

CLIA Update 2009

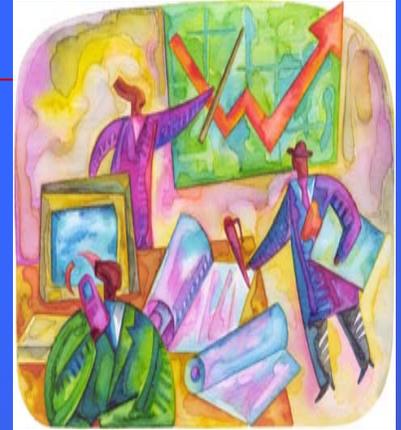
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CLIA Update

Topics for Discussion:

- Current Statistics
- Cytology PT NPRM & Data
- Oversight of Genetic Testing
- PT Regulation Update Plan
- CMS QC Policy
- CLSI EP-23: Alternative QC for Laboratories
- Partners in Laboratory Oversight
- PT Referral
- Waived Test Oversight
- Questions & Answers



Current Statistics

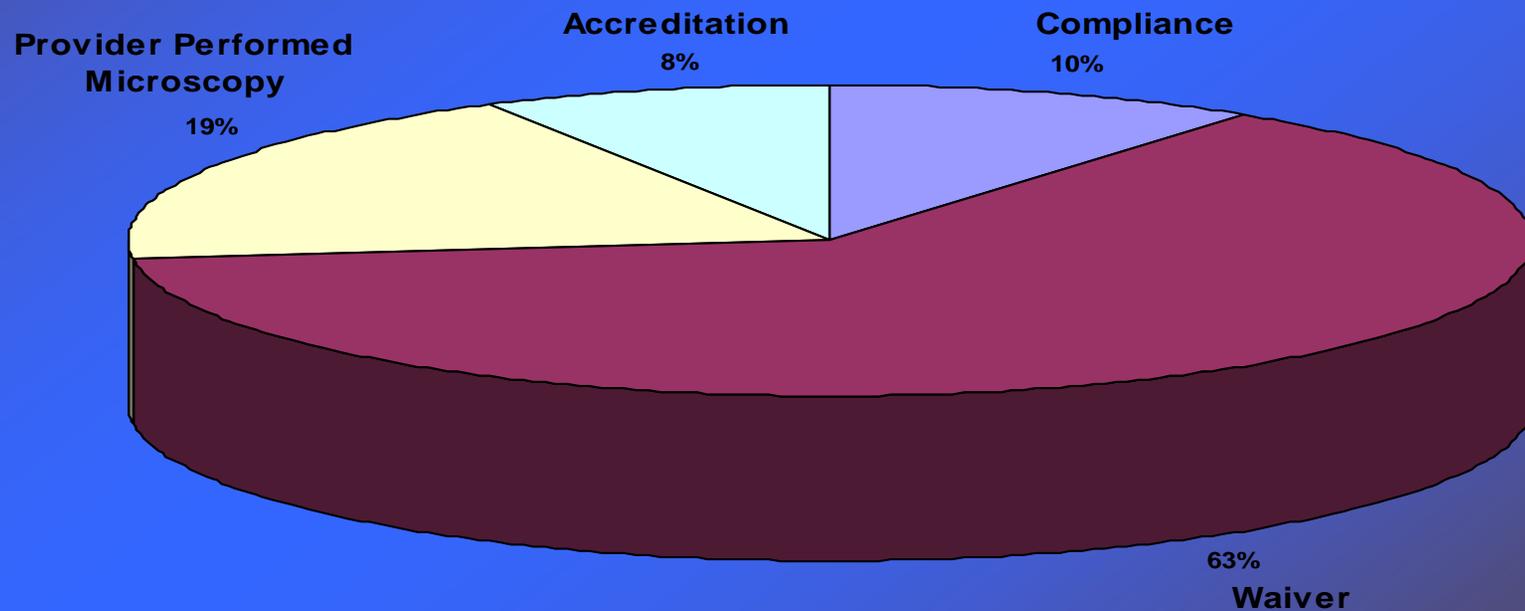
- Total Number of Laboratories: 206,940
 - Compliance: 19,412
 - Accredited: 16,261
 - Waived: 126,219
 - Provider Performed Microscopy: 38,783
 - Exempt: 6,265
 - NY: 3,124
 - WA: 3,141



