

# **CBC Waiver Panel CMS Issues & Concerns**

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Friday, July 18, 2008**



# Topics to be Discussed

- Background & history of CMS CW Project
- CLIA Data & Certificate Types
- CMS concerns about CBC Waiver
- CMS/CLIA contact information

# By CLIA definition.....

Waived tests are;

“.....simple laboratory examinations & procedures which –

Employ methodologies that are so simple & accurate as to render the likelihood of erroneous results negligible;

Pose no reasonable risk of harm to the patient if the test is performed incorrectly”.

# CERTIFICATE OF WAIVER (CW) PROJECT Background

- The only standard for CW laboratories is to follow manufacturer's instructions & register w/ CMS.
- As part of the CW project, each CW laboratory responded to questions about waived testing it performed.

# CERTIFICATE OF WAIVER (CW) PROJECT DATA Background

## 1999 Pilot Project:

- CO & OH each visited 100 CW & PPMP laboratories; 50% had quality problems!
- As a result of findings in CO & OH, CMS expanded the pilot to the 8 other States.

# CERTIFICATE OF WAIVER (CW)

## PROJECT DATA

### Background to Present

#### 2000-2001 Expanded Pilot:

- Surveyors in MA, NY, PA, MS, NM, IA, AZ, ID visited 436 COW & PPMP laboratories; 32% had quality problems.

#### Present

- CMS-CLIA initiated CW Project April 2002 to survey 2% of CW labs per year & it's ongoing.

# Results of CMS CW Project FY 2006



## Initial visits

- Of 1947 labs visited, 69% answered “yes” to Question #5; meaning they were following the manufacturer’s instructions.



## Follow-up visits

- Of 414 labs revisited for not following manufacturer’s instructions, 353 or 85% *improved upon revisit.*

## September 2004 CLIAC Meeting

The CDC reported issues found in CMS CW surveys correlate w/ CDC study findings

New York State DOH reported similar findings from their visits

Presentation CLIAC\_Waived testing update\_Sept 2004.ppt

## CDC Findings Include...

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

(Presentation CLIAC\_Waived testing update\_Sept 2004.ppt)

