Waived Testing Laboratories

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"I have your lab results. Some of your readings are too high and some are too low. No, they don't balance out."
What is a Clinical Laboratory?

• “...any facility which performs laboratory testing on specimens obtained from humans for the purpose of providing information for health assessment and for the diagnosis, prevention, or treatment of disease.”

• CLIA 1967 definition only included laboratories involved in interstate commerce – CLIA 1988 expanded the universe of testing
What does that mean?

- Clinical Laboratories in physician offices, commercial businesses, clinics, pharmacies, ambulatory surgery centers, nursing homes, rehabilitation centers and others.
- Physicians performing testing solely on their own patients.
CLIA Levels of Testing

- CLIA High complexity testing -> CLIA high complexity requirements
- CLIA Moderate complexity testing -> CLIA moderate complexity requirements
- FDA/CLIA Waived testing -> CLIA waived requirements
- The highest level test done in a facility will dictate what complexity requirements apply
Waived Test: Definition

- “Cleared by the FDA for home use; or
- That employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
- That pose no reasonable risk of harm to the patient if the test is performed incorrectly.”
CLIA Waived Testing Requirements

- Apply for certification with Centers for Medicare and Medicare (CMS) as a waived testing laboratory
- Pay a certification fee
- Follow the manufacturer’s instructions
- Permit inspections as part of random compliance evaluations or complaint investigations
- (CLIA inspectors are required to inspect 2% of all waived testing labs annually and provide educational guidance.)
CLIA 1988 Waived Exemptions

- Health and safety standards
- Personnel requirements
- Patient test management
- Quality control
- Proficiency testing
- Quality assurance
- Routine inspections
Original Eight Waived tests

Dipstick or Tablet Reagent Urinalysis (Non-automated) for the following:

- Bilirubin;
- Glucose;
- Hemoglobin;
- Ketone;
- Leukocytes;
- Nitrite;
- pH;
- Protein;
- Specific gravity; and
- Urobilinogen.

Fecal occult blood;

Ovulation tests—visual color comparison tests for human luteinizing hormone;

Urine pregnancy tests—visual color comparison tests;

Erythrocyte sedimentation rate— non-automated;

Hemoglobin—copper sulfate—nonautomated;

Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use;

Spun microhematocrit
Regulations to Implement the Law
Published February 28, 1992

- Proviso: Tests under commercial development seeking waived status, be assessed and classified according to a system designed to determine what is “simple” and “relatively error free”
- Characteristics defining what is “simple” and “relatively error free” published in Sept. 1995
- Initially CDC was categorizing tests; in 2000 the responsibility was moved to FDA
• **Summary of Test System Characteristics Used to Classify Waived Tests (September 13, 1995 Rules)**  Already Approved by FDA for home use or

• Uses direct unprocessed specimens, requires no specimen manipulation before analysis or analyst intervention during analysis, and provides direct readout of results. Quantitative tests must be fully automated while qualitative tests are limited to simple reagent impregnated devices that produce only a positive or negative result.

• Contains fail-safe mechanisms rendering no results when the results are outside of the reportable range or when the test system malfunctions;

• Requires no invasive test system troubleshooting, or electronic or mechanical maintenance; and
Contains instructions written at a comprehension level no higher than seventh grade. Instructions would have to include step-by-step system operation and maintenance procedures; reagent preparation and storage; and calibrator and control preparation, storage, frequency of assay, and action to be taken if control or calibrator results are out of range.
1995 Rulemakers Predicted:

“....that over time the effect of this rule will be to expand the universe of waived tests, to the benefit of patients, laboratories, manufacturers, and producers. However, we are unable to quantify these likely long run effects because they depend on market decisions, research results, and technological change that cannot be predicted.”
You cannot fight unreason, and as these dead multitudes will tell you — are telling you right now — certitude is the enemy.

(Steven Erikson)
Today

- Over 5,000 waived tests for over 120 analytes on the CLIA webpage
- Over 100 new methods were FDA approved in the first half of 2014 alone
- Close to 4,800 Certificate of Waiver laboratories registered in New Jersey alone
- # labs performing lab testing that are not registered??
Why Should This be a Problem?

