



Update: Good Laboratory Practices for Waived Testing Sites

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CLIAC Meeting

September 7, 2005

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Good Laboratory Practices for Waived Testing Sites



- Chronology of activities to date
- Overview of document
 - ❖ Synopsis of survey findings
 - ❖ Summary of contents
- Next steps

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Summary of Activities to Date



Feb and Sept 2004	<ul style="list-style-type: none">•CMS CW survey data presented to CLIAC•CLIAC recommended publishing data and practice guidelines for CW testing sites
Jan 2005	Workgroup met and developed guideline recommendations
Feb 2005	<ul style="list-style-type: none">•Recommendations presented to CLIAC•CLIAC approved and recommended publication
June 2005	Manuscript drafted and submitted for <i>MMWR Report and Recommendation</i>
Sept 2005	<ul style="list-style-type: none">•Manuscript in <i>MMWR</i> pipeline•Other targeted documents under development



Rationale for Publication



- The use of waived testing is increasing
- Results from CMS CW surveys in 2002-2003 demonstrated quality issues and a lack of knowledge about basic good laboratory practices
- Results from CDC-funded studies through the Laboratory Medicine Sentinel Monitoring Networks (LMSMN) during 1999-2003 showed similar results
- CMS on-site visits included an educational component that was well-received
- *MMWR* is regarded as a reliable source for information



Increases in Waived Testing 1993-2004



	1993	1998	2000	2003	2004
# Analytes for waived tests	9	40	53	74	76
# Waived test systems*	203	608	832	1,495	1,638
# CW laboratories†	67,294	78,825	85,944	102,123	105,138
% laboratories with a CW†	44%	50%	52%	57%	58%
Medicare Part B waived test volume	NA§	NA	14,663,751	20,781,297	23,041,693
% Medicare Part B volume for waived tests	NA	NA	6.50%	7.80%	8.10%
Medicare Part B payments for waived tests	NA	NA	\$69,765,453	\$112,247,706	\$128,169,398

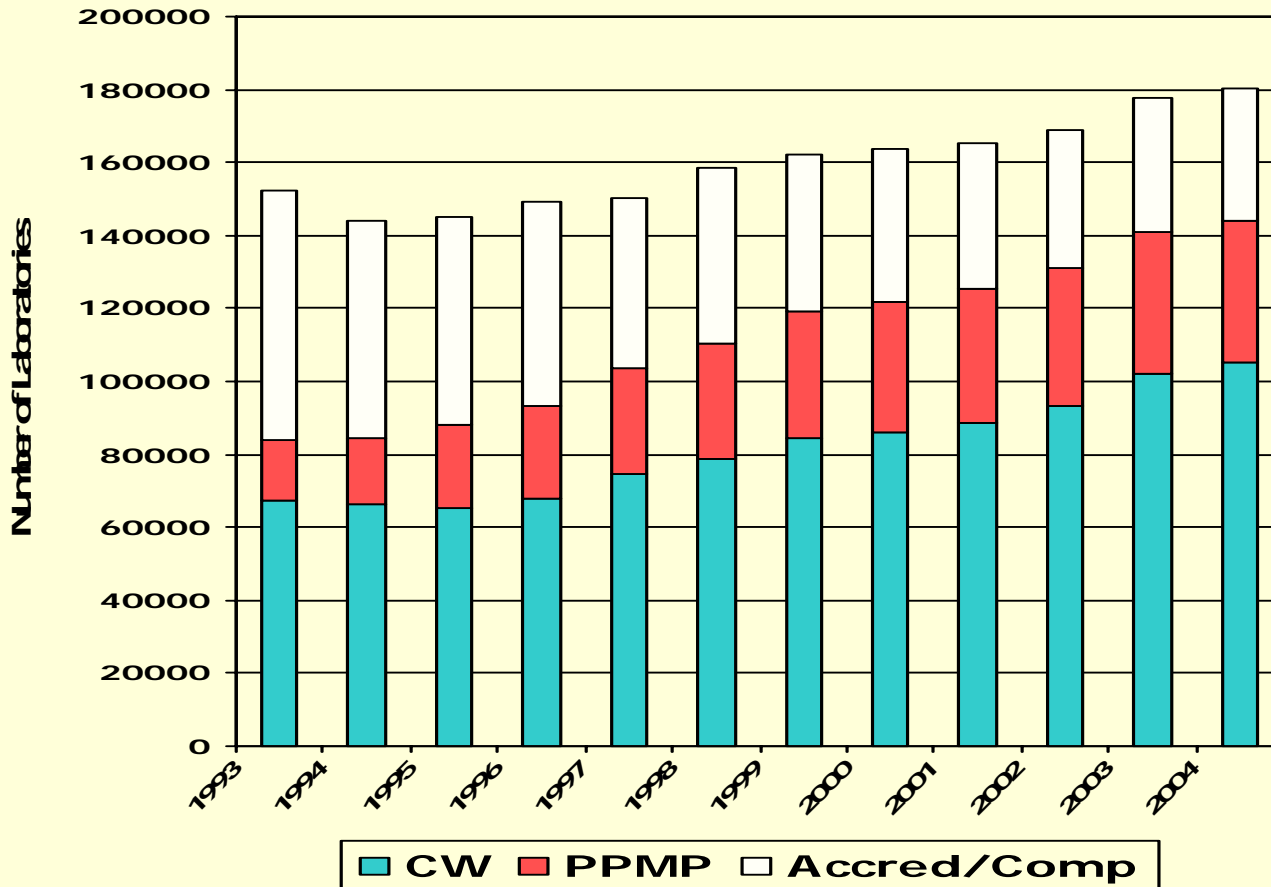
*Numbers reflect multiple names under which individual tests are marketed and may include waived tests no longer sold.

