VQA PROGRAM TESTING REQUIREMENTS FOR NEW LABORATORIES TO OBTAIN APPROVAL FOR HIV DNA DBS TESTING IN NIH-FUNDED PROTOCOLS

QUALITATIVE HIV-1 DNA DETECTION

Practice Testing: All new laboratories may request from the ***VQA LAB*** practice panels for any of the proficiency programs prior to enrollment in that proficiency program. Results from these panels will be assessed for informational purposes only.

Prequalification Testing: Prequalification panels are used to preliminarily assess a laboratories performance prior to participation in the real-time testing programs. For VQA HIV DNA DBS prequalification testing, laboratories must assay a minimum of 2 VQA HIV DNA DBS proficiency testing panels that were previously tested in the field by participating laboratories. Each panel shall consist of 8 DBS cards, each card containing four-five blood spots (only one donor shall be spotted per card). One spot (or more as outlined in the laboratory SOP for testing) from each sample card must be tested and the results sent to the VQA for analysis. Prequalification shall be achieved if a testing laboratory passes two consecutive panels with a score of C or obtains two scores of C and one score of PC out of three panels. Once prequalified, a laboratory shall proceed to normal track testing or to fast track approval depending on their performance. NOTE: the normal track or fast track options must begin within one year of passing the prequalification panels. If real-time testing is postponed beyond one year of testing, then prequalification must be repeated.

A new laboratory must obtain an **APPROVED** performance rating prior to performing any protocol testing. A laboratory's performance rating (PR) shall be based on the sum of the scores four (4) most recent consecutive panels tested (Performance Score, PS). Numeric scores are assigned to each technical score: a numeric score of "1" shall be assigned to a technical score of C (Certified); a numeric score of "2" shall be assigned to a technical score of PC (Provisionally Certified); and a numeric score of "4" shall be assigned to the technical score of P (Probation). The Performance Score (PS) results in a Performance Rating (PR) are assigned as listed in the table below. For normal track testing, HIV DNA DBS panels will be shipped to the testing laboratory during regularly scheduled rounds of testing. Routine shipments for HIV DNA whole blood testing occur in February, April, August and October. HIV DNA DBS panels are created from blood collected during the whole blood rounds.

ASSESSMENT	PS	PR	Action
APPROVED	4-6	A	Eligible for protocol testing
PROVISIONALLY APPROVED	7-9	PA	Eligible for protocol testing at discretion of protocol virologist
NOT APPROVED	10-13	NA	Not eligible for protocol testing
MANDATORY EXPULSION	≥ 14	ME	Not eligible for protocol testing

Fast Track and Normal Track Approval: A new laboratory may obtain a **Fast Track** APPROVAL rating after prequalification by passing an additional two rounds of testing with scores of C. These panels may be tested outside the routine proficiency testing window using stored HIV DNA DBS panels. Laboratories that receive a score of PC on one of the

two panels must achieve a score of C on a third HIV DNA DBS panel. Subsequent approval ratings shall be based on the cumulative scores of the last consecutive four panels tested. Scores of P on any panel will require additional testing until the cumulative score falls within the Approved rating (**Normal Track**). NOTE: The final determination of whether or not a laboratory may perform protocol testing shall be at the discretion of the program leadership for whom the laboratory does testing.

Continued Approval: To retain an Approved status, all laboratories must participate in routine proficiency testing as scheduled by the VQA Program. Laboratories participating in the VQA HIV DNA DBS program must receive a minimum of 2 challenges (total of 16 samples) per year. Additional panels may be required for fast-track approval or reapproval, or at the discretion of the network leadership for whom the laboratory does testing.

Withdrawal/Removal: A laboratory may voluntarily withdraw from any proficiency testing program at any time. A laboratory that has not participated in a proficiency testing program for 12 contiguous months will be automatically removed from that program. A laboratory may request to be put "On Hold" as a result of operational circumstances (e.g., personnel problems, change of assay, etc.) for up to 12 months. After 12 months the laboratory will be automatically removed from that program. A laboratory that is "On Hold" for VQA proficiency testing must not test clinical trial specimens during the time in which they are "On Hold". If a laboratory misses one round of testing they may request to be included in the next round without any additional testing. If a laboratory is "On Hold" for an extended period of time, they may be required to pass a proficiency testing panel, or do extra testing before they are able to resume testing. This decision shall be made by the network leadership for whom the laboratory does testing.

Re-Certification: If a laboratory withdraws from or is removed from a proficiency program and wishes to reenter the program at a later time, that laboratory will be required to repeat the prequalification and approval testing as a new laboratory (see the Fast Track and Normal Track Approval section above).

Proficiency Testing Panels: VQA HIV DNA DBS proficiency testing consists of sending each laboratory a panel of eight coded specimens (DBS cards) that consists of single or replicate samples from two or more blood donors (replicate spots on each card are from a single donor and contain 75uL of blood). A minimum of one spot from each of the eight samples must be extracted, amplified, and detected according to the SOP used for HIV DNA testing. All samples and assays must be valid according to VQA DNA SOP that can be found on the HANC web site (https://www.hanc.info/labs/labresources/vqaResources/Pages/AssaySpecificSops.aspx). The entire panel must be repeated if any of these criteria are not met.

Proficiency scores shall be determined by comparing the outcome of PCR with the infection status of the blood donors with an 80% consensus requirement. A complete discussion of the Qualitative DNA PCR proficiency testing criteria is located on the ACTG web site (https://www.hanc.info/labs/labresources/vqaResources/ptProgram/Pages/participationDocs.aspx).

Domestic and International Shipments: Whole blood shall be sent out from the ***VQA LAB*** during the month of February, April, August and October; DBS panels shall be created at the point of collection and shall be sent out two to four weeks after the data from the whole blood round are due. All DBS specimens shall be stored in the freezer (-70C) until they are shipped. The will be thawed and shipped under ambient conditions to the testing laboratories. Laboratories must monitor the level of humidity before testing; additional desiccants shall be added if necessary by the receiving laboratory. Laboratories must refer to the testing schedule to determine when they should expect to receive samples.