- Large number of waived tests being performed
- More and more sites are performing waived tests
- Only 2% of waived testing laboratories are being visited by inspectors per year
- The balance of non-regulated (waived) versus regulated (non-waived) tests is tipping toward non-regulated
What do we know about these labs?

- In the November 11, 2005, Morbidity and Mortality Weekly Report (MMWR) *Good Laboratory Practices for Waived Testing Laboratories: Survey Findings from Testing Sites Holding a Certificate of Waiver Under the Clinical Laboratory Improvement Amendments of 1988 and Recommendations for Promoting Quality Testing*, CMS reported results of a survey of 4,214 CW laboratories conducted in 8 states, between April 2002 and November 2004. They found that many CW laboratories were out of compliance. Some of the errors detected included:
  - no manufacturer’s instructions in the laboratory
  - lack of a routine check for new product insert changes
  - omission of units or proper terminology in reporting results
  - lack of documentation linking patient data to kit lot numbers and expiration dates
  - Other errors were also identified. 4
THEY'RE TRYING TO CUT OUR PENSIONS...

WHAT'S A PENSION?
COLA: Commission on Office Laboratory Accreditation

- In 1988 a group of physicians founded COLA as a private alternative to help POLs stay in compliance with CLIA
- Physician directed, not for profit
- In 1993 the HCFA (now CMS) granted COLA deeming authority in all 50 states under CLIS, and in 1997 JCAHO also recognized COLAs accreditation program
- Today COLA accredits almost 8,000 medical laboratories
COLAs Experience

- Agree: Increased amount of waived testing
- Agree: “…evidence is mounting that significant quality problems exist in the largely unregulated labs relying on these.”
- 31-43% of waived labs do not follow the manufacturers instructions
- >20% do not regularly check the manufacturers instructions for changes
- >20% do not perform QC testing as specified by manufacturer’s instructions
- Nearly half do not document the name, lot# and expiration dates for tests performed
New Jersey CLIA Inspectors

- Every state is federally funded to host a program for CLIA inspectors for all levels of complexity
- Between 11/18/13 and 9/8/14 the New Jersey CLIA inspectors visited 49 Certificate of Waiver laboratories (in addition to many other types)
- 9/49 (20%) were not able to follow the manufacturers instructions and received a letter of corrections or suggestions.
“We were just as surprised by the test results as you. We’re still scratching our heads over it.”
New Jersey Regulation

- NJ does not recognize 99.9% of the currently waived tests, and only recognizes the original eight waived tests
- Consequently all clinical laboratories, whether CLIA waived OR not, should possess a NJ license
- Only 50 of the 4,800 CLIA Certificate of Waiver laboratories hold a NJ license
What to Do?

- **It’s a national problem** – registering CWs and regulating them (20% noncompliance)
- **It’s a state problem** – very few know they need state licensure
- Education is the only answer at this point
APHL Innovations in Training Grants

• Association for Public Health Laboratories (APHL) offers competitive public health laboratories grant dollars training for Quality Improvement initiatives
• NJ was awarded the grant in 2012 and 2014
• What did we do?
APHL Innovations in Training Grants

• 2012 NJ Goals
  • Improve the quality of CLIA waived testing among personnel in Certificate of Waiver (CW) laboratories residing in New Jersey through training
  • Determine if NJ licensed CW laboratory personnel have more pre-training knowledge regarding laboratory testing than non-NJ licensed CW personnel
Waived Testing in Your Laboratory

Meet Federal and New Jersey State Regulatory Requirements

Freehold, NJ
March 29, 2013: 8:30 AM – 12:30 PM
Star and Barry Tobias Center of CentraState Medical Center

Voorhees, NJ
April 5, 2013: 8:30 AM – 12:30 PM
Barry D. Brown Center of Virtua Health

Paramus, NJ
April 10, 2013: 8:30 AM – 12:30 PM
Dorothy B. Kraft Center of the Valley Hospital

Somers Point, NJ
April 12, 2013: 8:30 AM – 12:30 PM
The Conference Center of Shore Memorial Hospital
APHL Innovations in Training Grants

