



# CDC Update: Waived Testing

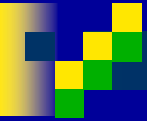
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CLIAC Meeting  
September 22, 2004

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# February 2004 CLIAC Proposals



1. Publish data from CMS surveys (MMWR?)
2. Develop and publish “best practices” guideline for waived testing



# CDC/CMS Activities to Date

- Editing/verification of CMS data (2002, 2003)
- Comparison of CMS survey findings to CDC data on waived testing
- Determined brief report for MMWR not appropriate
- Conferred with K. Foucar, CLIAC workgroup chair
- Investigated publication of MMWR  
*Recommendations and Reports*



# Issues Identified in CMS Surveys Correlate with CDC Study Findings

- High staff turnover in waived testing sites
- Lack of formal laboratory education
- Limited training in test performance and QA
- Lack of awareness concerning “good laboratory practice”
- Partial compliance with manufacturers’ QC instructions ( ~55-60%)



# Reports from the Laboratory Medicine Sentinel Monitoring Networks

<http://www.phppo.cdc.gov/mlp/pnlmsmn.aspx>

Waived and PPMP Sites- Testing Personnel Turnover	Pacific NW January 2003
Assessment of Waived Testing and PPMP Practices	New York October, 2002
On-Site Review of CLIA-Waived Testing in Moderate and High Complexity Laboratories	Pacific NW August 2002
Patterns of Quality Assurance Activities in CLIA Waived Testing	Arkansas April 2001
Inventory of CLIA-Waived Tests	Pacific NW April 2002
Quality Assessment of Waived Test Systems	Pacific NW January 2001
Waived and PPMP Sites: Quality Assessment Activities	Pacific NW December 2000



# Use of Quality Control Methods by Laboratory Certification Level in Washington

Quality Control Method	Mod/High Complexity Laboratories	Waived/PPMP Laboratories
Liquid controls	67%	38%
Procedural controls	91%	60%
Electronic controls	70%	77%
Proficiency testing	52%	13%
Comparison to patient history	26%	72%

Steindel SJ, Granade S, Lee J, Avery G, Clarke LM, Jenny RW, and LaBeau KM. Practice patterns of testing waived under the Clinical Laboratory Improvement Amendments. Arch Pathol Lab Med, 126: 1471-1479, 2002.



