

VQA RNA Proficiency Testing Program “NO DATA” Score

The Virology Quality Assessment (VQA) Program currently provides proficiency testing programs for HIV DNA, HIV RNA, HIV Culture and HIV GENO. Panels are sent to NIAID sponsored laboratories to help evaluate the quality of virology testing being performed for clinical trials.

Upon completion of any proficiency panel, a laboratory is given a technical score- ‘C’ for Certified, ‘PC’ for Provisionally Certified and ‘P’ for Probation. A number (1 or 2) will be added to the technical score (letter) if the data are received late one time (1) or more than one time (2) within eight months.

Technical scores are converted to a numeric proficiency score to permit cumulative scores that determine approval ratings. A technical score of C, PC, and P are assigned proficiency scores of 1, 2, and 4, respectively. Late penalties assessed to a technical score result in a down-graded proficiency score (e.g. a technical score of C1 will be downgraded to a proficiency score of 2 points).

The cumulative rating is determined by adding together the proficiency scores from the last four consecutive panels. The laboratory’s Testing Approval status is then assessed using the following table:

Assessment	Cumulative Score	Rating	Testing Approval Status
Provisionally Approved	0-1	PA	Eligible for protocol testing at the discretion of the Network
Approved	2-6	A	Eligible for protocol testing
Provisionally Approved	7-9	PA	Eligible for protocol testing at discretion of the Network
Not Approved	10-13	NA	Not eligible for protocol testing
Mandatory Expulsion	>=14	ME	Not eligible for protocol testing

C= scored as 1, PC= scored as 2, and P= scored as 4, C1= scored as 2, C2= scored as 4, PC1 and PC2= scored as 4, P1 and P2= scored as 4.

A late penalty is assessed when data are received after the deadline that is defined in the package insert that accompanies a proficiency testing panel. A laboratory may contact the VQA to request an extension or exemption from a proficiency testing round if that laboratory is experiencing technical problems or not currently running clinical trial specimens. This request must be made **BEFORE** the due date in order to avoid a late penalty.

If a laboratory does not submit results by the deadline, they will be contacted by the VQA to determine the reason for missing the data submission deadline. Laboratories will be given a new deadline to submit their data, with the understanding that a late penalty will be assessed to the technical score that is obtained on the panel. If a

laboratory misses the new due date without contacting the VQA **PRIOR** to the new due date, they will not be permitted to submit data for an analysis. The resultant score for that panel round will be a ND (NO DATA). This score will replace the technical score and the proficiency score will be worth 4 points.

Extensions for proficiency testing panels will be given up to two weeks from the original due date. After that time, no data will be accepted for that analysis. Retrospective analyses may occur in the case of new laboratories that need to fast-track their approval status, or existing laboratories that are experiencing technical problems and are in the process of troubleshooting problems. **No late data will be accepted two weeks after the original due date without the approval of the VQA. NO DATA scores will add penalty points to the cumulative rating and will affect your approval rating in the VQA Program.**

Please contact Cheryl Jennings (VQA Manager, vqa@rush.edu, 312-942-5954) or Dr. James Bremer (VQA Director, jbrem@rush.edu, 312-942-3308) if you have any questions regarding the scoring of VQA Proficiency Testing Data.