- 4 regional workshops titled “Waived Testing in Your Laboratory: Meet Federal and New Jersey State Regulatory Requirements”
- Paper mailing to 4,500 CW laboratories
- 440 responded, 173 were pre-registered and 117 attended the courses
- All were administered an anonymous survey before the class started. Licensed versus non licensed were identified.
<table>
<thead>
<tr>
<th>Location of laboratory</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians Office</td>
<td>62</td>
</tr>
<tr>
<td>Ambulatory Surgery Center</td>
<td>15</td>
</tr>
<tr>
<td>Dialysis Center</td>
<td>7</td>
</tr>
<tr>
<td>Health Clinic</td>
<td>5</td>
</tr>
<tr>
<td>School</td>
<td>4</td>
</tr>
<tr>
<td>Health Department</td>
<td>4</td>
</tr>
<tr>
<td>Rehabilitation Center/Nursing Homes</td>
<td>3</td>
</tr>
<tr>
<td>Substance Abuse Treatment Center</td>
<td>3</td>
</tr>
<tr>
<td>Urgent Care Center</td>
<td>3</td>
</tr>
<tr>
<td>Employee Health Clinic</td>
<td>2</td>
</tr>
<tr>
<td>Hospital</td>
<td>2</td>
</tr>
<tr>
<td>Home Health Care</td>
<td>2</td>
</tr>
<tr>
<td>Military (Coast Guard)</td>
<td>2</td>
</tr>
<tr>
<td>Prison</td>
<td>1</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>1</td>
</tr>
<tr>
<td>Consultant Group</td>
<td>1</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>117</strong></td>
</tr>
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</table>
## Survey Results

<table>
<thead>
<tr>
<th>Primary Responsibilities of Participants</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office and/or clinical management</td>
<td>38</td>
</tr>
<tr>
<td>Medical assistant</td>
<td>31</td>
</tr>
<tr>
<td>Patient care (nurse)</td>
<td>27</td>
</tr>
<tr>
<td>Laboratory testing</td>
<td>8</td>
</tr>
<tr>
<td>Patient care (physician)</td>
<td>7</td>
</tr>
<tr>
<td>Laboratory management</td>
<td>3</td>
</tr>
<tr>
<td>Dialysis technicians</td>
<td>2</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>117</td>
</tr>
</tbody>
</table>
**Survey Results**

**Participants Performing Laboratory Testing at Least Monthly**

(n = 71)

<table>
<thead>
<tr>
<th>Primary Responsibility</th>
<th>NJ Licensed</th>
<th>Non NJ Licensed</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical assistant</td>
<td>6</td>
<td>16</td>
<td>22</td>
</tr>
<tr>
<td>Patient care (nurse)</td>
<td>4</td>
<td>18</td>
<td>22</td>
</tr>
<tr>
<td>Laboratory testing</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Health educator</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Physician</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Other: Clinical or office administrative personnel, dialysis technicians, pharmacist</td>
<td>1</td>
<td>15</td>
<td>16</td>
</tr>
<tr>
<td>TOTAL</td>
<td>12</td>
<td>59</td>
<td>71</td>
</tr>
<tr>
<td>Good Laboratory Practice</td>
<td>Licensed (n=21)</td>
<td>Non Licensed (n=96)</td>
<td>Total (n=117)</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
<td>-----------------</td>
<td>---------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Proficiency testing</td>
<td>18 (86%)</td>
<td>43 (45%)</td>
<td>61 (52%)</td>
</tr>
<tr>
<td>Training and Competency Testing</td>
<td>13 (62%)</td>
<td>44 (46%)</td>
<td>57 (49%)</td>
</tr>
<tr>
<td>Maintaining Temperature Logs</td>
<td>19 (90%)</td>
<td>76 (79%)</td>
<td>95 (81%)</td>
</tr>
<tr>
<td>Maintaining Quality Control Logs</td>
<td>17 (81%)</td>
<td>60 (63%)</td>
<td>77 (66%)</td>
</tr>
<tr>
<td>Maintaining Patient Logs</td>
<td>12 (21%)</td>
<td>60 (63%)</td>
<td>72 (62%)</td>
</tr>
<tr>
<td>Maintaining Inventory Tracking Log</td>
<td>14 (67%)</td>
<td>41 (43%)</td>
<td>55 (47%)</td>
</tr>
<tr>
<td>External Controls</td>
<td>14 (67%)</td>
<td>42 (44%)</td>
<td>56 (48%)</td>
</tr>
</tbody>
</table>
Knowledge of Quality Assurance (n=117, 12 questions)