CMS data base 6/2008

Current Statistics

CLIA Labs by Certificate Type (Non-Exempt Only)

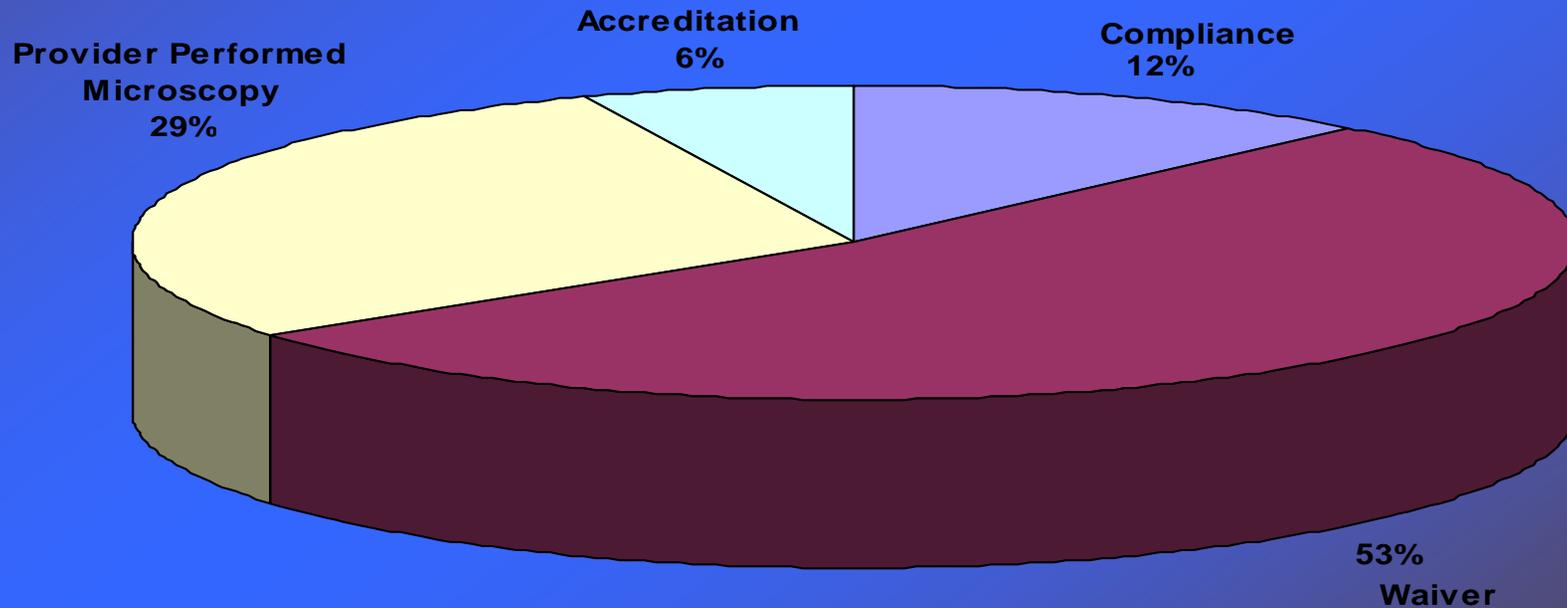


Source: CMS CLIA database 6/10/2008



Current Statistics

Physician Office Laboratories by CLIA Certificate Type (Non-Exempt Only)

