Laboratory “How-To” for the Small Student Health Center

Chris Rooney, BSN RN BC

ACHA May 31, 2012

Millersville University of Pennsylvania
Handouts

If you can’t read this, just give up on the handout and see the ACHA website post. Or email me for an electronic copy.
Objectives

• Describe the CLIA regulations and state licensure for the student health laboratory
• Discuss the application of CLIA and state regulations
• Identify advantages of providing in-house laboratory services for students
Millersville University

- 8700 students
- Founded in 1855
- Public Coed
Health Services

- Medical Director: Susan Northwall, D.O.
- 2 Nurse Practitioners, 5.5 RN’s, 2 Office Staff
- Health Service Fee, Do Not Bill Insurance
- EHR – 10000 visits per year
Laboratory Services

• Point of Care Testing
  – Strep A
  – Infectious Mono
  – Urine Pregnancy
  – Influenza A and B
  – Fecal Occult Blood
  – Automated Urinalysis

• Provider Performed Microscopy
  – Vaginal Wet Mounts with KOH
  – Urine Sediment
Send Out Testing

- Utilization of four reference laboratories
- Venipuncture and specimen collection
CLIA Regulations

How do they apply to the Student Health Center
**Purpose of CLIA ‘1988**

Establish quality standards to ensure the accuracy and timeliness of laboratory test results regardless of test location.

Sets standards to improve quality – includes specifications for quality control, quality assessment, test management and personnel

Minimum standards – states may have more stringent requirements

Certifies laboratories and/or laboratory practices not tests or individuals performing tests
Clinical Laboratory Improvement Amendments 1988

- 10/1988 Public Law CLIA '88
- 2/1992 Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA)
- 9/1995 CLIA Program; Categorization of Waived Tests
- 10/1997 Part 493 Laboratory Requirements
  Updates – 1999 yearly to 2005
- 2009 PPM/Waived designation change survey of COW labs
- 3/2010 Revised Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services in Appendix C of the State Operations Manual to Facilitate the Electronic Exchange of Laboratory Information ", S&C-10-12-CLIA.
Student Health Center Laboratories

CLIA requires all facilities that perform even one test, including waived tests, on “materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings” to meet certain Federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed.
CLIA '88

- Subpart B: Certificate of Waiver
- Subpart H, I, J, K: Proficiency Testing
- Subpart M: Personnel
- Subpart C: Certificates of Registration, PPM, Compliance
- Subpart D & E: Accreditation
- Subpart A: General Provisions
- Subpart Q: Inspection
One bite at a time.
Let’s take a bite or two

• Part A General Provisions
  – All labs certified
  – Test Complexity

• Part B – Certificate of Waiver
  Fee required
  Only Waived
  Certain P. H. Entities

• Part C – Certificates
  – Registration
  – PPM
  – Compliance

• Parts D & E - Accreditation
More CLIA

- Part F  General Administration
  - Fees
  - Other general
- Parts H and I
  Proficiency Testing for Non-Waived Testing
  Includes PPM
- Part J – Facility Admin and record retention
- Part K – Quality
- Part M – Personnel
- Part Q – Inspection
QUALITY STANDARDS

Agency Functions

- CMS - Centers for Medicare & Medicaid Services
  ✓ charged with the implementation of CLIA
- CDC - Centers for Disease Control and Prevention
  ✓ responsible for the CLIA studies
- FDA - The Food and Drug Administration
  ✓ responsible for test categorization.
Complexity of Testing determines applicable regulations

- Waived Testing
- Non Waived - Moderate including PPM
- High Complexity
Waived Testing – must enroll in CLIA, pay Fee and follow manufacturer’s instructions.

