

# Assessing the Performance and Impact of Waived Testing

CLIAC Meeting

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# Overview

- Background
- Summary of waived testing data
- Additional sources of data and information
  - CMS Certificate of Waiver Project
  - Proficiency testing (PT) program data from voluntary participation in waived testing PT
- Solicitation of CLIAC input

# Increases in Waived Testing Over Time

Waived Testing Measurement Parameter	1993	1998	2003	2008
No. of analytes for which waived test systems are available	9	40	74	84
No. of waived test systems*	203	608	1,495	3228
No. of laboratories with a Certificate of Waiver†	67,294	78,825	102,123	129,219
Percentage of laboratories with a Certificate of Waiver†	44%	50%	57%	64%

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

†Does not include CLIA exempt laboratories in New York and Washington.

**Source:** CDC and FDA CLIA Test categorization databases and CMS On-line Survey, Certification, and Reporting database.

# Previous CLIAC Discussions Regarding Waived Testing

- Since 1992, CLIAC has addressed waived testing on 28 occasions and has convened 5 subcommittees or workgroups
- In February 2009, after discussion of potential waiver of devices for white blood cell counts and/or differentials, CLIAC recommended the following to CDC: *Conduct a study to gather data about the impact of waived testing on patient outcomes, clinician behavior, and other similar issues*

# Collection of Data on Waived Testing Practices

- Studies and laboratory surveys have identified gaps in quality that could lead to errors and patient harm
  - CDC Sentinel Monitoring Networks
    - <http://wwwn.cdc.gov/mlp/pnlmsmn.aspx>
      - Pacific Northwest, 1995-2003
      - New York, 1999-2001
      - Arkansas, 1999-2001
    - CMS Certificate of Waiver Project, 1999-2009
    - HHS Office of Inspector General Investigation, 2001

# Waived Testing: CDC Publications

- Quality Control of Test Systems Waived by the Clinical Laboratory Improvement Amendments of 1988: Perceptions and Practices. LaBeau KM, Simon M, Steindel SJ. *Arch Path & Lab Med* , 2000.
- Practice Patterns of Testing Waived Under the Clinical Laboratory Improvement Amendments. Steindel SJ, Granade S, Lee J, Avery G, Clarke LM, Jenny RW, LaBeau KM.. *Arch Pathol Lab Med*. 2002
- Scope of Rapid HIV Testing in Hospitals Across the United States. Bogart LM, Howerton D, Lange J, Becker,K, Setodji CM, & Asch SM. *Public Health Reports*, 2008.
- Good Laboratory Practices for Waived Testing Sites. Howerton DA, Anderson N, Bosse D, Granade S, and Westbrook G, *MMWR*, 2005.
- Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988.  
<http://www.cdc.gov/hiv/topics/testing/rapid/index.htm#lab>

# PATIENT TESTING IS IMPORTANT.

## Get the right results.

**READY?**

**SET?**

**TEST!**

- 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>



# Current CDC Project: Evaluating the Use of Rapid Testing for Influenza in Outpatient Medical Settings

- Cooperative agreement awarded to Joint Commission in September 2007 focused on use of rapid influenza tests in outpatient medical settings
- Study Objectives
  - Determine the scope of rapid influenza test use in physician offices, hospital emergency departments, community health centers
  - Characterize the outpatient settings that use rapid influenza tests
  - Describe the linkage between outpatient settings and public health system
  - Identify gaps in knowledge required for quality improvement
- Identify potential opportunities to
  - Provide guidance to users
  - Provide means to enhance connectivity with the public health system
- Future projects will address use of rapid influenza tests following novel H1N1 outbreak

# 2009 Literature Review on Waived Testing Outcomes

- Approximately 30 articles were identified that compared waived test performance for specific analytes to nonwaived tests conducted in hospital laboratories (see references provided)
  - Search strategy included accuracy, test utilization, results interpretation and reporting, results recording, turnaround time (TAT), and hospital length of stay (LOS)
  - Analytes - glucose, influenza, prothrombin time, group A streptococcus, urine dipstick, fecal occult blood, sodium, potassium, chloride, blood urea nitrogen, hematocrit, and hemoglobin

# 2009 Literature Review Comments

- With the exception of glucose and prothrombin time, waived test accuracy for published analytes is comparable to nonwaived tests performed in the laboratory
  - Fingertick glucose results for waived tests were higher than nonwaived serum glucose results
  - Some waived prothrombin time results provided higher international normalized ratio values than nonwaived tests
- Based on publications reviewed, although TAT for waived test results may be shorter, the impact on LOS or clinical outcome is not clear

# Limitations and Challenges in Assessing Waived Test Impact and Outcomes

- Studies have not evaluated waived versus nonwaived test performance in the same hospital or healthcare setting
- Studies have not assessed differences in performance based on the personnel conducting the testing
- Studies have not clearly demonstrated a direct correlation between waived test results and patient outcomes

# Additional Data and Information Regarding Waived Testing Performance

- CMS Certificate of Waiver Project - Ms. Daralyn Hassan
- PT Program Presentations
  - American Academy of Family Physicians - Dr. Verlin Janzen
  - American Proficiency Institute - Mr. Dan Edson
  - College of American Pathologists - Dr. Paul Bachner
  - Medical Laboratory Evaluation - Ms. Connie Laubenthal
  - Wisconsin State Laboratory of Hygiene - Ms. Barbara Hill
- *What are the trends in voluntary enrollment for waived testing PT modules with respect to analytes and demographics of participating laboratories?*
- *Has waived testing quality (as indicated by PT results) changed over time?*

# Questions for CLIAC Consideration

- Where are the gaps in what we now know about waived test performance and its impact?
- How should CDC address the gaps?
  - How can waived testing performance be assessed in nontraditional testing sites?
  - Should waived test performance be assessed for particular analytes or test systems? If so, which should we focus on?
  - Should a waived test study focus on specific types of testing personnel? If so, what groups should be assessed – nurses, medical assistants, others?
- How can the impact of waived testing on patient care be measured?