Oregon State Public Health Division
Laboratory Compliance Section
7202 NE Evergreen Pkwy., Ste. 100, Hillsboro, OR 97124
Ph:503-693-4125 Fax:503- 693-5602 TDD 971-673-0372
http://www.healthoregon.org/lcqa

Synopsis of 42 CFR, Part 493; Subpart H and I and OAR 333-024-0040

Proficiency Testing Requirements For Clinical Laboratories

The performance of proficiency testing (PT) is applicable to all *moderate* and *high* complexity laboratories performing specific common laboratory tests (analytes). Refer to Regulated Analytes or Tests Requiring Proficiency Testing Enrollment or 42 Code of Federal Regulations (CFR), Part 493.909 through 493.945 for a complete list of regulated analytes.

Laboratories performing 'regulated analytes' must:

- Subscribe to a CMS approved Proficiency Testing (PT) Program for each of the regulated analytes; most PT sets must contain five (5) specimens for each analyte and consist of three (3) events per year; bi-annual verification is required for all non-regulated analytes performed.

- Enroll for only one test even when multiple methods or instruments are used; (Example: syphilis test would require enrollment for the RPR *or* the FTA).

- Stay with a given PT program for an entire year.

- Treat all PT specimens as if they were patient specimens.

- Document all steps in PT performance; testing personnel and the director must sign the attestation statement following each testing event.

- Maintain all PT records for two years including investigations of unsatisfactory performance.

- Obtain a passing score on each analyte tested: 80% is a passing score for most analytes; 100% for ABO, Rh and compatibility testing.

- Investigate *all* scores less than 100% and follow up to assure corrective action was effective; document all investigative and monitoring actions.

- Inform the PT provider to send all reports to Laboratory Compliance, P.O. Box 275, Portland Oregon 97207-0275.

- Notify Laboratory Compliance of additions or deletions of regulated analytes performed, within 30 days of the change.

- Notify Laboratory Compliance prior to date report is due to the PT provider, if the laboratory is unable to test PT specimens due to equipment malfunction.

Monitoring of PT by Laboratory Compliance

Laboratory Compliance monitors each laboratory's PT performance throughout the year. When a laboratory obtains an unacceptable score for two consecutive or two out of three events for the same test or specialty/subspecialty Laboratory Compliance sends a letter requesting information regarding the unacceptable performances. In order to continue performance of the test, specialty or subspecialty, the laboratory must prove to Laboratory Compliance that patient test results are accurate. The laboratory must explain in detail what action was taken during the investigation process, the outcome of the investigation and follow-up action, to prove corrective action was effective and test performance is once again accurate. Failure to send requested information in the time requested, or prove accuracy of test results will result in further adverse action. Adverse actions could include discontinuance of a specific test, revocation of specialty or subspecialty, revocation of CLIA certificate and subsequent denial of Medicare and Medicaid payment.

Recommendations for successful PT performance

- Mark a calendar with the dates of PT shipment for each set to which you subscribe; phone PT provider if specimens do not arrive when expected.

- Review PT report form for completeness and accuracy; clerical errors are just as wrong as analytical errors.

- Save PT specimens for problem resolution or investigation of failures, when possible (i.e. freeze serums).

- Rotate PT specimens among applicable personnel to assist in meeting the requirements for personnel competency.

- Review PT results from all participants to assess performance of kits and methods used in your laboratory.

- Review PT data over a period of time to detect shifts and trends.

- Review all code 10" or ungraded results to determine if your results are in the ballpark of other laboratory results (except when specimens were contaminated).

- Thoroughly investigate and document all unsatisfactory results taking a systems wide approach during the investigation; Example: assess if the failure is due to lack of adequate policies and procedures, inadequate training, lack of adequate equipment maintenance or frequency of calibration, clerical errors, etc.

Take PT performance seriously. It is a window on your laboratory's performance between on-site inspections. Careful monitoring of PT, along with other quality control and quality assurance monitors, should result in detection of potential problems before they result in two consecutive failures requiring adverse action.

Adverse Action:

- **Sending PT specimens to another laboratory for testing** (prior to the PT reporting date) will result in a suspension or revocation of the laboratory's CLIA Certificate for a period of one year. **Comparing PT results with other laboratories** will result in adverse action.

- **Failure to successfully participate for two out of three test events** will initiate the process of revocation or withdrawal of the specialty or subspecialty or analyte. The laboratory must demonstrate sustained satisfactory performance on two consecutive PT events before reinstatement can occur.

- **Failure to subscribe or perform PT** is a serious deficiency and will result in adverse action which may include revocation of a test, specialty, subspecialty or CLIA Certificate.

*****

In accordance with the ADA this document is available in alternate formats by calling 503-693-4100.

I:/LC Files/PT Synopsis