Non Waived – quality standards for proficiency testing (PT), patient test management, quality control, personnel qualifications and quality assurance – this includes PPM
Interpretive Guidelines for Laboratories

APPENDIX C

Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services

The items listed below replace the current Publication 7, Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services. This material was rewritten due to publication of CMS-2226-F: 42 CFR 493 Medicare, Medicaid, and
Clinical Laboratory Improvement Amendments (CLIA)

CLIA Content
- Chronology
- Test Complexities
- Lab Demographics
- CLIA Law
- Regulations

Related Content
- DLS Home
- Genetics
- International
- MASTER
- Publications
- Training
- Waived Tests

Latest News
The Division of Laboratory Science and Standards (DLSS) is developing educational materials on good laboratory practices for waived and genetic testing. For waived testing, materials currently available include a poster, postcard, and booklet for personnel who perform waived testing, as well as online training based on good laboratory practices for those who perform waived testing. A different booklet is also available for those individuals who wish to initiate waived testing or implement a new waived test. For molecular genetic testing, materials include fact sheets for laboratories, health professionals and patients. Online training based on good laboratory practices for molecular genetic testing is in development.

Quick Links
- Biosafety
- Upcoming Events
- Guidelines

Key Resources
- CLIAC

CLIA Related Publications
CLIA vs. State Regulations

Every state has a Dept of Laboratories:
Who Can Order Laboratory Testing

CLIA - 493
(a) The laboratory must have a written or electronic request for patient testing [with data elements that satisfy those required at 42 C.F.R. sec. 493.1241(c)] from an authorized person. [An authorized person is defined at 42 C.F.R. sec. 493.2 to be an individual authorized under State law to order tests or receive test results, or both. 42 C.F.R. sec. 493.2.]
## Proposed CLIA Amendment Change

### Table 3--Impact of Proposed Rule Change on Laboratories

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Richardsite: **Go** and **Ask Your Mother** - cartoon
network54.com
Standards for SHC

Requirements for CLIA License/ State Licensure

Good Laboratory Practices
  Personnel
  Test Management

Quality Assessment – Quality Control/PT

Policy and Procedure Manuals
**Personnel**

- Waived – capable of performing test. Demonstrated and documented competency. Follow manufacturer’s directions
- PPM – Performed by licensed professionals in timely manner. **Director:** MD, DO, NP, PA
- Non-Waived - Specific personnel qualifications for specific personnel positions
  i.e. Lab Director of Mod Complex lab – MD, DO with special training, previous experience
Competency

- Initial Orientation for all new hires.
- Yearly lab updates
- OSHA and Blood borne Pathogen Training
- Documentation of yearly competency
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<th>A</th>
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**Criteria**

- A Preparation of patient
- B Follows specimen collection procedures
- C Follows specimen processing/testing procedure
- D Follows Quality Control Procedures
- E Reports Lab results per policy
- F Documents according to policy
- G Follows Universal precautions/Safety measures
- H Follows Maintenance/Storage Procedures

**Comments**

Employee Signature

Reviewer's Signature

Director's Signature

BB Pathogen Review Date

QA Document Review Date

P F
Patient Test Management

- Record Keeping
- Patient Identification
- Test Referral
- Confidentiality
- Procedural specification
Quality Control

- Specifications that each test is working correctly each day
  - Calibration
  - External Controls/Internal Controls
- Quality Assessment
  - Remedial Action plans when Controls are outside acceptable ranges
  - Documentation
Control Logs

• Include date opened/expiration
• Lot Number
• External Control Results
• Technician
Documentation

- Clear Patient Identification
- Order by authorized individual
- Date and time
- Result with reference range
- Each result must indicate the kit lot number and expiration date and the technician performing
Note Kit Number
Policy/Procedural Documents

• Specific for each analyte or test performed
• Basic requirements for each
• May refer to package inserts
• Maintain current insert with documents
• Include Quality Control and Quality Assessment Protocols
• State/Accrediting body may be more stringent than CLIA
Strep A

Testing is done following MD/DO/NP request or as deemed necessary by nurses according to nursing protocol and standing orders. Patient is informed of Strep procedure requiring a throat swab. Universal precautions are maintained during procedure. Test is performed immediately upon collection of specimen. Specimen rejection is per package insert and may include contamination of swab by touching tongue.

