Educational Resources to Improve Waived Testing Practices

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CLIAC
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The findings and conclusions in this report are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Outline

- Laboratory Demographics
- Educational Product Distribution
- Ready? Set? Test! Online Training
LABORATORY DEMOGRAPHICS
Number of CLIA Certified Laboratories by Certificate Type – 1993-2013

- Certificate of Accreditation/Certificate of Compliance
- Provider performed Microscopy Procedures Certificate
- Certificate of Waiver

*Data obtained from CMS OSCAR database (08/06/2013)
Numbers include laboratories in CLIA-exempt states of NY and WA.
# Trends in Waived Testing Over Time

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</thead>
<tbody>
<tr>
<td>No. of analytes for which waived test systems are available</td>
<td>9</td>
<td>40</td>
<td>74</td>
<td>84</td>
<td>87</td>
<td>88</td>
</tr>
<tr>
<td>No. of waived test systems*</td>
<td>203</td>
<td>608</td>
<td>1,495</td>
<td>3,228</td>
<td>4,369</td>
<td>6,811</td>
</tr>
<tr>
<td>No. of laboratories with a Certificate of Waiver**</td>
<td>67,294</td>
<td>78,825</td>
<td>102,123</td>
<td>129,219</td>
<td>153,702</td>
<td>166,472</td>
</tr>
<tr>
<td>Percentage of laboratories with a Certificate of Waiver</td>
<td>44%</td>
<td>50%</td>
<td>57%</td>
<td>64%</td>
<td>67%</td>
<td>70%</td>
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*Numbers reflect multiple names under which individual tests are marketed and might include waived tests no longer sold.
**Numbers include laboratories in CLIA-exempt states of NY and WA.

Source: CDC and FDA CLIA Test categorization databases and CMS On-line Survey, Certification, and Reporting database.
U.S. Laboratory Demographics, 2013
Laboratory types, all CLIA-Certified Laboratories

- Physician Office Laboratory: 117,903
- Skilled Nursing/Nursing Facility: 14,931
- Hospital and Independent: 14,925
- Home Health Agency: 14,658
- Outpatient Clinics*: 8,880
- Public Health Laboratories: 6,800
- Other**: 67,647

Total: 239,624

Additional Laboratory Demographics:
- 333,000 laboratory personnel
- >13 billion tests/year
- >$52 billion/year in laboratory revenues

1 Data obtained from CMS OSCAR database, 08/06/2013. OSCAR data are self-reported. Numbers include laboratories in CLIA-exempt states of NY and WA.
3 Data obtained from http://www.kalorainformation.com/Clinical-Laboratory-Services-2565239/

*Community clinic, rural health clinic
**Insurance, pharmacy, tissue bank/repositories, blood banks, ambulance and mobile units, industrial, health fair, ancillary test sites, school/student health service, other not specified.
Percentage of Tests in Each Category
August 2013

- Waived: 11%
- Moderate: 71%
- High: 18%

Data obtained from FDA CLIA database (08/06/2013)
EDUCATIONAL PRODUCT DISTRIBUTION
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Continuing Education Activity........................................CE-1
To Test or Not to Test?
Considerations for Testing

- Describes considerations when beginning to test or adding a test to your menu
- Intended to assist those who want to initiate or direct CLIA-waived testing
- Contains helpful information for all physician offices or point-of-care settings
**Ready? Set? Test!**

Assuring the Quality of Tests Performed

- Describes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a CLIA Certificate of Waiver.

- Contains tips, reminders, and resources along with forms and examples for use in the testing site.
PATIENT TESTING IS IMPORTANT.

Get the right results.

• Have the latest instructions for ALL of your tests.

• Know how to do tests the right way.

• Know how and when to do quality control.

• Make sure you do the right test on the right patient.

• Make sure the patient has prepared for the test.

• Collect and label the sample the right way.

• Follow instructions for quality control and patient tests.

• Keep records for all patient and quality control tests.

• Follow rules for discarding test materials.

