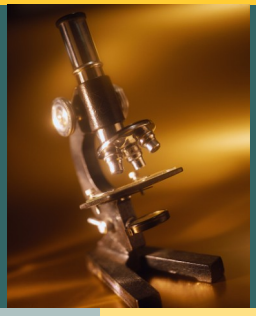
Spring 2012



NORTH DAKOTA DEPARTMENT OF HEALTH
DIVISION OF HEALTH FACILITIES

CLIA BITS

CLIA Celebrates 20 Years

The Centers for Medicare & Medicaid Services (CMS) regulates laboratories performing tests on human specimens used to aid in the diagnosis, prevention or treatment of disease, or the assessment of health of human beings. February 28, 2012, marked the twentieth anniversary of the publication of the Clinical Laboratory Improvement Amendments (CLIA) final regulations. Expectations for safety and accuracy in clinical laboratory testing were established with this legislation, which has become a model for the world. Due to the implementation of CLIA regulations and CMS oversight, health-care providers and patients can be assured that laboratory results are accurate and reliable. For further information, please visit the CMS/CLIA website at www.cms.hhs.gov/clia/.

Do you Know? . . .

- *The impetus for CLIA was deaths due to incorrectly read Pap tests.*
- *70% of all medical decisions are based on a laboratory result.*
- *Approximately 230,000 laboratories are enrolled with CLIA.*
  - *67% certificate of waiver*
  - *17% certificate of provider performed microscopy*
  - *9% certificate of compliance*
  - *7% certificate of accreditation*
- *Laboratory testing represents 3% of Medicare payments, but all laboratories are covered by CLIA, regardless of payment method.*
- *There are approximately 4,000 laboratory tests available; over 1,000 conditions are now detectable by molecular technologies.*
- *CLIA is administered by three Health and Human Services agencies: CMS, Federal Drug Administration, and Centers for Disease Control and Prevention, with CMS having overall responsibility.*
- *CLIA is entirely user fee funded (based on test volumes) by the laboratories.*

Inside this issue:

If you would like to receive CLIA Bits electronically, please send your e-mail address and company name to Bridget Weidner at bweidner@nd.gov.

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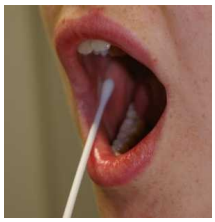
Questions and Answers (Q & A)

The Centers for Medicare and Medicaid Services (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.

1. **What should we do if the specialties listed on our CLIA certificate are not correct?**
   If you have a certificate of compliance, contact your State CLIA Agency. If you have a certificate of accreditation, contact your Accrediting Organization.
2. **Why does the State CLIA Agency conduct surveys at accredited laboratories?**
   CMS directs the State CLIA Agencies to conduct these surveys to ensure the accrediting organizations are holding their laboratories' performances to a standard that is equal or more stringent than required by CLIA. These surveys are called validation surveys. The surveys may be conducted simultaneously with the accrediting organization or no later than 90 days after the accrediting organization's inspection.
3. **How can my lab comply with the quality control requirements for potassium hydroxide (KOH)?**
   There must be documentation the laboratory checked the KOH to ensure that it performs as expected. In other words, does the KOH dissolve epithelial cells and preserve fungal elements?

   This can be done numerous ways:

   - Purchase commercial controls
   - Laboratory produced controls
     - Epithelial cells: Skin scraping or swab from inside the cheek.
     - Fungal elements: Fungus from your micro stock cultures (e.g. Candida), Fungus grown on food (e.g. bread or strawberries), reconstituted baker's yeast, etc.
   - Split samples that are positive for fungus and epithelial cells tested with the old lot number and with the new lot number
   - Split samples from another lab that are known to be positive for fungus and epithelial cells.

   The documentation of QC performance must be retained for the life of the reagent or at least two years.

Spring makes its own statement, so loud and clear that the gardener seems to be only one of the instruments, not the composer.

~Geoffrey B. Charlesworth

Sources: Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services and State Operations Manual, Chapter 6 - Special Procedures for Laboratories; CMS/CLIA website at www.cms.hhs.gov/clia/.

CLIA Bits is published by:
Division of Health Facilities
North Dakota Department of Health
600 E. Boulevard Ave., Dept. 301
Bismarck, N.D. 58505-0200
Phone: 701.328.2352
Fax: 701.328.1890
Web: www.ndhealth.gov

Terry Dwelle, M.D., M.P.H.T.M., State Health Officer
Darleen Bartz, Ph.D, Chief, Health Resources Section
Bruce Pritschet, Director, Health Facilities
Bridget Weidner, Program Manager
Shelly Heilman, CLIA Surveyor
Rocksanne Peterson, Newsletter Design