VQA Survey Results
14 October 1999

A total of 42 Laboratories participated in the VQA Survey. 63% of the Laboratories that participate in the VQA Proficiency Programs responded to the survey. These data include responses from 100% of ACTG ATLs, both Pediatric and Adult. The purpose of this survey was three fold: 1.) To document the current status of the laboratories with respect to the types of assays performed and the kits used; 2.) To monitor the participation of laboratories participating in the different VQA Proficiency Programs; and 3.) To evaluate the participation of the testing laboratories in the VQA Proficiency Programs. The following is a summary of the data, sorted by assay:

Culture Results-

Quantitative Microcultures are performed in 29/42 Laboratories for protocols including ACTG, WIHS, MACS, NICHD, and REACH. Qualitative Macrocultures are performed in 30/42 laboratories for ACTG, NICHD, MACS and REACH protocols. 23/42 Laboratories perform Qualitative Microcultures for the ACTG, NICHD, MACS and WITS groups. Yet only 5/42 Laboratories currently use the Ultra-sensitive culturing methodology for ACTG protocols.

The Dupont p24 ELISA kit is used in eight laboratories, the Coulter p24 ELISA kit is used in 16 laboratories, the Abbott p24 ELISA kit is used in eight laboratories and the OTC p24 kit is used in two laboratories.

Overall participation in the VQA QMC Proficiency Testing Program is 98% for laboratories currently running cultures for government sponsored protocols. In addition, only 3/42 laboratories participate in another outside QA Program; in this case all participate in a CDC-sponsored QA Program.

Action Items:

- ✓ **Assure that 100% of the testing Laboratories are participating in the VQA QMC Proficiency Testing Program.**
- ✓ **Follow up on the status of Ultra-sensitive Microcultures to see if there is a need to implement such a QA Program**

DNA PCR Results-

The Qualitative DNA PCR assay is performed in 19/42 laboratories for ACTG, NICHD, AVEG, WITS and ICTA protocols. 4/42 laboratories perform the Quantitative DNA PCR assay for ACTG protocols.

All 19 laboratories use the Roche assay for the Qualitative DNA PCR assay. Eight laboratories use the whole blood specimen prep, four laboratories use the PBMC specimen prep, and seven laboratories utilize both techniques. For Quantitative DNA PCR assays, two laboratories use a modified Roche kit, while the other two laboratories use Home Brew assays.

Overall participation in the VQA QDNA Proficiency Testing Program is 95% for laboratories running DNA PCR assays for government sponsored programs. Two of these laboratories also participate in CDC sponsored QA Programs. Three of the DNA testing laboratories utilize an internal standard to QC for genomic DNA using primers for HLA-DQ.

Action Items:

- ✓ **Assure 100% of testing Laboratories are participating in the VQA QDNA Proficiency Testing Program.**

- ✓ **Follow up on the Quantitative DNA PCR Assays to see if there is a need to implement such a QA Program**
- ✓ **Follow up on the QC tools for detecting genomic DNA in PCR assays**

RNA Results:

Nineteen laboratories perform both the Standard and Ultra-sensitive RNA assays for ACTG, REACH, WITS, WIHS, NICHD, or AVEG protocols. Two laboratories perform the Ultra-sensitive assay only, and nine laboratories only perform the Standard RNA assay.

Twenty-five laboratories use the Roche HIV-1 Monitor assay, three laboratories use the Chiron Quantiplex v 3.0, and seven laboratories use the Organon Teknika NucliSens assay.

Overall participation in the VQA RNA Proficiency Testing Program is 90% for the Standard RNA assay and 86% for the Ultra-sensitive RNA assay for labs running RNA assays for government sponsored programs. Additionally, 9 laboratories also participate in a CDC and or CAP sponsored QA program.

Action Items:

- ✓ **Assure 100% of testing Laboratories are participating in the VQA QRNA Proficiency Testing Program for the Standard and/or Ultra-sensitive Methodologies.**

Genomic Sequencing Results-

Nineteen laboratories perform Genomic Sequencing for ACTG, ENVA, CFAR, or AVEG protocols.

Fourteen laboratories use the ABI system; nine laboratories use Visible Genetics, Inc., 1 laboratory uses Affymetrix, and two labs use LIPA technologies.

The VQA is currently participating in a Working Group to develop Sequencing Proficiency Panels, so overall participation in this Proficiency Program is not available. However, five of these testing laboratories participate in ENVA QA Programs, one laboratory participates in a CAP sponsored QA program, and one laboratory participates in a CDC sponsored QA program.

Action Items:

- ✓ **Continue with the development of a Genomic Sequencing QA Program.**

Blood Spot Results-

Four laboratories perform Blood Spot analyses for ACTG protocols.

No assay kit information was provided.

The VQA is currently participating in a Working Group to evaluate this technology, and no Proficiency Testing Program exists. Additionally, none of the testing laboratories participate in any outside QA Program.

Action Items:

Continue with the evaluation of the Blood Spot technology.