

Educational Resources to Improve Waived Testing Practices

Heather Stang, MS, MT
Health Scientist

The Division of Laboratory Programs, Standards, and
Services (DLPSS-proposed)

CLIAC
August 21, 2013

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.

Office of Public Health Scientific Services (OPHSS–proposed)

Center for Surveillance, Epidemiology and Laboratory Services (CSELS–proposed)



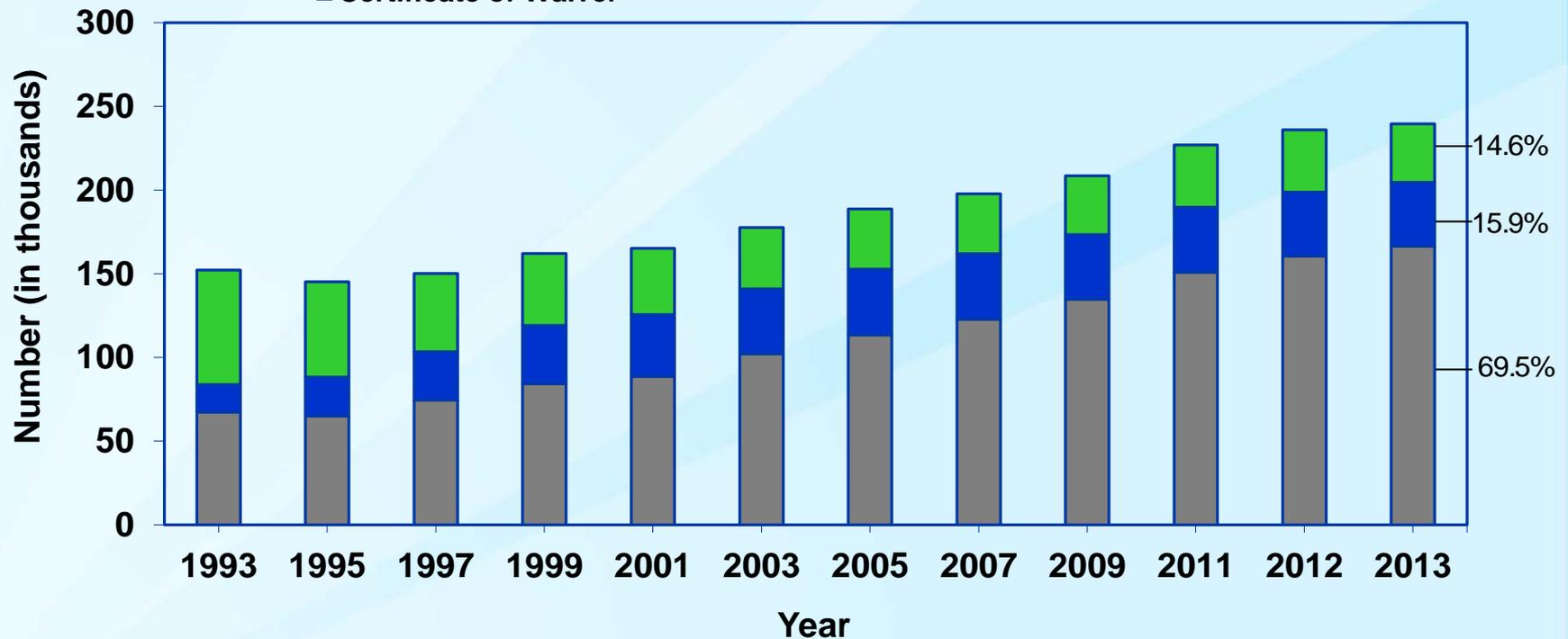
Outline

- ❑ **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

Waived Testing Measurement Parameter	1993	1998	2003	2008	2011	2013
No. of analytes for which waived test systems are available	9	40	74	84	87	88
No. of waived test systems*	203	608	1,495	3,228	4,369	6,811
No. of laboratories with a Certificate of Waiver**	67,294	78,825	102,123	129,219	153,702	166,472
Percentage of laboratories with a Certificate of Waiver	44%	50%	57%	64%	67%	70%

