Waived Testing Background and History

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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.

Center for Surveillance, Epidemiology, and Laboratory Services
Division of Laboratory Programs, Standards, and Services

OUTLINE

- Waived Testing Origin and Regulatory Requirements
- Criteria and Process for Waiver
- Concerns with Waived Test Performance
- Waived Testing Trends and Current Laboratory Statistics
- Upcoming Presentations

WAIVED TESTING ORIGIN AND REGULATORY REQUIREMENTS

Origin of Waived Testing

- **Waived tests defined in the CLIA law passed on 10/31/88:**

  …simple laboratory examinations and procedures which, as determined by the Secretary, have an insignificant risk of an erroneous result, including those which—

  (1)have been approved by the Food and Drug Administration (FDA) for home use,

  (2)employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or

  (3)the Secretary has determined post no reasonable risk of harm to the patient if the test is performed incorrectly.

- **The law exempted waived tests from the CLIA standards for personnel, patient test management, quality control, proficiency testing, quality assurance, and routine inspections**

Tests Waived by Regulation

Eight tests listed in the final CLIA regulations published on 2/28/92:

(1) non-automated dipstick or tablet reagent urinalysis

(2) fecal occult blood

(3) ovulation tests - visual color comparison tests for human luteinizing hormone

(4) urine pregnancy tests – visual color comparison tests

(5) erythrocyte sedimentation rate – non-automated

(6) copper sulfate hemoglobin – non-automated

(7) blood glucose by monitoring devices FDA-cleared for home use

(8) spun microhematocrit

Test added 1/19/93

(9) hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

Regulatory Requirements for Performing Waived Tests

- **The 2/28/92 final CLIA regulations require laboratories that perform only waived tests to –**
  - Obtain a Certificate of Waiver
  - Follow manufacturers' instructions for testing
- **CMS does not routinely inspect laboratories or other sites that test under a Certificate of Waiver except:**
  - To investigate a complaint
  - To determine if a site is performing nonwaived tests
  - If there is risk of harm to a patient due to inaccurate testing
  - To gather information about waived tests

CRITERIA AND PROCESS FOR WAIVER APPROVAL

CLIAC Discussions

- **CLIAC discussions in 1992-1993 (and more than 1000 Comments to 2/28/92 regulation) concerned the criteria for waiver and the process for granting waived status. Examples of early CLIAC comments/recommendations:**
  - *Need to consider risks when using blood glucose monitors in clinical settings versus for home use*
  - *Risk is contextual and difficult to evaluate – eliminate risk of harm as a waiver criterion*
  - *Consider the need for access to testing when making waiver decisions*
  - *Develop definitive criteria for granting waived status, and declare moratorium on review of tests for waiver until criteria developed*
- **CLIAC has provided eight recommendations over time related to the criteria and process for waiver (additional recommendations express concerns with waived test performance)**

Steps Taken to Clarify Waiver Criteria

- 1993 - CDC established a moratorium on waiver and developed guidelines to clarify waiver criteria and specify studies to demonstrate that waived tests are simple with low risk of error
- 1995 – CDC published a proposed rule containing the criteria for waiver requesting public comments
- 1997 – FDA Modernization Act (FDAMA) revised the CLIA law to clarify that tests cleared for home use are automatically waived and added “by the user” to the waiver provision requiring demonstration of simplicity and accuracy

Transfer of Waiver Responsibilities to the FDA

- **2000 – Responsibility for test categorization and waiver determinations for commercial tests systems transferred from CDC to FDA, which led to FDA's development of draft guidance for review of waiver requests and application of the statutory waiver criteria**
  - 8/14-15/00 – FDA CLIA Waiver Criteria Public Workshop solicited input on the waiver criteria and process
  - 9/28/00 – CLIAC was charged with establishing a workgroup to provide input regarding the waiver criteria and sent letter to HHS Secretary requesting opportunity to provide comments on waiver process and recommending that FDA follow guidelines for waiver approval described in 1995 proposed rule