• Report all test results to the doctor.

http://www.cdc.gov/dls/waivedtests

Poster and Postcard

Promotion of Good Laboratory Practices For Waived Testing

Background

Current practice shows an increased trend for medical decisions based on simple tests performed using compact or handheld instruments at the point of patient care, many of which are designated as waived tests and can be performed without routine regulatory oversight. These tests are often used in a variety of test settings by physicians, nurses, and other personnel, e.g., emergency departments, hospital rooms, physician offices, community counseling centers, pharmacies, nursing homes, ambulances, and health fair. To promote quality testing, reduce testing errors, and enhance patient safety in these non-traditional testing sites, in 2015 the Centers for Disease Control and Prevention (CDC) published the MMWR Recommendations and Reports, “Good Laboratory Practices for Waived Testing Sites.” Subsequent to this report, CDC also developed related free educational materials described below.

The report and educational materials address pre-testing considerations such as management responsibility for testing, regulatory requirements, and other considerations, including sampling, specimen collection, errors, and documentation. Additionally, they address good laboratory practices for the three phases of testing:

• Before testing: test ordering and specimen collection;

• During testing: correct testing, test performance, and result interpretation and recording; and

• After testing: result reporting, documentation, confirmation testing, and biohazard waste disposal.

Educational Materials

www.cdc.gov/dls/waivedtests

To Test or Not to Test? Booklet

This booklet describes considerations and pre-preparations needed prior to performing waived testing and may assist those who want to implement and oversee waived testing or offer a new test under a CLIA Certificate of Waiver. The booklet contains tips, reminders, and resources along with forms and examples for use in your testing site.

Ready? Set? Test! Poster

This poster can readily be displayed in a testing area to remind testers of 10 important practices to follow for accurate and reliable testing. A poster-sized version of the poster is also available.

Ready? Set? Test! Booklet

This booklet recommended practices for physicians, nurses, medical assistants, and others who perform patient testing under a CLIA Certificate of Waiver. The booklet contains tips, reminders, and resources along with forms and examples to use in your testing site.

Ready? Set? Test! Online Course

The goal of this course is to promote reliable, high quality testing and enhance patient safety by explaining steps of the waived testing process and to provide the learner with additional resources to assist on the job. The target audience includes individuals without formal laboratory training who perform testing in waived testing sites (e.g., physician offices, nursing facilities, home health agencies, clinics, pharmacies, and other non-laboratory sites throughout the United States. This course offers continuing education credits.

You can request copies of the products at WaivedTesting@cdc.gov or by calling 404-498-2290.

Waived Testing Educational Products Fact Sheet
Waived Testing Good Laboratory Practice
Product Distribution

Total Posters Distributed = 4,167
Total Postcards Distributed = 17,937
Total Ready? Set? Test! Booklets Distributed = 12,050
Total To Test or Not To Test? Booklets Distributed = 4,462

http://wwwn.cdc.gov/clia/Resources/WaivedTests/
Ready? Set? Test!

Patient testing is important.
Get the right results.

Launch Course
Course Overview

Course Goal

- To promote reliable, high quality testing and enhance patient safety by explaining steps of the waived testing process and to provide the learner with additional resources to assist on the job.

Course Objectives:

- Ready?
  - Identify the basic requirements for performing waived testing.
  - Identify at least three good laboratory practices for preparing the laboratory or testing site to produce high quality test results.

- Set?
  - Select at least two good laboratory practices that assure the right sample type is obtained from the correct patient.
  - Identify patient samples that are labeled correctly.