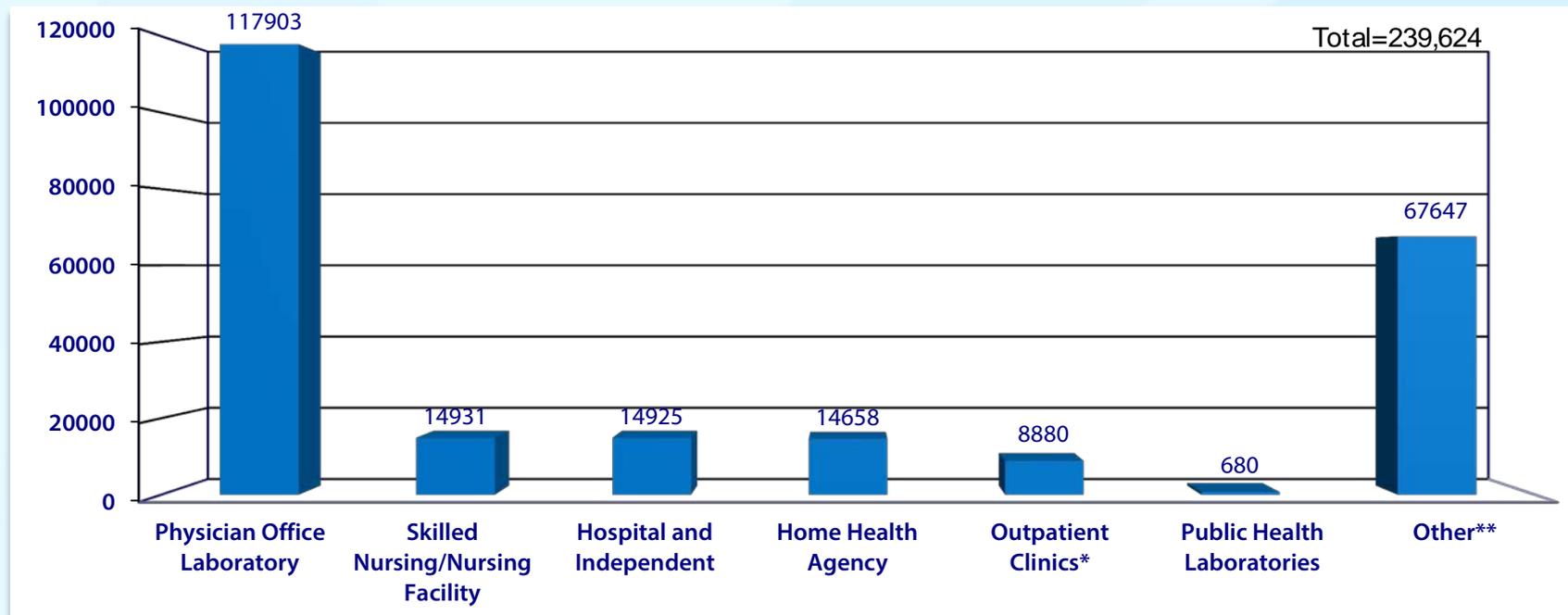
*Numbers reflect multiple names under which individual tests are marketed and might include waived tests no longer sold.

**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 Laboratories¹



Additional Laboratory Demographics:

- ❑ 333,000 laboratory personnel²
- ❑ >13 billion tests/year¹
- ❑ >\$52 billion/year in laboratory revenues³

¹Data obtained from CMS OSCAR database, 08/06/2013. OSCAR data are self-reported. Numbers include laboratories in CLIA-exempt states of NY and WA.

