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

QUALITATIVE HIV-1 DNA DETECTION

Pre-Certification Testing: All new laboratories may request from the ***VQA LAB*** test panels for any of the proficiency programs prior to enrollment in that proficiency program. Results from these panels will be assessed but no certification score will be assigned.

Certification Testing: Prior to enrollment into the routine DNA PCR proficiency testing program, all new laboratories must test a 30 member frozen PBMC panel. Each pellet contains a known number of HIV-1 genomic DNA copies. A laboratory must provide acceptable performance on the 30 member panel prior to initiating whole blood testing. NOTE: the normal track or fast track options must be begun within one year of passing the certification panel. If real-time testing postponed beyond one year of testing, then another certification panel must be passed before testing in the VQA program may resume.

Normal Track: A new laboratory must obtain an **APPROVED** performance rating prior to performing any protocol testing. A laboratory's performance rating (PR) is based on the sum of the scores for the four (4) most recent proficiency panels (Performance Score, PS). Individual proficiency panels are scored a "1" for a Certified (C), "2" for a Provisionally Certified (PC), and "4" for a Probation (P). The Performance Score (PS) results in a Performance Rating (PR) are assigned as listed in the table below.

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: A new laboratory may obtain a "fast-track" APPROVED performance rating after only an initial two rounds of testing if they receive a certified grade (C). Laboratories that receive a provisionally certified grade (PC) or a probationary (P) score anytime during the first two rounds of testing cannot fast track and are given a NOT APPROVED performance rating until conditions outlined in the table above are met. NOTE: The final determination of whether or not a laboratory may perform protocol testing is at the discretion of the program leadership for that laboratory, not the VQA Laboratory.

Continued Approval: To retain an Approved status, all laboratories must participate in routine proficiency testing as scheduled by the VQA Program.

Withdrawal/Removal: A laboratory may voluntarily withdraw from any certification proficiency program at any time. A laboratory that has not participated in a certification program for 12 contiguous months will be automatically removed from that program. A

laboratory may request that proficiency testing for any proficiency program 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 may not use an assay to test protocol specimens while "On Hold" for a certification program for that particular assay.

Re-Certification: If a laboratory should withdraw or be removed from a particular proficiency program and that laboratory wishes to reenter the program at a later time, that laboratory will have to be recertified as a new laboratory (see Fast Track or Normal Track sections above).

Proficiency Testing Panels: Proficiency for HIV-1 DNA PCR is examined by sending each laboratory a panel of eight coded specimens that consists of replicate samples from two or more blood donors. Each of the eight samples should be extracted once then amplified/ detected in duplicate, according to the consensus method for HIV DNA testing. All runs must be valid according to VQA DNA SOP that can be found on the ACTG web site (http://aactg.s-3.com/vqa-testing-Cert-Requirements.htm). The entire panel must be repeated if any of these criteria are not met.

Proficiency scores are 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 (http://aactg.s-3.com/vqa-testing-Cert-Requirements.htm).

USA & Canada: Whole blood will be sent out from the ***VQA LAB*** at two month intervals; frozen panels may be sent more frequently to speed up the certification process. If a laboratory does not meet the fast track criteria, they will continue to receive whole blood/frozen specimens at one-two month intervals until an "Approved" score is achieved.

Outside USA & Canada: Whole blood will be sent out from the ***VQA LAB*** at two month intervals, if bloods can be delivered to the site within ten days of collection; frozen panels may be used if shipping constraints prevent the use of whole blood shipments. Frozen panels may also be sent more frequently to speed up the certification process. If a laboratory does not meet the fast track criteria, they will continue to receive whole blood/frozen specimens at one-two month intervals until an "Approved" score is achieved.