Evaluation of An Alternate Proficiency Testing Program in a Tertiary Care Laboratory

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Objective and Relevance: To meet laboratory accreditation requirements we developed an alternate proficiency testing (PT) program and have been using it for one year (2 separate challenges). The alternate PT program has 4 options: 1) split sample testing within the laboratory (2 analytes); 2) split sample testing between geographically separate laboratories (43 analytes); 3) testing of assayed materials (1 analyte) and 4) validation of results with clinical correlation (12 analytes). For each analyte, the most appropriate option was chosen. To improve the program, we reviewed the first year's results.
Methodology: Results from each semiannual challenge were tabulated and reviewed for compliance, adequacy of documentation and usefulness of acceptance criteria.
Results: For 6 analytes no alternate PT was done. Staff forgot to send samples for 2 tests, 3 analytes (pyruvic acid, fecal/fluid bile acids, fecal porphyrin) lacked suitable samples and 1 clinical validation was not performed. For the remaining 52 analytes alternate PT was performed. Review and documentation was adequate for 40 of the analytes. Documentation for 11 clinical validations and 1 within laboratory split sample test was either incomplete or missing. Most of the alternate PT testing was performed using similar methods (n = 24). Alternate PT evaluation of these analytes was based the magnitude of the paired differences which were compared to medically allowable error. Most failures occurred at the lower limits of the analytical measurement range (AMR). For tests that were performed by different methodologies (n = 8) a constant relationship between results indicated acceptable assay performance and were aided with contingency tables (3x3 or 2x2) based on each test method's reference range. For qualitative tests (n = 7) interpretive agreement with the alternate laboratory result provided an acceptable measure of assay performance.
Conclusions and Recommendations: The most common reason for noncompliance was the failure to submit specimens. To prevent this problem, a schedule should developed for PT submission. For the three analytes that lacked suitable specimens, we recommend that the PT be correlative rather than analytical. Changes for the acceptance criteria in the lower part of the AMR are recommended, ie expanding the allowable range for low concentration specimens. The alternate PT process allows the laboratory to evaluate assay performance in the absence of a graded proficiency testing scheme. Periodic assessment of the program will dramatically improve its usefulness.