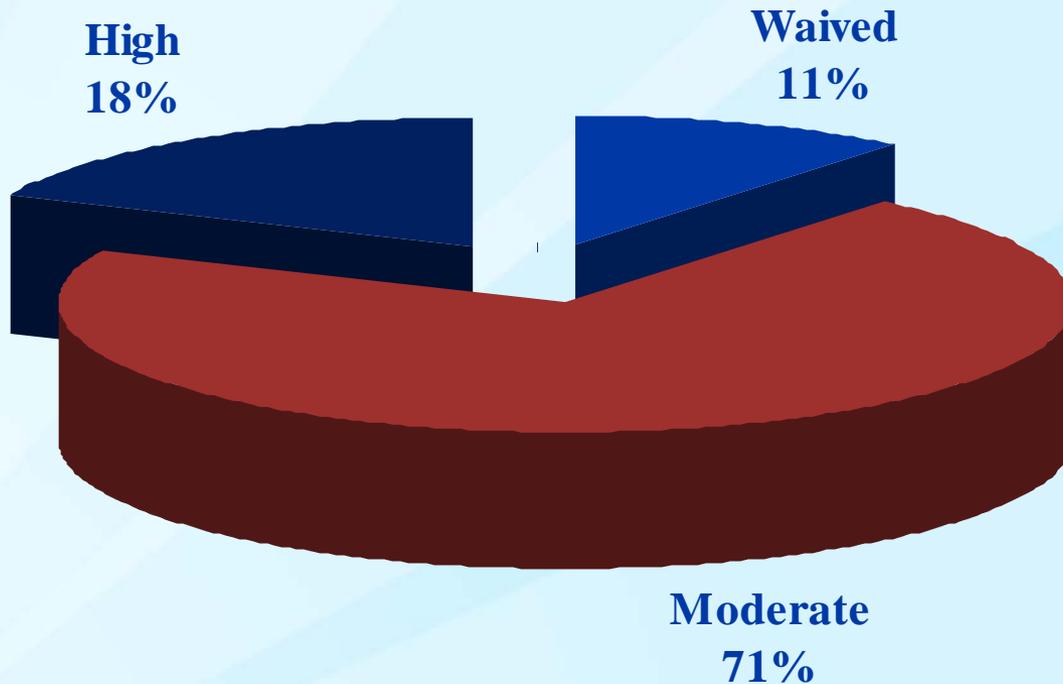
²Data obtained from US Department of Labor Bureau of Labor Statistics Occupational Employment Statistics (OES) at <http://www.bls.gov/oes/#tables>

³Data obtained from <http://www.kaloramainformation.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



Data obtained from FDA CLIA database (08/06/2013)

EDUCATIONAL PRODUCT DISTRIBUTION



MMWR™

Morbidity and Mortality Weekly Report

Recommendations and Reports

November 11, 2005 / Vol. 54 / No. RR-13

Good Laboratory Practices for Waived Testing Sites

Survey Findings from Testing Sites Holding
a Certificate of Waiver Under the Clinical
Laboratory Improvement Amendments
of 1988 and Recommendations
for Promoting Quality Testing

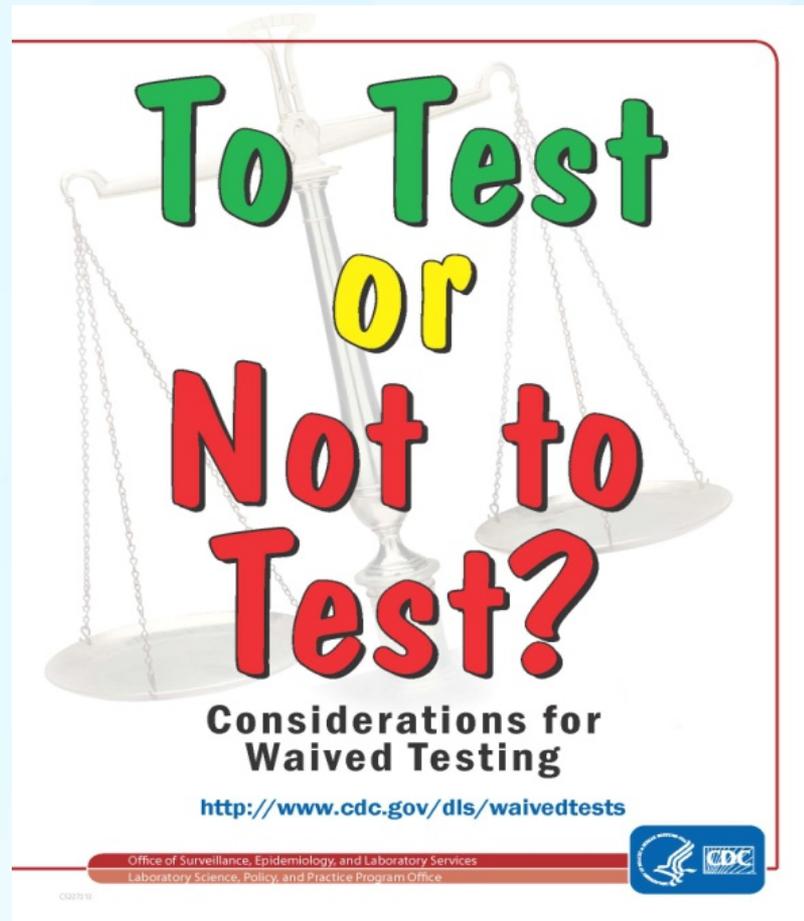
INSIDE: Continuing Education Examination

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

CONTENTS

Introduction.....	1
Background.....	2
Surveys of Waived Testing Sites.....	4
Recommended Good Laboratory Practices.....	8
Conclusions.....	19
Acknowledgments.....	19
References.....	19
Terms and Abbreviations Used in this Report.....	22
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

**READY?
SET?
TEST!**

**PATIENT TESTING
IS IMPORTANT.**
Get the right results.
<http://www.cdc.gov/dls/waivedtests>

Office of Surveillance, Epidemiology, and Laboratory Services
Laboratory Science, Policy, and Practice Programs Office

Ready? Set? Test!