FDA's Development of Waiver Guidance

- **2001 – FDA draft waiver guidance shared with CLIAC for comments and issued for public comment**
  - 2/7-8/01 – CLIAC provided initial recommendations on draft guidance regarding required waiver studies and indicated more recommendations would follow
  - 5/30/01 – CLIAC considered issues presented by waiver workgroup and made comprehensive recommendations to FDA
- **2003 – AdvaMed submitted a waiver criteria proposal to CMS and FDA, and shared it with CLIAC**
  - 9/17-18/03 – CLIAC recommended a workgroup consider appropriate changes to the waiver determination process and oversight of waived tests
  - 2/11-12/04 – CLIAC provided recommendations for development of waiver criteria and oversight guidance to FDA (and AdvaMed) based on workgroup suggestions

FDA's CLIA Waiver Guidance

- **2005 – FDA issued draft guidance and posted it on their website**
  - "Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices"
  - Includes an approach for manufacturers to demonstrate that a device meets the CLIA statutory criteria for waiver and is simple with an insignificant risk of an erroneous result
- **2008 – FDA issued final waiver guidance for manufacturers**
  - http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm079632.htm

CONCERNS WITH WAIVED TEST PERFORMANCE

CLIAC Concerns with Waived Test Performance

- **CLIAC concerns with waived testing performance were first discussed in 1992 and have been raised periodically since that time**
- **Aspects of waived testing have been discussed through formal presentations or as part of agency updates at 29/49 CLIAC meetings**
- **Four recommendations made expressing concerns or suggesting good laboratory practices to be followed; three recommendations addressed the need to collect waived testing data and information**
  - concerns prior to waiver of rapid strep and HIV tests
  - convene a workgroup to explore publication of CMS waived testing data and develop good laboratory practices
  - collect information to assess the performance and outcome of waived testing

Assessing Waived Testing Practices

1993-2003	CDC funded studies of waived testing practices in Arkansas, New York, and Washington • Personnel turnover • Quality control/assessment practices • Inventory of CLIA-waived tests
2002-Present	CMS annual on-site educational surveys of a small sample of waived testing sites http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certificate_of_-Waiver_Laboratory_Project.html • Determine regulatory compliance for waived testing • Educate regarding good laboratory practices

Issues Identified in CDC Study Findings and CMS Surveys

- High staff turnover in waived testing sites
- Lack of formal laboratory education for testing personnel
- Limited training in test performance and quality control/assessment
- Lack of awareness of “good laboratory practices”
- Shortcomings in following manufacturer’s instructions or checking product inserts for changes

Development of MMWR Guidelines and Resources to Promote Good Laboratory Practices

- Concerns about quality gaps identified through studies and the increases in waived testing highlighted the need for good laboratory practice guidance
- CLIAC recommendations incorporated into CDC MMWR Recommendations and Reports – 11/5/2005
- CDC subsequently developed free educational booklets, posters, and online training to promote good practices in waived testing sites
- Educational booklets and training now available in English and Spanish
- http://wwwn.cdc.gov/clia/Resources/WaivedTests/