# Selected Deficiencies in New York Limited Testing Sites\*

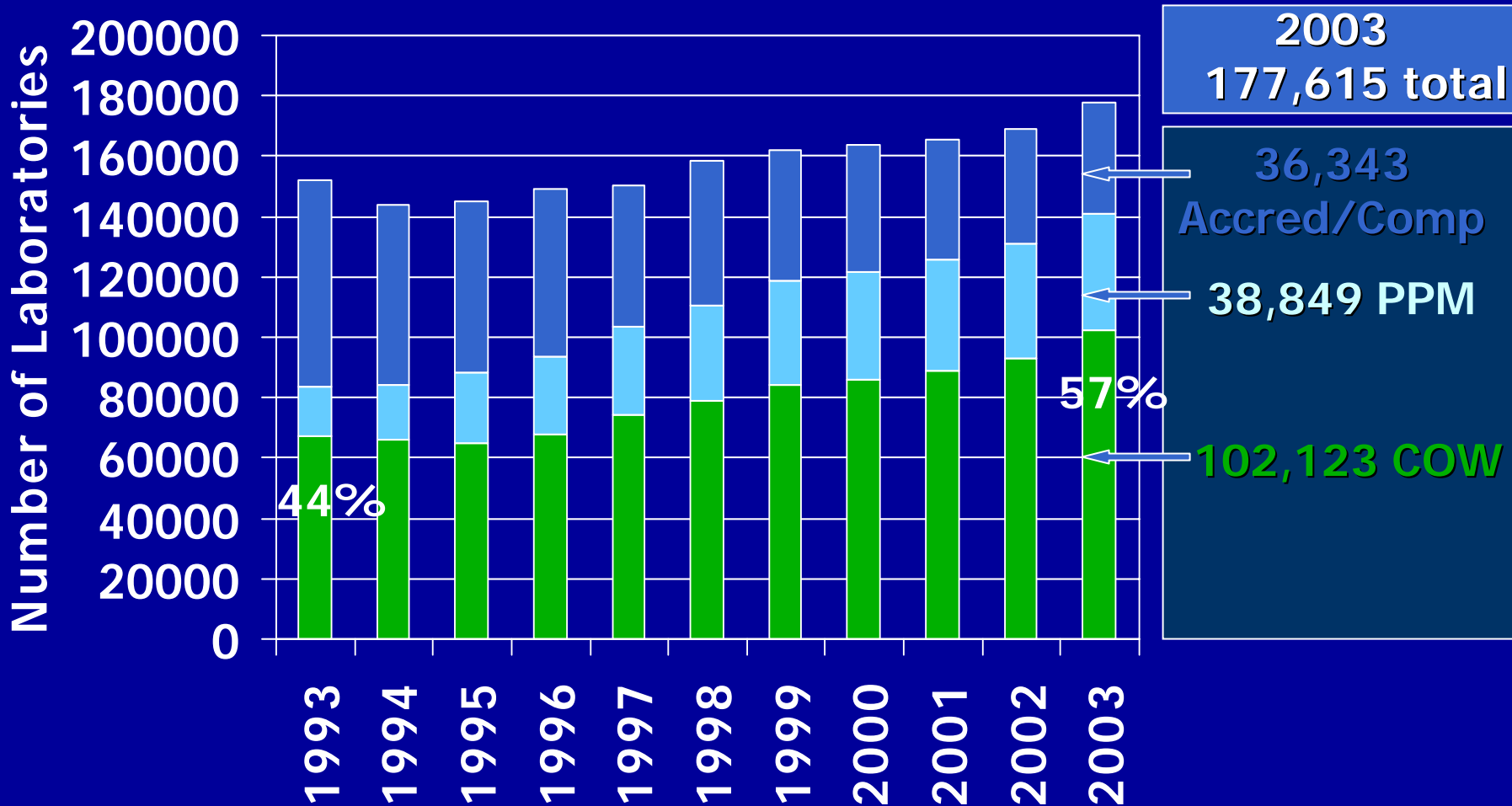
QA Deficiency	Affiliated (n=155)	Nonaffiliated (n=452)
Staff competency checks	10	40
Assay validation policies	22	71
Monitoring QC data	8	36
SOPM review by director	19	69
QA/QC oversight by director	10	34
Proficiency testing	39	88

\* Values are % of labs with the deficiency.



# Increase in Sites with Certificates of Waiver (COW)

## Laboratories by Certificate Type (Non-exempt States)





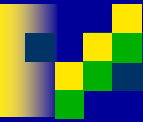


# Medicare Expenditures for Waived Tests

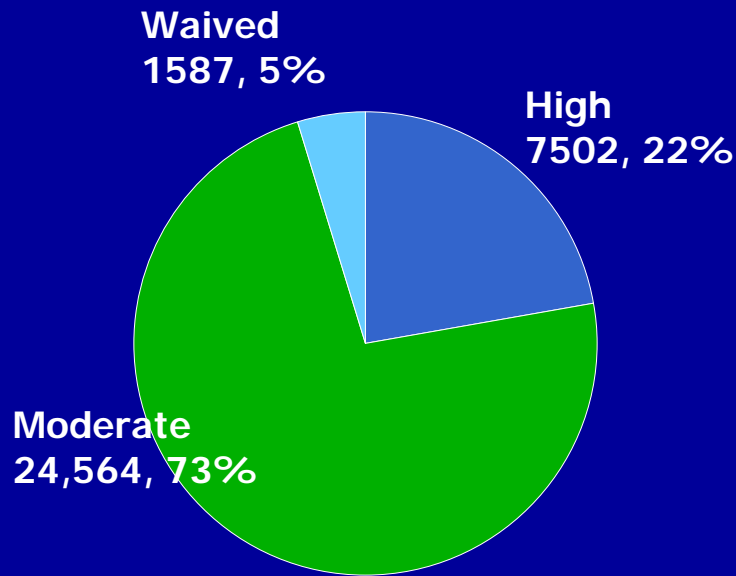
Year	Payment (in millions)		Tests (in millions)	
	Total	Waived (% of total)	Total	Waived (% of total)
2000	\$2307.7	\$69.8 (3.0%)	225.4	14.6 (6.5%)
2001	\$2568.6	\$85.6 (3.3%)	232.9	16.8 (7.2%)
2002	\$2885.5	\$99.7 (3.5%)	252.8	19.2 (7.6%)
2003 (98%)	\$3158.8	\$112.3 (3.6%)	266.8	20.8 (7.8%)



