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**A Revised Proficiency Testing Program for Quantitative HIV-1 RNA Assays.**

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The HIV-1 RNA Proficiency Testing Program of the Virology Quality Assessment Program was established to provide quality assurance for quantitative HIV RNA assays in ACTG clinical trials and other NIH-sponsored studies of HIV-1. Proficiency is assessed by sending coded panels of plasma spiked with HIV-1 at known concentrations to participating laboratories. Sixty-nine laboratories participated between 09/95 and 04/01, including 48 between 04/00 and 04/01. Initially, performance criteria emphasized precision in batch testing: the intra-assay standard deviation should permit detection of a five-fold difference between 2 samples from a patient in the same batch. Criteria for sensitivity (rates of negative results near the limit of detection) and specificity (rates of false positives on negative samples) were added later. However, real time RNA testing, which allows investigators to base treatment decisions on viral load, is now used in many trials. New performance criteria include the combination of intra-assay and inter-assay variation, to assess assay variation in real time testing, and the accuracy of RNA titers, to reflect the use of viral load in treatment decisions. Sensitivity and specificity will still be assessed. The HIV RNA proficiency testing program has therefore been revised. Test panels of 5 coded, HIV-spiked, samples will be assayed every 2 months, rather than the original schedule of one panel of 20 samples quarterly. Performance will be assessed using combined results from 4 successive panels (20 samples total). Statistical power to detect performance problems will be described and compared with the previous program. The benefits of such a program are manifested in the outcomes of proficiency testing. Approval ratings increased from 65% to 80% of participating laboratories between 9/95 and 4/01. The revisions to the proficiency testing program will ensure that future performance assessment is based on criteria relevant to the current state of research in HIV infection.