel may affect future analyses, each laboratory is given the option of repeating any five-member panel ("B" panel configurations are used for repeating five-member panels). If a score of C or PC is obtained for a given round of testing, a laboratory may opt to repeat that five-member panel. If a laboratory receives a score of P for a given round, they must repeat the five-member panel. The VQA lab will contact a laboratory regarding the option of repeating a panel only if the laboratory receives a PC. Any laboratory with a score of C that wishes to repeat a panel must contact the VQA laboratory manager in order to receive a repeat panel. All laboratories that receive a score of P will automatically receive a repeat panel. A five-member panel may only be repeated once, and may only be repeated during the round in which the error occurred. The repeat panel data, as well as the next five member panel data, will be due by the deadline for the next round of testing. "B" panel samples must not be analyzed in the same run as any other VQA samples to enable proper precision scoring. A laboratory will not receive a separate analysis for the "B" round testing, but the new data will replace the problematic data in future analyses.

In certain situations, the testing of a repeat panel may result in additional problems that cannot be corrected in a subsequent repeat testing. In these situations, it may be necessary for a laboratory to recertify. In this case, a laboratory will be provided a 20-member panel that will be tested in a single assay. A laboratory must achieve a score of C on this recertification panel in order to resume real-time testing. Additional panels may be needed in order to achieve this score. A laboratory will need to contact the VQA laboratory manager in order to request recertification panels.

For recertification, the 20-member panel will be scored in the same manner as a certification panel for a new laboratory. Assay sensitivity, specificity, accuracy and

intra-assay precision statistics will be applied. Subsequent analyses will include the data from the 20-member panel plus newly submitted results from 5-member panels until four 5-member panels are completed (after the first five member panel there will be 25 samples in the analysis, after the second, there will be 30, and after the third there will be 35). When four five-member panels are completed, the 20-member panel data will be removed and the four 5-member panel data will only be used for scoring. After that, each new 5-member panel will be added, and the last 5-member panel data will be removed, providing the cumulative scoring described in the scoring criteria document.

Precision scoring for the 20-member recertification panel will only include the intra-assay component of variation. Once five-member panel testing is begun, total assay precision statistics (including both inter- and intra-assay components of variation) will replace intra-assay precision statistics. During the recertification process, a laboratory will be provisionally certified. Cumulative scoring will be wiped clean and will not resume until four five-member panels are completed. Reapproval status may occur after a laboratory achieves a score of “C” on two successive five-member panels.

The cumulative table will continue to track laboratories proficiency testing scores, and will indicate when a recertification panel has been performed by placing an asterisk (*) after the score received on the first 5-member panel that follows the recertification panel. Scores for the recertification panel will not be tracked on the VQA cumulative table.