Assuring the Quality of Tests Performed

PATIENT TESTING IS IMPORTANT.

Get the right results.

- **READY?** Have the latest instructions for ALL of your tests.
- **SET?** Know how to do tests the right way.
- **TEST!** 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, physicians' offices, community counseling centers, pharmacies, nursing homes, ambulances, and health fairs. To promote quality testing, reduce testing errors, and enhance patient safety in these nontraditional testing sites, in 2005 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, safety, physical and environmental requirements, benefits and costs, staffing, and documentation. Additionally, they address good laboratory practices for the three phases of testing:

- before testing (test ordering and specimen collection),
- during testing (control testing, test performance, and result interpretation and recording), and
- after testing (result reporting, documentation, confirmatory testing, and biohazard waste disposal).

Educational Materials

www.cdc.gov/dls/waivedtests

To Test or Not to Test? Booklet

This booklet describes considerations and 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 postcard sized version of the poster is also available.

Ready? Set? Test! Booklet

This booklet describes recommended practices for physicians, nurses, medical assistants, pharmacists, 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.



Office of Surveillance, Epidemiology, and Laboratory Services
Laboratory Science, Policy and Practice Program Office



CS231963A

Waived Testing Educational
Products Fact Sheet

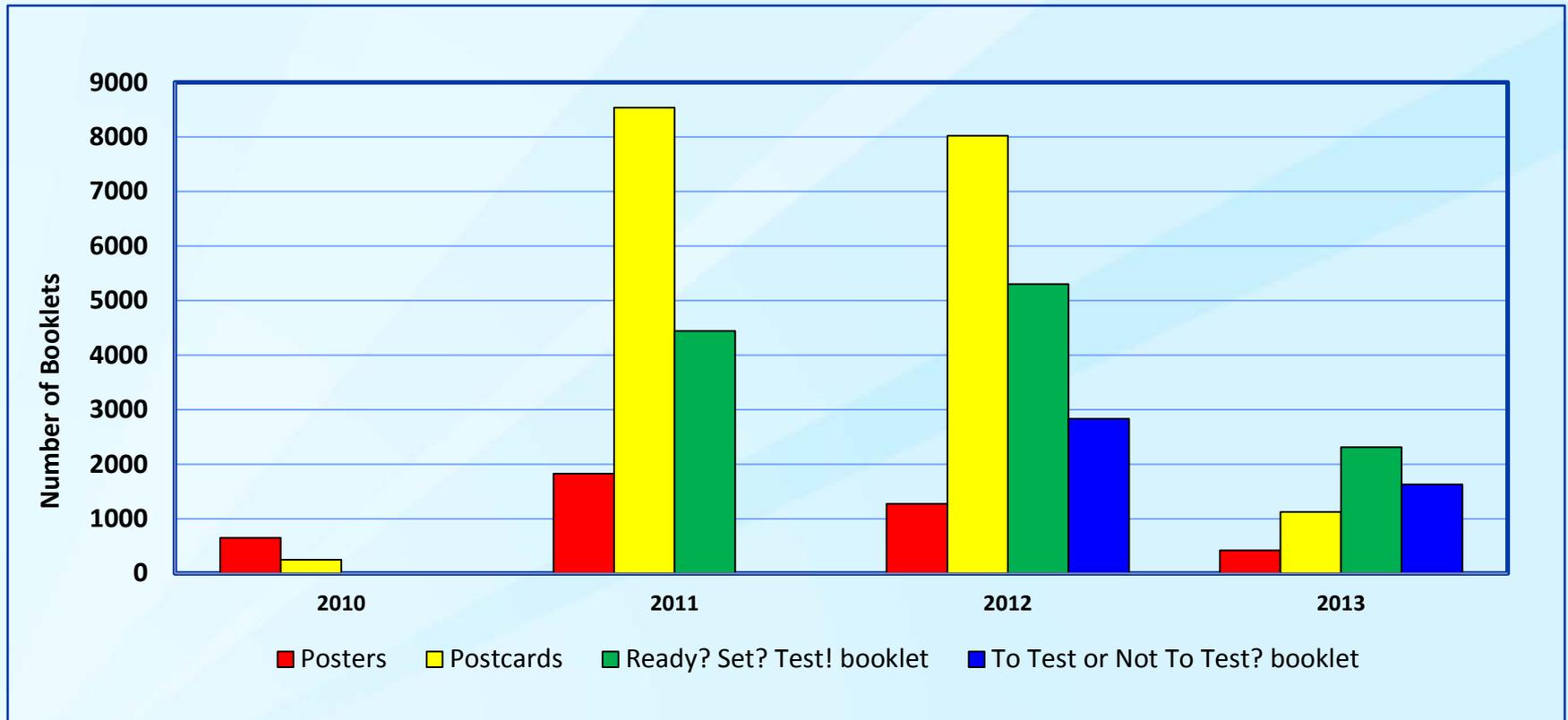
Waived Testing Good Laboratory Practice Product Distribution

