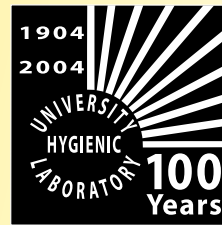


# CLIA Corner

The University of Iowa Hygienic Laboratory

Third Quarter 2007



Iowa CLIA Surveyors: Nancy Grobe, BS, MT(ASCP) & Kristine Rotzoll, BS, MT(ASCP)

## In This Issue...

### Tips for a Successful CLIA Survey

In this issue, we give you advice to help your laboratory prepare for and succeed at its next CLIA survey/inspection and to make the survey process easy, efficient and effective. Although the article focuses on surveys for laboratories with certificates of compliance (state agency conducts survey), the laboratories routinely inspected by an accrediting agency will find the tips useful in preparing for their inspections as well.

#### PRESURVEY

- In Iowa, as well as other State CLIA programs, upon payment of compliance fees, a presurvey packet is mailed to the laboratory. For Iowa laboratories, the packet consists of the following forms:
  - *Laboratory Personnel Report, HCFA-209;*
  - *CLIA Application for Certification, CMS-116; and*
  - *Laboratory Test Menu with Method/Manufacturer and Annual Volumes.*

The laboratory completes and returns the forms, following the instructions and guidelines provided. Be sure that the CLIA laboratory director signs all appropriate documents.

- Recertification, initial and validation surveys are announced with a two-week notice. Recertification surveys are to be conducted six to nine months prior to the expiration of the current CLIA certificate. For initial surveys, the survey is scheduled no sooner than three months and no later than 12 months from the effective date of the registration certificate. Validation surveys are to be conducted within 90 days of the accreditation survey unless it is a simultaneous survey.

- Be prepared and organized

The following is a check-off of the manuals and documents to have ready and retrievable for the survey:

- ✓ **Laboratory policies and procedures**; including package inserts, new and discontinued procedures, and operator's manuals.  
*(TIP – Procedures and policies must be up-to-date and approved by the current laboratory director, including operator's manuals and package inserts if used as procedures.)*
- ✓ **Personnel records for all laboratory staff**, including:
  - diplomas or transcripts from the highest education degree earned;
  - current license(s), as appropriate;
  - job duties/responsibilities and as applicable, which tests each laboratory personnel is authorized to perform;
  - orientation/training for new laboratory personnel;
  - in-service and continuing education;
  - training records for new test methods and systems; and
  - annual competency assessments (twice annual for new employees)
- ✓ **Proficiency testing (PT) records**, including:
  - reporting forms with signed attestation statements;

- testing records and instrument printouts;
  - program reports and summaries;
  - corrective action taken for any unsatisfactory or unsuccessful events; and
  - twice annual verification of accuracy for nonregulated analytes (*TIP – Arrange PT records in chronological order and organize all records and reports by the testing event.*)
  - ✓ **Quality control records**, including:
    - control results, daily, monthly and cumulative summaries and Levy-Jennings charts;
    - calibrations and calibration verifications;
    - instrument printouts of control and calibration results, if applicable; and
    - corrective action for unacceptable control and calibration results.
  - ✓ **Instrument and equipment maintenance and function check records**, including:
    - routine daily, weekly, monthly, etc. maintenance;
    - service and repair information;
    - electronic and function checks (e.g., centrifuge, blood bank alarm, pipettes, etc.); and
    - equipment and reagent monitoring (e.g., temperatures, water quality, expiration dates, etc.).*(TIP – The frequency of performing maintenance and functions checks needs to match the manufacturer guidelines or the laboratory’s policy.)*
  - ✓ **Patient test requisitions, records and reports** [*Tip – Check the retrieval process (e.g., LIS, patient work logs, patient charts, etc.)*]
  - ✓ **Performance specifications verifications for new test systems or methods**, including validating new lot numbers of thromboplastin reagent for protime/INR testing
  - ✓ **Quality assessment/assurance (QA) plan and records**
  - ✓ **Safety manuals, information and records**
- Self-inspect your laboratory. Check storage areas, refrigerators and freezers for outdated reagents and supplies.
  - Ensure that key laboratory and administrative personnel are informed of the survey and are available.

## **DURING THE SURVEY**

- Be cooperative.
- Be prepared to retrieve records and documents from the past two years and for transfusion related records for past 5 years.
- The survey process includes observation of facilities and processes, interviews, and record review. For reviewing patient records, a tracking process is used to demonstrate the laboratory is compliant with the preanalytical, analytical and post analytical quality systems.
- The regulations give us the authority to look at all documents necessary to assess compliance. As a health oversight agency, CLIA is exempt from the HIAAP requirements.
- The survey goal is to assess the laboratory’s performance, determine compliance with the regulations and ensure the quality of patient testing. If a problem(s) is revealed during the survey, the nature and seriousness of the problem is determined and whether a negative or potentially negative outcome exists.
- Condition-level deficiency is one that constitutes a significant or a serious problem that adversely affects patient test results/patient care, or has the potential for adversely affecting patient test results/patient care.
- Exit conference: The purpose is to review findings with the laboratory and is not meant to be all-inclusive. It offers the laboratory the opportunity to present additional information in response to the findings. If deficiencies are found, the surveyor provides instructions and timeframe for submitting plan of correction. (*Tip – This is an excellent time to ask questions, receive clarification and exchange new ideas.*)

## **POST SURVEY**

- Initiate corrective action prior to receiving the written Statement of Deficiencies, CMS-2567.
- The plan of correction must be written (in ink) or typed directly on the form provided.
- The plan of correction must include:
  1. *A step-by-step description of the method(s) used to correct the system level problem, which caused the deficiencies. The plan of correction must provide information that assures the intent of the regulation is corrected. A statement that correction has been made for the specific examples cited is not acceptable.*
  2. *State the method(s) to be used to maintain and monitor compliance. Indicate the position(s) responsible for monitoring the correction to prevent the deficiency's re-occurrence. State your anticipated frequency of monitoring.*
  3. *A realistic date of correction by month, date and year.*
- The plan of correction must be signed and dated by a representative of your laboratory.
- For any deficiency, a revisit or follow-up is conducted. The timeframe depends on the type of deficiency. For condition-level, evidence of compliance must be received or noted within 45 days of the survey. For standard-level, compliance must be met within 12 months of the survey.

Hard work and preparation will bring you good luck and success at your next inspection.

For more details about the survey process for CLIA surveys, go to [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia), click on “Interpretative Guidelines for Laboratories”, then to the first section, Policy for Conducting Surveys.