Results are documented in laboratory section of electronic medical record. MD/DO/NP is informed of positive results if available. Nursing care for positive result is per Nursing Policy and Procedure manual. If clinical condition warrants, patient will be referred to PMD or ER/Urgent Care for evaluation. Specimen is discarded according to OSHA regulations. Documentation in electronic medical record includes patient name, date, time, clinician initials, result as either positive or negative, indication that internal control was acceptable per manufacturer’s specifications with “IC OK,” and assigned box number per electronic control log.

Referral to reference lab for throat culture is per MD/DO/NP or standing orders. Test procedure is according to manufacturer’s specifications. Storage and preparation of materials is per package insert. See attached.

Manufacturer provided external controls are performed per manufacturer’s specifications. External controls are documented for each lot of test kits. Each kit is assigned a number and documented on the electronic Strep A Control Log and with each result. Remedial action for unacceptable results for quality control is per QC/QA procedure manual. See remedial action sheet.

Normal result is negative. Panic/alert is not applicable. No calibration or calculation is required.

Enrollment in proficiency testing is required. Proficiency testing will be maintained per PA State Dept. of Laboratories requirements by PLS.

______________________________
Laboratory Director               Date  

6/08 Laboratory Procedure Manual    Strep A    Revised 7/09, 7/11
Examples of P/P Manuals

• Copyright © 2010
  The University of Texas Medical Branch -

  Point of Care Testing

http://www2.utmb.edu/poc/forms.htm
**Proficiency Testing**

- Required for all PPM and Non Waived Testing
- Used to verify the accuracy of testing
- PT samples tested and scores returned to laboratories
- Peer review 2 tests/6 months per provider – PPM for vaginal wet mounts
Proficiency Testing Providers


Proficiency Testing Providers

The download below contains the list of the Clinical Laboratory Improvement Amendments (CLIA) approved proficiency testing programs for 2012.

Downloads

Proficiency Testing Providers [PDF, 100KB]

Page last Modified: 04/30/2012 2:22 PM
# Peer Review Documentation

<table>
<thead>
<tr>
<th>Date</th>
<th>Pt ID</th>
<th>Specimen</th>
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Performing Clinician: ________________________________

Peer Reviewer: ________________________________

Comments: ________________________________

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Peer Reviewer: ________________________________

Comments: ________________________________

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Peer Review for Vaginal Smear Wet Mounts. Performed 2 times a year.
Alternate option instead of peer review – only one practitioner in facility

http://www.michigan.gov/mdch/0,4612,7-132-2945_5103_7168-74548--,00.html

Internal Proficiency Program for Wet Mount Microscopy

Michigan Regional Laboratory Wet Mount Proficiency Program

The Michigan Regional Laboratory Program seeks to evaluate and document proficiency of practitioners in local health departments for the microscopic examination of vaginal discharge specimens (wet mount analysis). The primary vaginal infections identified during wet mount analysis are bacterial vaginosis (caused by a symbiotic overgrowth of Gardnerella vaginalis and Mobiluncus species), yeast infections (primarily caused by Candida albicans), and trichomoniasis (caused by Trichomonas vaginalis).

This proficiency testing program challenges the practitioner with 3 sets of photo-micrographs of cellular elements commonly observed in vaginal discharge specimens and asks the participant to identify these elements.
<table>
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<tr>
<th>Wet Mount Proficiencies:</th>
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<td><strong>Critiques:</strong></td>
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<td><strong>Proficiency 2011B Instruction and Score Sheet</strong></td>
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<td><strong>Proficiency 2011A Instruction and Score Sheet</strong></td>
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Quality Assessment

• Ongoing, continuous plan to assure quality testing and results
• QA Policy
• Competency
• Remedial Actions
• New Proposed changes 3/2010
• CLSI – proposed QA guidelines 10/11
Test Management QA

- Tracking lab results  33% failure
- Location of results – EHR  100%
  20% not notified
- Timely Follow-up –
  10.2 % results never acknowledged
  6.8% did not receive timely notification
Is 99.9% good enough?