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! ONLINETRAINING

Ready? Set? Test! Online Training



Centers for Disease Control and Prevention
Your Online Source for Credible Health Information

[HOME](#) | [ABOUT](#) | [COURSE MAP](#) | [EXIT](#)

READY?
SET?
TEST!

**PATIENT TESTING
IS IMPORTANT.**
Get the right results.

[Launch Course](#)



Centers for Disease
Control and Prevention
Scientific Education and
Professional Development
Program Office

Version 2.0, published 06/2011

Centers for Disease Control and Prevention 1600 Clifton Rd. Atlanta, GA 30333, USA
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, 24 Hours/Every Day - cdcinfo@cdc.gov

USA.gov
Government Made Easy



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 GED
- 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

This screenshot shows the 'About This Course' page. It features the CDC logo and navigation buttons for 'HOME', 'ABOUT', 'COURSE MAP', and 'EXIT'. The main text explains the course's goals: to promote reliable, high-quality testing, enhance safety by explaining steps of the waived testing process, and provide additional resources for on-the-job assistance. It lists three learning objectives: identifying basic requirements for performing waived testing, following manufacturer's instructions, and recalling good laboratory practices. A 'Good Laboratory Practices' callout box states: 'These basic general important laboratory practices that help you achieve the best possible results when performing a test.' A 'CMA Requirements' callout box states: 'These basic general requirements that must be met when performing waived testing.' A 'Resources' button is also visible, with a note that it indicates helpful tips, suggestions, or other information. The footer includes the CDC address: 1600 Clifton Rd., Atlanta, GA 30333, USA, and contact information: 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, 24 Hours/Every Day - cdcinfo@cdc.gov.

This screenshot shows the 'Scenarios' page. It features the CDC logo and navigation buttons for 'HOME', 'ABOUT', 'COURSE MAP', and 'EXIT'. The main text explains that waived testing can be performed at different sites, many of which are not traditional laboratories. Three scenarios have been provided: nursing home, hospital, and doctor's office buildings. A 3D aerial view of a city street is shown with labels for 'Triumph Home Health', 'Serenity Hospital North', 'Serenity Hospital South', 'Serenity Fire Dept', 'Dr. James MD', and 'Nurse Nursing Home'. The footer includes the CDC address: 1600 Clifton Rd., Atlanta, GA 30333, USA, and contact information: 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, 24 Hours/Every Day - cdcinfo@cdc.gov.

This screenshot shows the 'Specimen Collection and Preparation' page. It features the CDC logo and navigation buttons for 'HOME', 'ABOUT', 'COURSE MAP', and 'EXIT'. The main text includes instructions for specimen collection and preparation, such as 'prepare Mr. Patel's hands for sample collection?' and 'to ensure optimal blood flow.' A 'View: Manufacturer's Instructions for Specimen Collection and Preparation' link is provided. A photograph of a person in a white lab coat working at a desk is shown. The footer includes the CDC address: 1600 Clifton Rd., Atlanta, GA 30333, USA, and contact information: 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, 24 Hours/Every Day - cdcinfo@cdc.gov.