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

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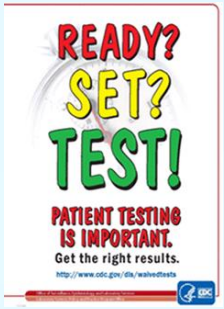
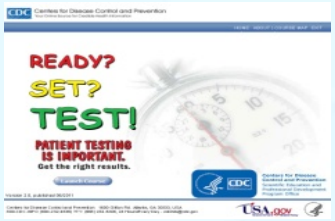
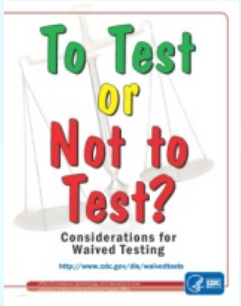
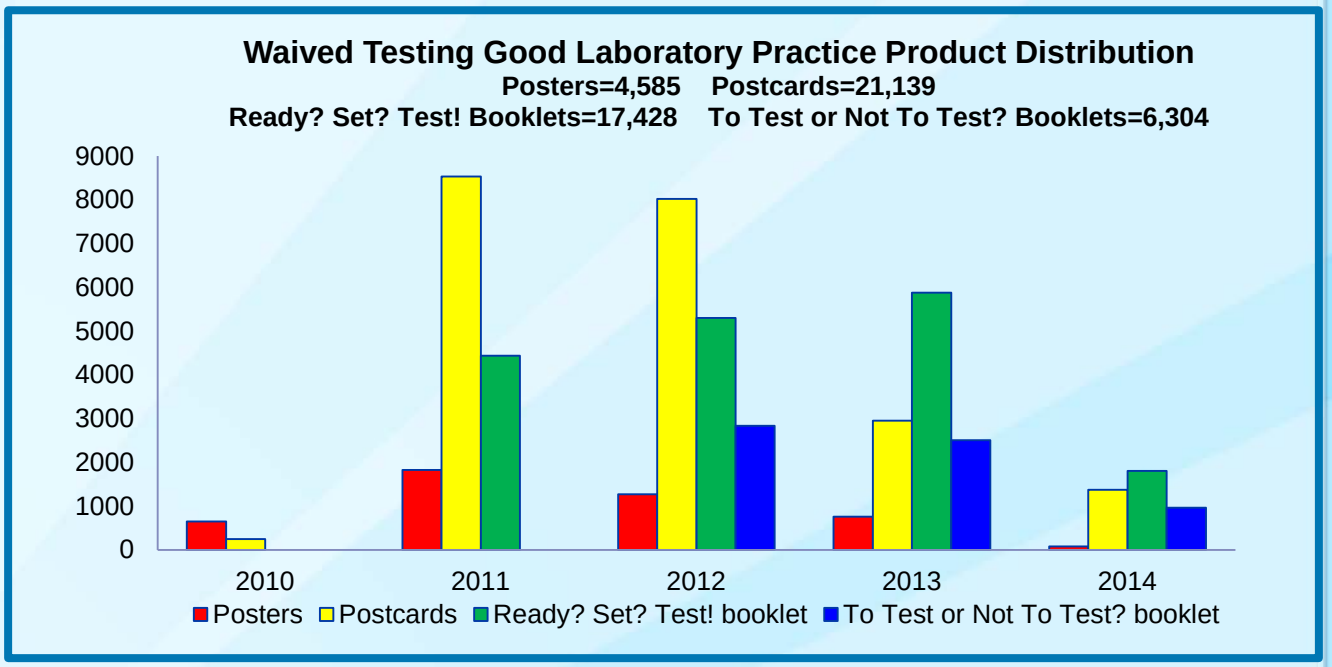
Waived Testing Educational Products









Ready? Set? Test! Online Course Participation (Nov 2011-Sept 2014)

Course Registration	
Total Registered	3087
Completed	2538
In Progress	478
Withdrawn	71

Credit Type	Total Hours Awarded
CEU/CE (0.1 hours)	115.2
CME (1.0 hours)	206
CNE Contact Hours (1.0 hours)	379
Pharmacists Contact Hours (0.1 hours)	4.1