†Does not include CLIA exempt laboratories in states of New York or Washington

§Not Available



Changes in Laboratory Certification, 1993-2004



In 2004:

36,425
(20%)

38,884
(22%)

105,138
(58%)

180,447 total

*Does not include CLIA-exempt laboratories in the states of New York and Washington; CMS On-line Survey, Certification, and Reporting (OSCAR) database



Top 10 Types of Facilities with a Certificate of Waiver



Facility Type	CMS Surveyed Sites 2002-2004	All CW Sites* As of 2/25/05
	Percent [†] (n = 4,214)	Percent [†] (n = 109,820)
Physician Office	47	46
Nursing Facility	14	13
Ambulatory Surgery Center	4	3
End-Stage Renal Disease Dialysis Center	4	3
Home Health Agency	3	8
Community Clinic	3	2
Pharmacy	2	3
School - Student Health	2	1
Industrial	2	1
Hospital	1	1

*Data Source: CMS On-line Survey, Certification, and Reporting database

†Totals may not equal 100% due to rounding

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Overview of CMS Findings (2002-2004, n=4214)



- High turnover rates of testing personnel
 - ❖ 43% of CW sites had changes in testing personnel in the past year
- Limited training in the waived tests being performed
- Lack of awareness of good laboratory practices
- Partial compliance in having or following current manufacturer's instructions



Overview of CMS Findings, cont'd



- **Following manufacturer's instructions**
 - ❖ 12% did **not** have current manufacturer's instructions
 - ❖ 21% did **not** routinely check new product inserts for changes*
- **Based on current manufacturer's instructions**
 - ❖ 21% did **not** perform quality control testing
 - ❖ 18% did **not** report test results with terminology or units described in package insert
- **Documentation**
 - ❖ 45% did **not** document the name, lot number, and expiration date for all tests performed*
 - ❖ 35% did **not** maintain a quality control log*
 - ❖ 31% did **not** maintain a log of tests performed

n = 4214 for 2002-2004, *n = 3317 for 2003-2004



Contents of the Report

"Good Laboratory Practices for Waived Testing Sites:

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

- **Background**
- **Surveys of waived testing sites**
 - ❖ **Demographics**
 - ❖ **Personnel and training**
 - ❖ **Testing practices**
- **Recommended good laboratory practices**
 - ❖ **Considerations before introducing testing or a new test**
 - ❖ **Developing procedures and training personnel**
 - ❖ **Recommended practices**
- **Terms and abbreviations used in the report**
- **Continuing medical education activity**

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Recommended Good Laboratory Practices



Considerations before introducing waived testing or offering a new waived test:

- Management responsibilities for
 - ❖ testing oversight
 - ❖ meeting regulatory and safety requirements
 - ❖ facility management
 - ❖ evaluating benefits and costs
- Personnel training and competency assessment, provision of written test procedures and access to technical assistance



Recommended Good Laboratory Practices

Recommended practices for conducting waived testing:

Before Testing	Testing	After Testing
<ul style="list-style-type: none">• Test ordering• Patient identification, preparation• Specimen collection, handling• Preparing materials, equipment, and testing area	<ul style="list-style-type: none">• Control testing/checks• Test performance• Results interpretation• Recording results	<ul style="list-style-type: none">• Reporting• Documenting• Confirmatory testing• Patient follow-up• Disease reporting• Biohazard waste disposal

- Documents and records
- Quality assessment
- Components of manufacturer's product insert
- Pretest task checklist



Acknowledgements

CLIAC Work Group



Jared Schwartz, MD, PhD

Kathyrn Foucar, MD

Jennifer Alfisi, JD

Kimberle Chapin, MD

Mary Beth Clark, RN

Martha Crenshaw, MD

Jacinto Del Mazo, MD

Paula Garrott, EdM

Barbara Goldsmith, PhD

Partricia Maloney

Luann Ochs, MS

Barbara Robinson-Dunn, PhD

Lou Turner, DrPH

Robin Weiner

Thomas Williams, MD



Acknowledgments CDC and CMS Staff



CDC Staff:

Nancy Anderson, MMSc, Diane Bosse, MS, Sharon Granade, Glennis Westbrook, John Hancock, Jim Handsfield, M.P.H., Rhonda Whalen, M.S.

Division of Public Health Partnerships, National Center for Health Marketing, Coordinating Center for Health Information and Service

CMS Staff:

Daralyn Hassan, M.S. and the CMS Waived Laboratory Project Team
Division of Laboratory Services, Survey and Certification Group,
Center for Medicare and State Operations



Next Steps

- Complete *MMWR* publication process
- Promote *MMWR* recommendations as a comprehensive source document
- Develop other adaptations to reach targeted audiences, such as nurses, physicians, medical assistants and office managers

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Questions?



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