<table>
<thead>
<tr>
<th></th>
<th>Licensed Labs (n=21)</th>
<th>Non-licensed labs (n=96)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average performance per question</td>
<td>93.5</td>
<td>84.5</td>
<td>Better discrimination between the two groups can be seen when the very easy questions and the poorly discriminating questions are eliminated</td>
</tr>
<tr>
<td>Average performance for questions 13,14,17,19, 22,23</td>
<td>91</td>
<td>75</td>
<td></td>
</tr>
</tbody>
</table>
CW Testing in NJ

NJ Licensed CLIA Registered CW Laboratories  n = 50

Non NJ licensed CLIA Registered CW Laboratories  n = 4,500

Universe of Non NJ licensed, non CLIA registered CW laboratories  n = ?
How to Increase The Effect of Licensure?

2014-15 Grant Goals:

• Expand accessibility for the training developed in 2012-13 (pre/post training difference)
• Improve outreach to physicians to create awareness of federal and state regulations and to provide appropriate compliance resources
• Propose an update to NJ licensure regulations to recognize change in testing environment
Go the Distance

• Physician Webinar to be archived – working with Rutgers, Bioscience and Health Services, Center for Continuing and Outreach Education Rutgers RBHS-CCOE

• Online training based on 2012-13 workshops – working with Rutgers, New Jersey Agricultural Experiment Station, Office of Continuing and Professional Education; administrator of the New Jersey Learning Management Network

• Graduate student from Rutgers GSBS
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For over 40 years, CCOE has developed independent education, adhering to the highest standards of industry compliance. Our commitment to effective lifelong learning continues to improve clinician performance and impact positive changes in the health care industry. Whether meeting face-to-face, studying enduring articles, or interacting through the internet, our audiences have benefited from innovative programming that addresses relevant clinical topics and influences favorable treatment outcomes.

CCOE CATALOG
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About the Rutgers-UMDNJ Integration
# Classroom Course Catalog

## April 2015

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Topic</th>
<th>CEUs</th>
<th>Site</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apr 06, 2015</td>
<td>8:00 AM-4:00 PM</td>
<td>NJDOH Certified Animal Control Officer Course (RVCC) (Apr 2015)</td>
<td>No CEUs</td>
<td>Raritan Valley Community College/Somerset County Police Academy</td>
<td>Outside Registration</td>
</tr>
<tr>
<td>Apr 06, 2015</td>
<td>4:00 PM-7:30 PM</td>
<td>Public Health Symposium: Eliminate Health Disparities - Strategies That Make a Difference</td>
<td>Public Health CE #15381: 2.00 hour(s) Public Health CE #15382: 2.00 hour(s) NCH: 2.00 hour(s)</td>
<td>Rutgers - RWJ Medical School 675 Hoes Lane WEST Piscataway NJ 08854</td>
<td>Login to Register</td>
</tr>
<tr>
<td>Apr 06, 2015</td>
<td>8:15 AM-5:15 PM</td>
<td>Lead Inspector/Risk Assessor Initial</td>
<td>Public Health CE #15228: 35.00 hour(s)</td>
<td>NAETI 3321 Doris Ave, Bldg. B Ocean, NJ 07712</td>
<td>Outside Registration</td>
</tr>
</tbody>
</table>
Consulting Opportunities

- Medical Laboratory Scientists well positioned with knowledge of QA and science to advise POLs
- May need to develop business skills and regulatory knowledge
- May need to develop presentation skills for educating POL staff and for marketing services to physicians
- May need to develop writing skills to help write SOPs, and other documents.
Questions?