



CLIA BITS



North Dakota Department of Health
Division of Health Facilities Summer 2007

CLIA Quality Systems Assessment

Part 2 of a continuing series

Preanalytic Systems – 493.1240-493.1249

Preanalytic Systems is the second of four quality systems. Preanalytic Systems includes all laboratory activities performed prior to the actual testing of the patient specimens. The components of the preanalytic systems include test requisitions and specimen submission, handling and referral.

To perform patient testing, the laboratory must have a written or electronic request from an authorized individual. According to Clinical Laboratory Improvement Amendments, an “authorized” person is an individual authorized under state law to order tests or receive results. North Dakota state law is silent as to who is authorized to order laboratory testing. Each laboratory must establish its own policy as to who is authorized to order laboratory testing. Before authorizing an individual, verify the ordering of laboratory testing is within the scope of practice of the individual. Standing orders are acceptable if defined in written policy. The policy should include what tests may be covered by standing orders and at what interval standing orders should be reconfirmed. CLIA accepts verbal orders if the laboratory requests written authorization within 30 days and maintains the authorization. The laboratory should maintain documentation showing the attempt to obtain the written authorization. Hospital regulations, facility bylaws and policies may require authentication of verbal orders within 48 hours. *(Continued on page 2)*

RECALL ALERT

Ortho-Clinical Diagnostics and Food and Drug Administration notified health-care professionals of a nationwide recall of the Vitros Immunodiagnostic Products, Troponin I Reagent Pack, lots 3151 and 3170. The product was recalled after a small number of clinical laboratories administering the test reported shifts in quality control results, causing the potential for false negative troponin I results at very low levels of troponin elevation. Laboratories in possession of the identified lots are instructed to discontinue use of the product and notify health-care professionals who ordered the test in recent weeks. Read the complete 2007 safety summary, including a link to the manufacturer's press release regarding this issue, at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Vitros>

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The test request must include the following information:

- Name and address of the authorized individual ordering the test.
- Patient's name or unique patient identifier.
- Patient's sex and age or date of birth.
- Test(s) to be performed.
- Source of the specimen, when appropriate.
- Date and, if appropriate, time of specimen collection.
- For Pap smears, patient's last menstrual period and patient's history.
- Any additional relevant information (e.g., patient's history or therapeutic medications).

The patient's chart may be used as the test requisition if it provides all the necessary information. The chart must be available to the laboratory at the time of testing and to Centers for Medicare & Medicaid Services (CMS) upon request.

The laboratory must have a mechanism in place to ensure manual entries of requisition information into a record system or laboratory information system (LIS) are accurate.

The laboratory must establish and follow policies and procedures for specimen submission, handling and referral. The policies should include:

- Patient preparation (e.g., fasting or dietary restrictions).
- Specimen collection (e.g., appropriate technique or proper containers).
- Specimen labeling, including patient name or unique identifier and source, if appropriate.
- Specimen storage and preservation (e.g., temperature or separating).
- Specimen transportation.
- Specimen processing (e.g., receiving, accessioning or preparing).

- Specimen acceptability and rejection criteria.
- Specimen referral.

The laboratory must document the date and time of specimen receipt if different from the collection time and date. The laboratory must send referral specimens to a CLIA-certified or equivalent laboratory. If the laboratory accepts referral specimens, it must provide the clients with written instructions.

Preanalytic areas to consider monitoring include:

- Completeness of the test requisition.
- Frequency of rejected specimens.
- Mislabeled or unlabeled specimens.
- Problems with specimen handling.
- Problems with specimen transport.
- Proper identification of the patient.
- Accuracy of test requisition information into record system or LIS.
- Receipt of specimen by reference laboratory.
- Current written instructions available to referral clients.
- Manufacturer's instructions for specimen collection and storage.
- Follow-up of verbal orders.

Quality assessment is an ongoing process. When errors or potential problems are identified, corrective action must be initiated to resolve the problem and must be communicated to the appropriate people. Over time, monitor the corrective action to ensure the problem does not recur.

Most laboratory errors occur in the preanalytic phase. What is your laboratory doing to prevent or reduce preanalytic errors?

Sources for this article: Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; CLIA Basic and Beyond Training September 2006; National Laboratory Training Network Teleconference, January 19, 2006.

QUESTIONS AND ANSWERS (Q & A)

CMS provides specialized CLIA training courses for state surveyors. During these training courses, surveyors from across the country ask CMS staff questions regarding the survey process. Although the questions and answers do not represent official CMS policy, they contain valuable information regarding the survey process. The Q & A is a regular feature of the CLIA Bits newsletter. We hope you find this information interesting and useful. Readers are welcome to submit questions to bweidner@nd.gov or sheilman@nd.gov.

- Q. Are new validation studies required when equipment is moved from one site to another?
- A. The CLIA regulations for verification or establishment of performance specifications do not specifically address the moving of equipment. The laboratory should ensure the equipment was not damaged and is still working properly. Also, check the manufacturer's requirements for moving equipment.
- Q. How many times should the laboratory run a new lot number of controls prior to use?
- A. The CLIA regulations at 493.1256(d)(10) do not state a specific number of times a control material must be tested. In general, 20 replicate tests would be considered the minimum.



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