- 1 hour of unsafe drinking water every month.
- 2 unsafe plane landings per day at O'Hare Airport in Chicago.
- 12 newborns will be given to the wrong parents daily.
- 50 babies dropped at birth every day.
- 291 pacemaker operations will be performed incorrectly each year.
- 500 incorrect operations each week.
- 315 entries in Webster's Dictionary will be misspelled.
- 18,322 pieces of mail will be mishandled/hour.
- 20,000 incorrect prescriptions every year.
- 22,000 checks deducted from the wrong bank account each hour.
- 32,000 missed heartbeats per person each year.
- 880,000 credit cards in circulation will turn out to have incorrect cardholder information on their magnetic strips.
- 2,000,000 documents will be lost by the IRS this year.
- 2.5 million books will be shipped with the wrong covers each year.
- 5.5 million cases of soft drinks produced will be flat each year.
- A typical day would be 24 hours long (give or take 86.4 seconds.)

What are your POCT compliance rates?

By Jeff Dewar
Proposed change to Interpretive Guidelines for QA

Source: CLSI EP-23A
Change process

• Gradual
• Will provide interpretive guidelines
• Continues to adhere to concept of continuous improvement and maintenance of quality laboratory testing.
Enid was finally ready to admit that compliance was a bit more complicated than she first thought.
Quality Assessment

- Confidentiality
- Specimen ID and integrity
- Complaints
- Communications
- Personnel Competency
- Proficiency testing
- Test request
- LIS operation
- Specimen
- Procedure manual
- Quality control
- Corrective Actions
- Test records/reports
- Employee safety
CLIA Survey

- Tour of facility
- Observe testing
- Review Policy Manuals
- Interview Personnel
- Review PT scores and remedial actions
- Quality Assessment
- Plan if deficiencies found

- **Waived/PPM** – not subject to biennial survey, may be surveyed without notice.
- **Non Waived** – biennial survey, scheduled and drop in survey
Why Do Testing
Laboratory tests help determine the presence, extent, or absence of disease and monitor the effectiveness of treatment. An estimated 60 percent to 70 percent of all decisions regarding a patient's diagnosis and treatment, hospital admission and discharge are based on laboratory test results.
Why should SHS do Laboratory Testing?

- Safe Quality Care
- Diagnostic Aid
- Timely - Rapid Results
- Improved tx plans
- Effective – EBP
  - Appropriate use of antibiotics
  - Improve effectiveness of antivirals
**Bottom Line**

- Economics
- Cost savings to student
- Income for Health Center
- POCT/ usually waived
  - Less training of staff
  - Reliable
# Cost of Waived Testing

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<th>License Fee</th>
<th>State:</th>
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<td>CLIA Certificate</td>
<td>Varies by state from $0 to +$300</td>
<td>CLIA Required for PPM /QA for COW</td>
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<td>$100 Initial Reg.</td>
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<td>Price /Test</td>
<td>CMS fee Mid Point</td>
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<td>Mono</td>
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<td>Cost based on volume</td>
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Take Home

1. If you test – you need to have CLIA Certificate
2. State Regulations may be more stringent than CLIA
3. Good Laboratory Practices
   Personnel, Test Management
   Quality Assessment – Quality Control/PT
   Policy and Procedure Manuals
4. Point of Care Testing
   Rapid Quality Care
   Value for Students and Health Center
5. Proposed changes to Interpretive Guidelines
6. Use Resources
   CDC and CMS websites
   State Laboratories or Accrediting Agency
Future Educational Opportunities

• Quality Control and CLIA
  June 7, 2012  2:00 p.m. EDT
  Free Webinar

• CLIA Update 2012: "Hear What's in the Works"
  June 27, 2012  2:00 p.m. EDT
  $119.00
  http://www.aacc.org/events/meetings/Pages/6917.aspx#
Resources

• CMS.gov -- CLIA Amendments

• CDC – CLIA

• Your State’s Clinical Laboratory Website
Additional Resources

- American Association of Clinical Chemistry
  Clinical Laboratory News
- Newsclips@aab-pts.org
- Laboratory Advance- for lab administrators
  http://laboratory-manager.advanceweb.com/
Thank YOU!

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