Ready? Set? Test! Online Course Participation (Nov 2011—July 2013)

Total Registered	1843
Completed	1604
In Progress	222
Withdrawn	17

Credit Type	Total Hours Awarded
CEU/CE	79.2
CME	84
CNE Contact Hours	288
Pharmacists Contact Hours	1.6

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

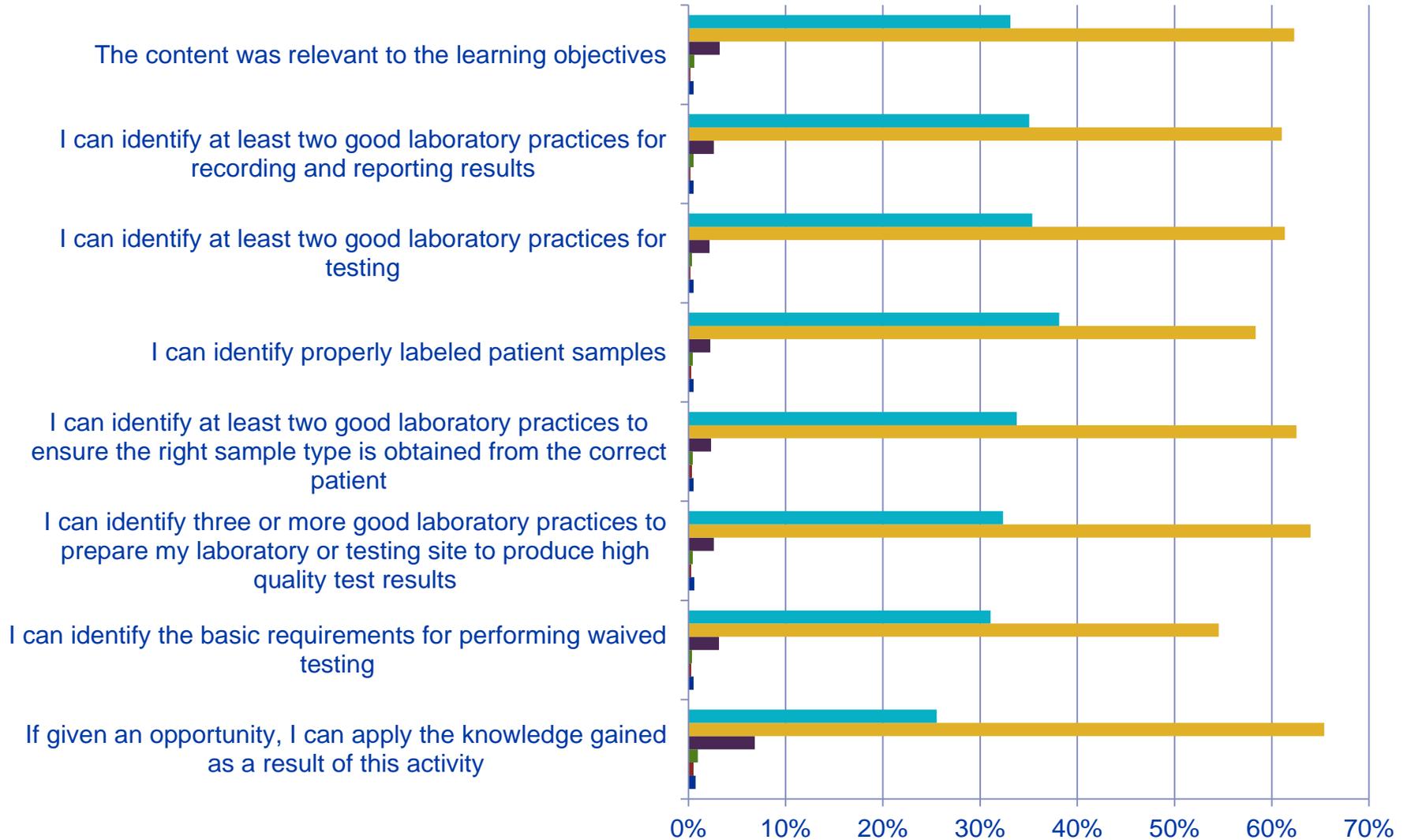
Course Evaluation

Strongly Agree Agree Neither/Undecided Disagree Strongly Disagree Not Applicable



Course Evaluation

■ Strongly Agree ■ Agree ■ Neither/Undecided ■ Disagree ■ Strongly Disagree ■ Not Applicable



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**

Contact Information

Waived Testing materials:

<http://wwwn.cdc.gov/cia/Resources/WaivedTests/>

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

*Contact information: Heather Stang
404-498-2769
btg0@cdc.gov*

