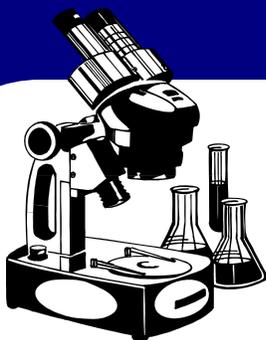


CLIA BITS



North Dakota Department of Health
Division of Health Facilities Summer 2006

Plan of Correction

A sound plan of correction is the first step toward successful and continued compliance. The following are guidelines for writing an acceptable plan of correction:

- Address how the deficiency will be corrected. (I.e., outdated chemistry reagents were discarded and replaced with current dated reagents.)
- Explain how other test systems with the potential to be affected by the same deficient practice will be identified. (I.e., expiration dates of all laboratory supplies were checked.)
- Describe how the system-wide process will be corrected to ensure the problem does not recur. (I.e., no outdated supplies will be used in the laboratory.)
- Explain how the effectiveness of the corrective action will be monitored. What quality assessment monitor will be implemented to ensure the deficient practice does not recur? (I.e., the laboratory will check expiration dates of supplies monthly for three months and quarterly thereafter.)
- Address who will monitor the corrective action and how often. (I.e., the laboratory supervisor will review the quality assessment monitor monthly for three months and quarterly thereafter.)
- Enter the date of correction in the far right hand column on the deficiency report.
- Do not use names on the deficiency report; use job titles instead. (I.e., laboratory director, not Dr. Jones.)
- Ensure the deficiency report is signed and dated at the bottom of the first page by the director or other authorized official.

If the plan of correction is not acceptable, the deficiency report (CMS-2567) will be returned to the laboratory for revision or amendment or the laboratory will be contacted by telephone for clarification.



Updated CLIA Proficiency Testing Requirements

Antibody detection proficiency testing meets the requirement for direct antiglobulin test (DAT) proficiency testing if all of the steps required to perform the DAT are a subset of the steps required to perform antibody detection by the indirect antiglobulin testing. However, if the laboratory routinely uses different methods for DAT and antibody detection, the proficiency testing for antibody detection would not cover the DAT. For example, a laboratory may use a gel technique for antibody detection and use a tube method for DAT. In this case, the laboratory would need to verify the accuracy of DAT twice annually to fulfill 493.1236(c)(1).

Reminder

Enrollment in proficiency testing is required for back-up strep cultures and non-waived strep A antigen testing kits. Using a waived strep A antigen kit and setting up back-up cultures requires proficiency testing for the back-up cultures, but not for the waived strep test.

Regulated Vs. Non-Regulated Analytes

What are regulated analytes and non-regulated analytes? Regulated analytes are those found in subpart I of the CLIA regulations. Regulated analytes must be enrolled in an approved proficiency testing program as a condition of participation in the CLIA program. Non-regulated analytes must be twice annually verified for accuracy. Accuracy verification can be accomplished through proficiency testing, blind testing of materials of known values, other external assessment programs, or split samples

with another laboratory instrument or method. Proficiency testing programs commonly provide two specimen events for non-regulated analytes. Some of the more common non-regulated analytes are the following: magnesium, phosphorus, CO₂, PSA, direct bilirubin, GGT, vaginal wet preparations, KOH preparations, pinworm preparations, urine sediment, nasal smear for eosinophils, stool WBCs, fern test, hemocytometer cell counts, post-vas sperm analysis, troponin, myoglobin, glycosylated hemoglobin and C-reactive protein.

Proficiency Testing (PT) Reminders

- Document all PT activities.
- Treat PT specimens in the same manner as patient specimens.
- Document the performance of dilutions or calculations for PT specimens.
- Investigate and take corrective action for all incorrect responses.
- Verify accuracy of results that are non-graded.
- Lab director must review PT results and corrective action.
- Sign attestation statements – testing personnel and director (or designee). The lab director may designate the technical supervisor/consultant to sign. Remember: the technical supervisor for immunohematology must be a pathologist or qualified physician. Do not delay sending in results for the lab director's signature; he or she may sign the laboratory's form later.
- Retain records for two years – test records, report forms, print-outs, attestation statements, results and corrective action.

SUMMER



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