Download from: http://wwwn.cdc.gov/clia/Resources/WaivedTests/

WAIVED TESTING TRENDS AND CURRENT LABORATORY STATISTICS

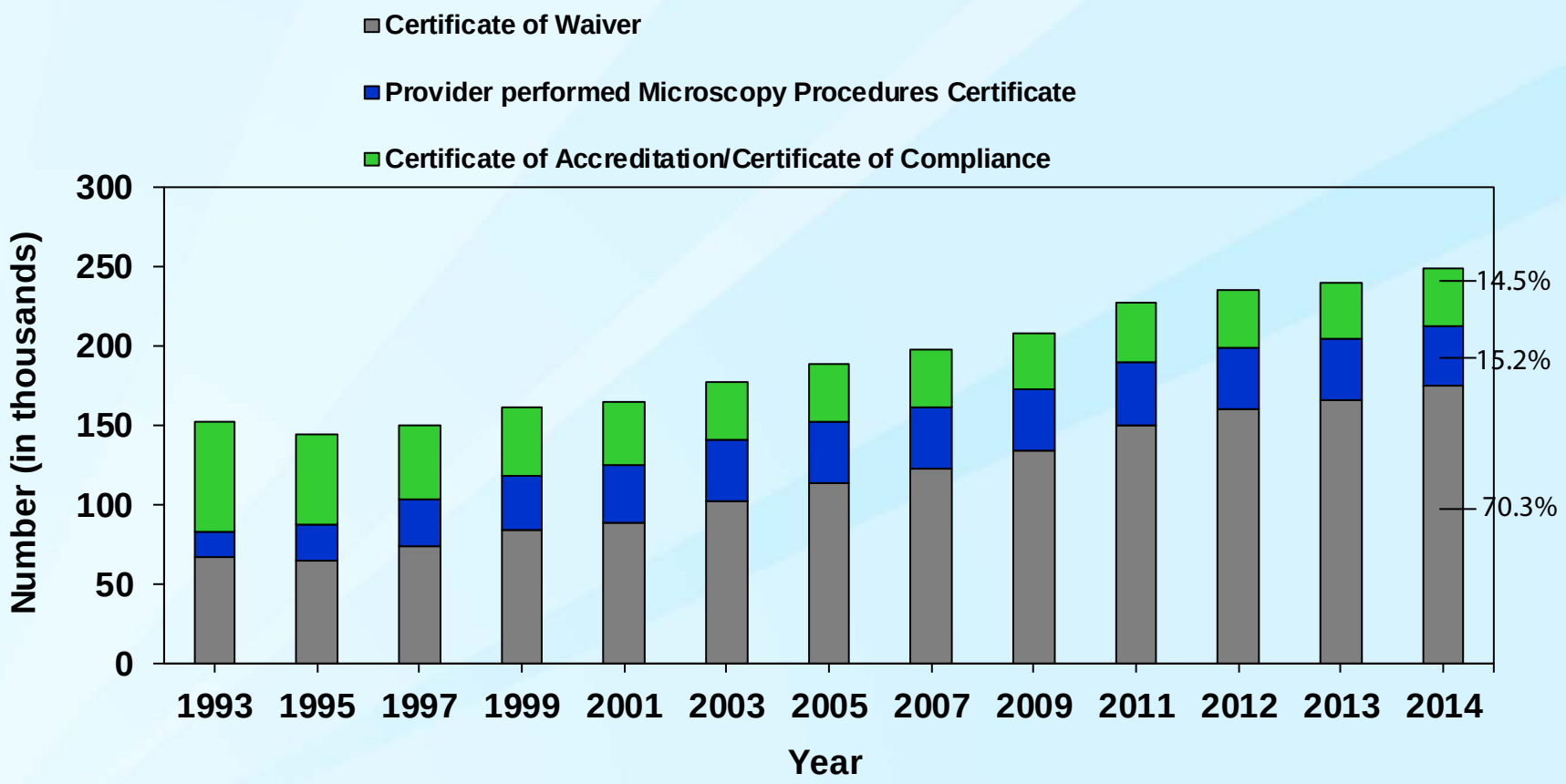
Trends in Waived Testing Over Time

Waived Testing Measurement Parameter	1993	1998	2003	2008	2011	2014
No. of analytes for which waived test systems are available	9	40	74	84	87	90
No. of waived test systems*	203	608	1,495	3,228	4,369	8,043
No. of laboratories/sites with a Certificate of Waiver	67,294	78,825	102,123	129,219	153,702	175,362
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.

