An Evaluation of Proficiency Testing by Laboratories Performing HIV Antibody Immunoassays

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Background

Under the Clinical Laboratory Improvement Amendment (CLIA) regulations, laboratories performing HIV antibody testing are required to participate in a proficiency testing (PT) program. Currently, few PT programs for HIV antibody are CLIA-approved and few of them are active. Some of the PT programs that have recently expanded to include rapid testing, even though some of the rapid tests are CLIA-validated. We were interested in reviewing the data available from PT programs to determine 1) the proportion of laboratories that report results using rapid testing, 2) what type of rapid tests are used, 3) the methods laboratories use to perform rapid HIV antibody testing, and 4) if there were any performance problems reported, and 5) how the laboratories performed that reported results using rapid test methods.

Methods

Two data sources were used for this evaluation. One source was the PT participant summary reports for surveys conducted during 2004 available over the 10 year period 1994-2004 indicated that the rates of FP and FN results.

Results

In 2004, a total of 2356 laboratories were enrolled in PT for the HIV antibody according to CLIA statistics. Of these, 82% were hospital (1320) and independent (589) laboratories. An analysis of CLIA data available over the 10 year period 1994-2004 indicated that the rates of PT events varied from 3% to 5% per year (failure is defined as a score of less than 80% (with 5 challenges/survey, failure = score of 0%-60%)

Conclusions

Proficiency testing results provide a data source for evaluating trends in the use of various commercially available test kits and laboratory performance over time. A review of the 2004 PT program summary reports and performance score data submitted to CMS from 1994-2004 reveals changes that reflect:

- The introduction of new technology, such as rapid testing.
- The use of manipulated (e.g., diluted) samples that do not invalidate the same way in all test kits, and an increase in failures in 2003 and 2004 due to submission of incorrect scores, as well as administrative errors such as untimely results reporting and failure to identify the test method.

As immunoassay technology changes, PT providers need to be aware that challenge samples acceptable for one test may not be acceptable for others (matrix effects). PT providers should address these issues to differentiate between poor performance and problems due to the PT sample. Also, laboratories need to be aware that submitting results late or providing incomplete information can result in PT failure.

Resources for Further Information


*CLSI is the Clinical and Laboratory Standards Institute, formerly HCLL.