# Test Categorization As of 9/1/2004

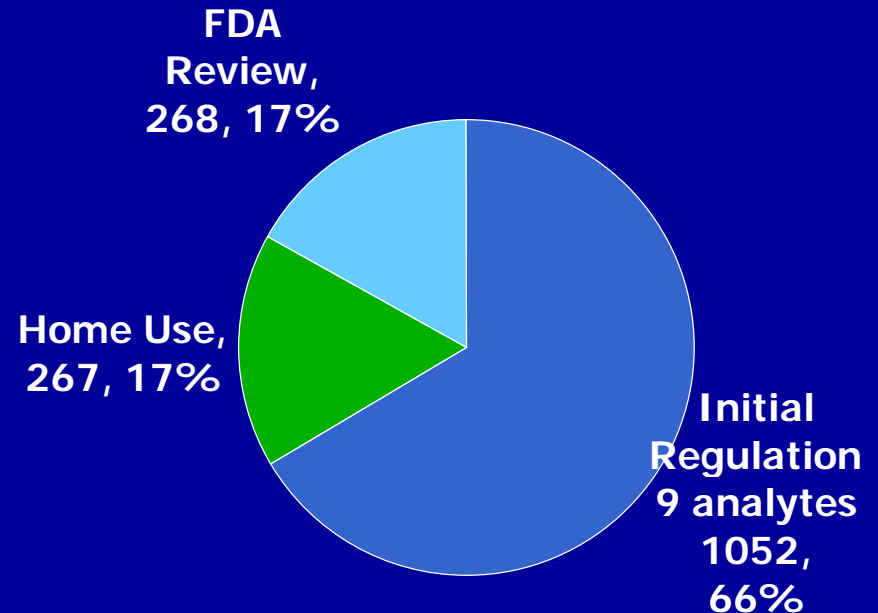


## Tests Categorized



33,653 test systems categorized

## Routes to Waiver Approval



1,587 test systems waived for 76 analytes



# Most Commonly Used Waived Tests

1. Glucose
2. Dipstick urinalysis
3. Fecal occult blood
4. Urine pregnancy test
5. Group A Streptococcal antigen



# Conclusions

- CMS survey data confirms continuing trends in COW sites:
  - ❖ Limited compliance with minimal requirements
  - ❖ Personnel turnover and lack of laboratory training
  - ❖ Increasing number of waived sites (majority of labs)
- New waived tests continue to be approved



# Proposed Action

1. Develop "good laboratory practice" guidelines for waived testing
  - ❖ Form CLIAAC workgroup
  - ❖ Present workgroup report to CLIAAC for recommendations
2. Publish CMS and CDC data along with practice guidelines in MMWR
  - ❖ Credible source
  - ❖ CME credits
3. Investigate other guideline delivery mechanisms
  - ❖ Nurses
  - ❖ Physicians
  - ❖ Medical office workers



# Guideline Workgroup Members

Representatives from:

- CLIAC
- Waived laboratories (clinical practitioners)
- Non-waived laboratories
- Industry (manufacturers, distributors)
- HHS (CMS, FDA, CDC)



# Document Development Timeline

Guideline Workgroup meets	Jan 2005
CLIAAC makes guideline recommendations based on workgroup report	Feb 2005
CMS survey data finalized (2002-2004)	Feb 2005
MMWR R&R drafted (with CLIAAC waiver publication workgroup review)	March 2005
CDC/CMS clearance	April – May 2005
Draft manuscript submitted to MMWR	June 2005
MMWR publication	September 2005