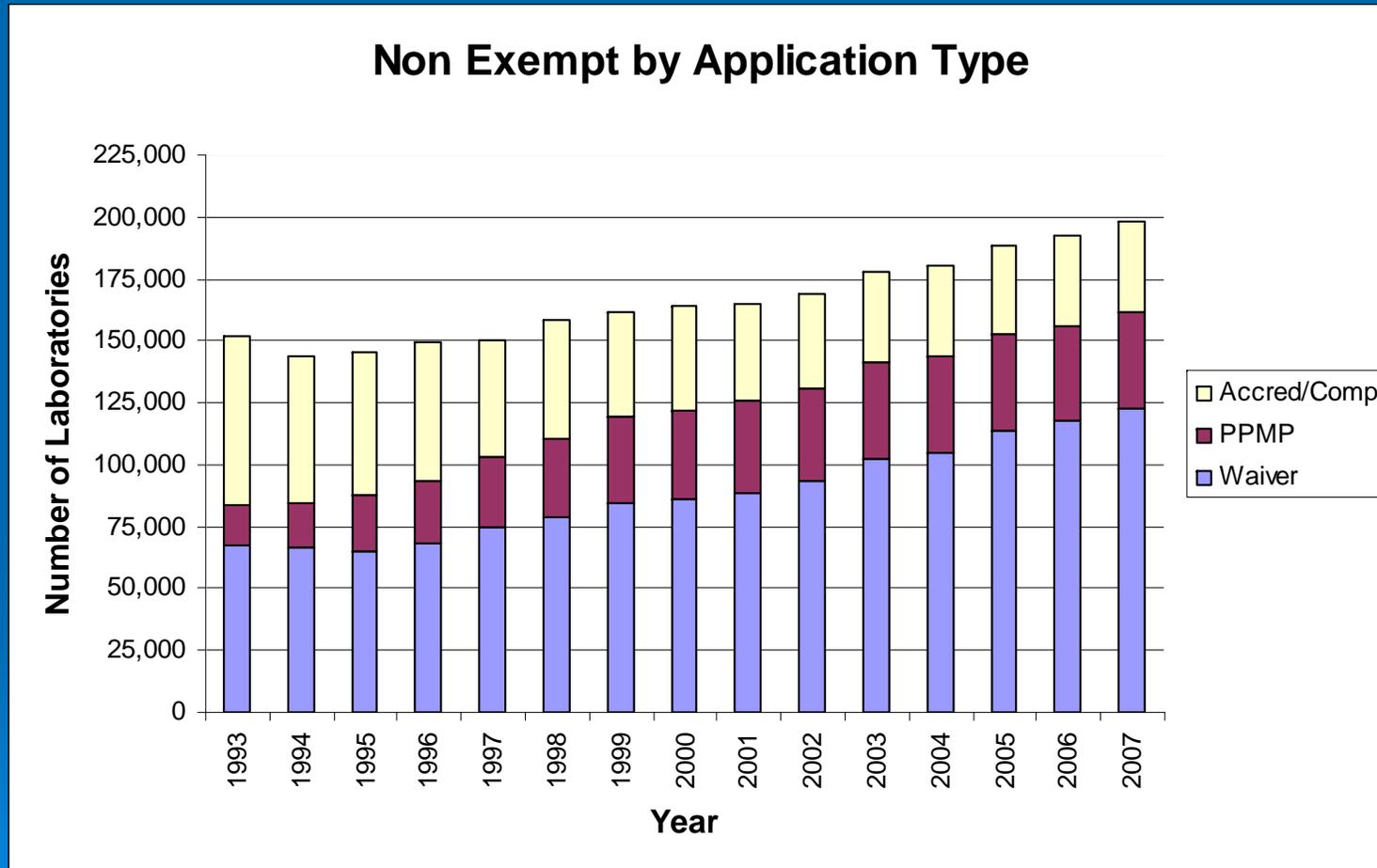
# Question? To Consider

*Have CW lab & test device performance improved sufficiently so that approval of a waived CBC test system will not be detrimental to patient care?*

## Since 1992.....

- The types of CLIA-waived tests have increased from 8 to about 100 tests.
  - This represents 1000's of test systems.
- The number of laboratories issued a CW has grown exponentially from 20% to 60% of the >200,000 laboratories enrolled.

# # of Non Exempt Labs by Application Type



# Total # of Registered Labs in 2007 = 203,939!



	1993	2007
<u>Waiver</u>	67,294	122,992
<u>PPMP</u>	16,443	39,014
<u>Accreditation/Compliance</u>	68,513	35,837
<u>Exempt</u>	2,490	6,096

# Waived Testing

- Provides for timely, efficient, convenient patient care
- Continues to increase
- Increased testing comes w/ issues:
  - Testing personnel less-trained; may not ID problems
  - No routine oversight w/ no funding/resources
  - Minimal manufacturer recommended QC



# CMS Concerns with the CBC Waiver

- General issues
- Pre-analytical Issues
  - Analytical Issues
- Post-analytical Issues

# General Concerns

- Should an automated differential be categorized as waived? Does it meet definition of “*simple*”?
- How does the device perform under real lab conditions w/ actual testing personnel?
- How are varying hematological clinical conditions & patient populations addressed?
- The level of expertise to operate the device & judgment required to interpret the test results
- Lack of data management capability

# Pre-Analytical Instrument

- Patient Identification (entry/storage of)
  - Number one patient safety issue
- Temperature/Humidity requirements
- Safety & Biohazard issues
- Maintenance

# Pre-Analytical Operator/Instrument

- Operator training is necessary
- Instrument Setup (level of difficulty)
  - Can operator change setup? Or--
  - Can setup features be locked?
- Reagent Preparation
  - Single or Multiple steps?

# Pre-Analytical Specimen Collection

- Detailed instructions for all specimen types (fingertstick, venipuncture, heelstick)
- Increase emphasis on.....
  - Collection technique (bubbles, clotting, volume)
  - Specimen interferences – lipemia, hemolysis
  - Errors due to delay in placing cartridge into device
  - Flags/errors when present?

# Analytical Instrument Validation

- Broaden studies to demonstrate simplicity & robustness of test system
  - Accuracy
  - Precision
  - Sensitivity
  - Specificity
  - Reportable range

# Analytical Instrument Validation

- Clinical validation studies should be expanded to include:
  - Hematological disease states
  - Different patient populations (pediatrics & oncology)
  - Comparison to analyzers w/ different methodologies

# Analytical Reagents & Quality Control (QC)

- Test limitations & precautions noted in PI & flagged?
- Are reagents temperature &/or light sensitive?
- Is the test process time-sensitive?
- QC must be required, at a minimum, w/ each new lot/operator.
- State clearly that external QC must comply w/ local, state & other applicable requirements.

# Analytical Internal QC/Calibration

- Does device have internal QC?
- Is it factory calibrated?
- How frequently are these performed?
- What do they monitor?
- Does the device store the results for retrieval?
- Does it flag the operator if not acceptable? Or Not produce a result?

# Analytical Patient Testing

- How are blood cells counted (technology)?
- Are all types of WBC's identified?
  - Cell size variability addressed?
  - Interfering substances?
- Abnormal cells correctly identified (NRBC's, Blasts, Sickle cells)? Flagged?

# Analytical Patient Testing

- Identify rouleaux, giant platelets, platelet clumps?
- Fail safes for fatal errors?
  - Does the software prevent result reporting?
- Error codes for other unacceptable situations?
  - Can error codes be overridden by operator?

# Post Analytical Results Reporting

- Level of result interpretation (normal vs. abnormal)
  - Abnormal results & error codes flagged?
  - Error codes flagged included on test report?
  - Can results be printed, saved, retrieved?
  - Does manufacturer provide reference ranges?
    - For various clinical/patient populations?

# Summary of General Concerns

- Should an automated CBC & differential be categorized as waived? Does it meet the definition of “*simple*”?
- Level of expertise to operate the device & judgment required to interpret the test results.
- How does device perform under real lab conditions w/ actual testing personnel?
- How are varying hematological clinical conditions & patient populations addressed?
- Is there no risk of harm if performed incorrectly?
- Issues throughout the entire testing process.
- Lack of data management capability.

## Final Comment

Based on the multiple concerns identified w/ this test system, there are still significant potential areas of risk that must be addressed to reduce the likelihood of harm to the patient.

## For Additional Information:

CMS CLIA web site:

[www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia)

CMS Central Office

410-786-3531

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