- Test?
  - Identify at least two good laboratory practices for testing.
  - Identify at least two good laboratory practices for recording and reporting results.
Course Overview

- **Target Audience:**
  - Nurses, (LPN, RN, NP, Midwife)
  - Medical Assistants, (MA)
  - Physicians, (MD, DO, DPM, DDS)
  - High school graduates or individuals with GEĐ
  - Emergency Medical Technicians (EMT), paramedics
  - Clinical Nursing Assistants (CNA) Certified Nursing Assistant (CNA), Patient Care Assistant (PCA), State Tested Nurse Aid (STNA) or Nursing Assistant-Registered (NA/R)
  - Pharmacists
  - Physician Assistants, (PA)
  - Phlebotomists or others

- **CE Credit**
  - CME and CNE offers 1.0
  - CEU, CE and CPE offers 0.1
Course Features

- Knowledge check questions throughout the course to reinforce learning
- Templates, checklists, resources to save/download
- Scenarios
### Ready? Set? Test! Online Course Participation (Nov 2011—July 2013)

<table>
<thead>
<tr>
<th>Total Registered</th>
<th>1843</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed</td>
<td>1604</td>
</tr>
<tr>
<td>In Progress</td>
<td>222</td>
</tr>
<tr>
<td>Withdrawn</td>
<td>17</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Credit Type</th>
<th>Total Hours Awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEU/CE</td>
<td>79.2</td>
</tr>
<tr>
<td>CME</td>
<td>84</td>
</tr>
<tr>
<td>CNE Contact Hours</td>
<td>288</td>
</tr>
<tr>
<td>Pharmacists Contact Hours</td>
<td>1.6</td>
</tr>
</tbody>
</table>

Ready? Set? Test! Credit Type(s) Awarded: 0.1 CEU/CE; 1 CME; 1 CNE Contact Hours; 0.1 Pharmacist Contact Hours

http://wwwn.cdc.gov/clia/Resources/WaivedTests/
Course Evaluation

- This activity effectively met my educational needs
- The learning environment was conducive to learning
- The instructional strategies helped me learn the content
- The delivery method used helped me learn the content
- The content experts demonstrated expertise in the subject matter
- Feedback I received during the activity was helpful
- The length and pace of the activity was appropriate
- The difficulty level was appropriate
- The content and learning materials addressed a need or gap in my knowledge or skills
Course Evaluation

- The content was relevant to the learning objectives
- I can identify at least two good laboratory practices for recording and reporting results
- I can identify at least two good laboratory practices for testing
- I can identify properly labeled patient samples
- I can identify at least two good laboratory practices to ensure the right sample type is obtained from the correct patient
- I can identify three or more good laboratory practices to prepare my laboratory or testing site to produce high quality test results
- I can identify the basic requirements for performing waived testing
- If given an opportunity, I can apply the knowledge gained as a result of this activity
Comments from Participants

- It is really helpful and very organized. I liked the method used to give us the necessary tools and the websites to clearly understand the content.
- Much more educational than I expected. I will direct staff nurses to this website in the future.
- The material was excellent. It helped me understand why we did all the documentation of lot numbers, expiration dates, etc. I realize the importance of all of our procedures now.
- Wonderful refresher for me. I could not explain QC, waived testing any better!
- I am going to make this a mandatory course for all of my staff who perform CLIA waived tests.
- I believe the course has helped me identify areas in the performance of Waived Testing procedures that I should emphasize in training staff.
- Content was simply explained and feedback kept my interest.
- Excellent course will require all Medical Assistants to take this test.
- I took this course to evaluate its potential use in training staff at my company. I believe it is useful for my purposes.
Summary

- Participants achieved course objectives
- The educational value was appreciated by the high number of positive comments

Suggestions for improving course:
- Allow for the ability to bookmark the course and return at a later time to complete (updated course to include the bookmark feature on June 2012)
- Improve course navigation especially pop-up boxes
- Increase CE credit
Acknowledgements

- Clinical Laboratory Improvement Advisory Committee
  - Waived Testing Workgroup
- Centers for Medicare & Medicaid Services
  - Division of Laboratory Services
- Food and Drug Administration
  - Office of In-Vitro Diagnostic Device Evaluation and Safety
- Centers for Disease Control and Prevention
  - Division of Laboratory Science and Standards
Waived Testing materials:
http://wwwn.cdc.gov/clia/Resources/WaivedTests/

For questions, comments, or to obtain free copies of waived testing materials, contact us: email - WaivedTesting@cdc.gov
phone - 404-498-2290

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