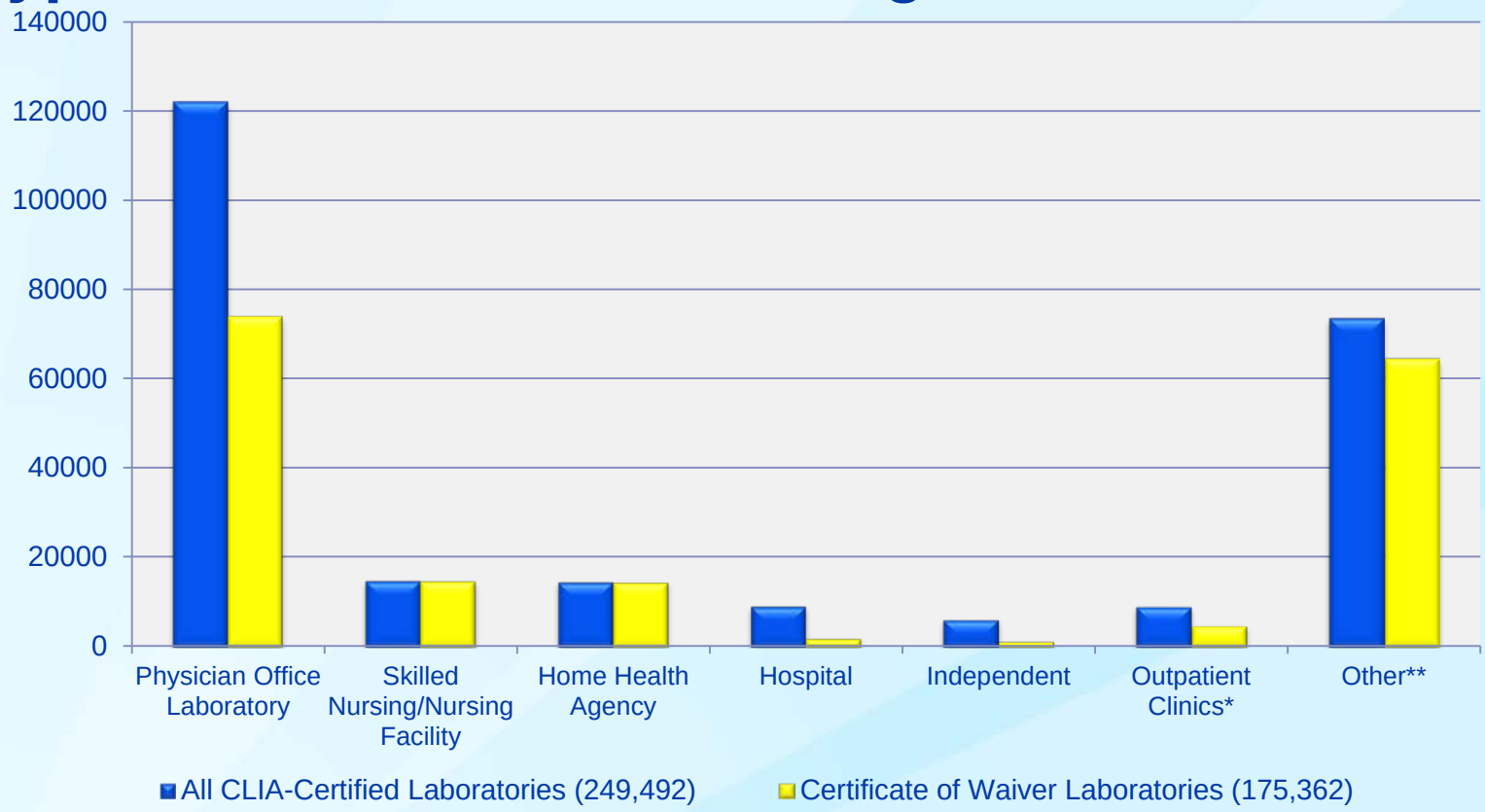
Source: CDC and FDA CLIA Test categorization databases and CMS On-line Survey, Certification, and Reporting database. Updated 10/22/2014

Numbers of CLIA Certified Laboratories by Certificate Type 1993-2014



*Data obtained from CMS OSCAR database (10/22/2014)
Numbers include laboratories in CLIA-exempt states of NY and WA.

Types of Laboratories/Testing Sites, October 2014



Additional Laboratory Demographics for All CLIA-Certified Laboratories:

- 319,000 laboratory personnel[2]
- >10 billion tests/year[1]
- >$52 billion/year in laboratory revenues[3]

[1]Data obtained from CMS OSCAR database, 06/18/2014. OSCAR data are self-reported. Numbers include laboratories in CLIA-exempt states of NY and WA.
[2]Data obtained from US Department of Labor Bureau of Labor Statistics Occupational Employment Statistics (OES) at http://www.bls.gov/oes/#tables
[3]Data obtained from http://www.kaloramainformation.com/Clinical-Laboratory-Services-2565239/
*Community clinic, rural health clinic
**Public health laboratories, insurance, pharmacy, tissue bank/repositories, blood banks, ambulance and mobile units, industrial, health fair, ancillary test sites, school/student health service, other not specified.

Upcoming Presentations

- **FDA CLIA Waiver Approval Process and Criteria**
  - **Dr. Prakash Rath**
- **CMS Waived Testing Update**
  - **Ms. Daralyn Hassan**