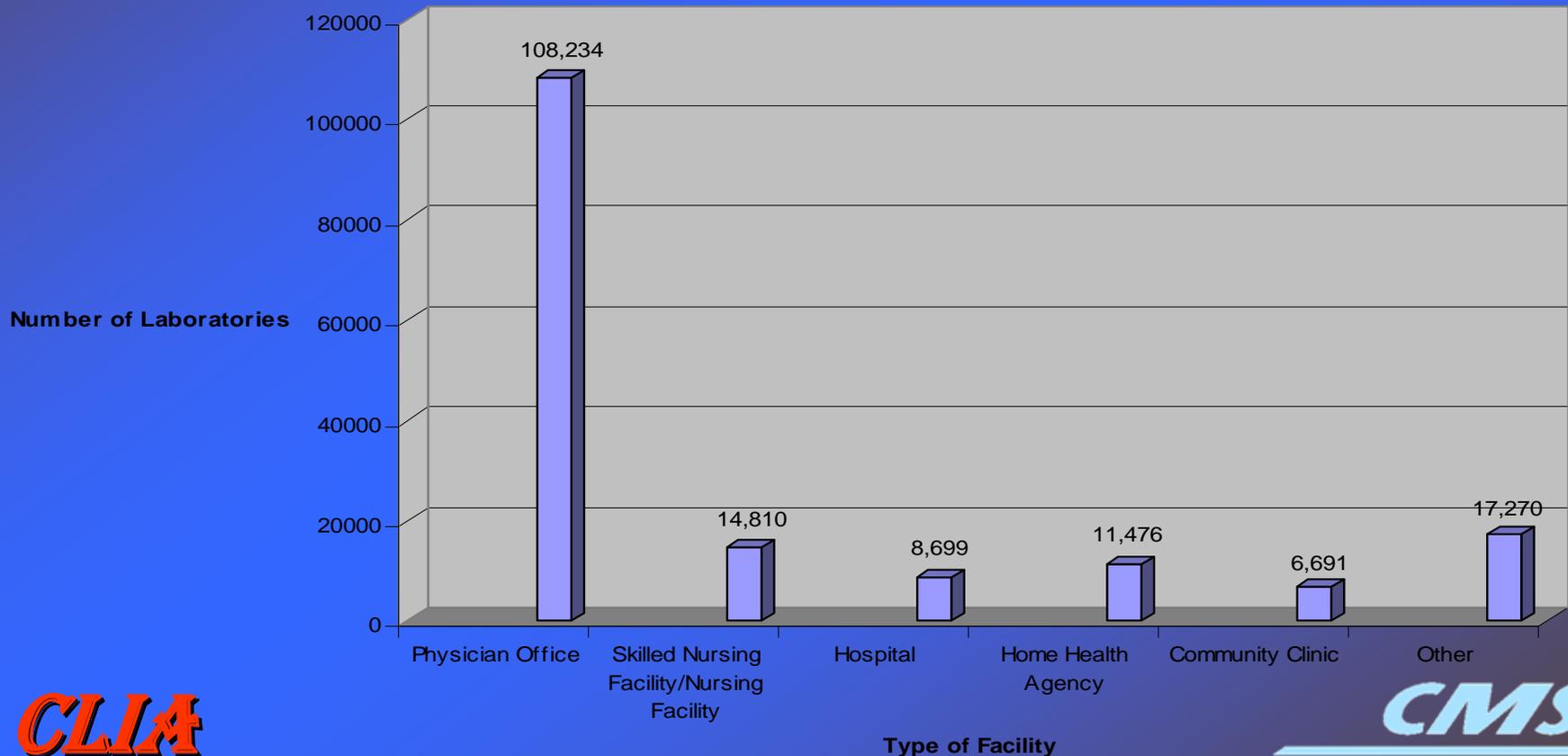


CLIA

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Current Statistics

Total CLIA Laboratories Registered Self-Selected Laboratory Types



Cytology PT

Regulation:

- Proposed rule considers 17 CLIAC recs.
- Published by CMS Jan. 16, 2009.
 - Joint CDC/CMS collaboration.
- Comments due Mar. 17, 2009.
- Contains questions & solicits comments.
- Comments accepted; both pos. & neg.!
- Comments analyzed & final produced.

Cytology PT

Current Regulation

10 Slides/Test
2 Hours/Test
Annual Test

Proposed Regulation

20 Slides/Test
4 Hours/Test
Biennial Test

Test Composition:

1 Unsatisfactory
1 Normal
1 Low Grade (LSIL)
1 High Grade (HSIL)/Cancer (CA)

Test Composition:

1 Unsatisfactory
1 Normal
1 LSIL
2 HSIL or CA

Cytology PT

Current Regulation

1 Missed HSIL/CA=Auto. Fail

Glass Slide Test Only

Slide Field Valid. Not Req'd.

Appeal Process Not Req'd.

Diff. Scoring Grids Path.& CT

Proposed Regulation

2 Missed HSIL or CA
= Auto. Fail

Glass Slide/New Tech.

Slide Field Valid.

Req'd.

Appeal Process Req'd.

Same Scoring Grid

Path. & CT

Cytology PT

2005—FINAL Initial Test (10 slides/2 hrs.)

	<u>Pass</u>	<u>%</u>
CT	6083	93%
Path w/o CT	312	67%
Path w/CT	5242	90%
<u>TOTAL Tested</u>		
12,831	11,637	91%

Cytology PT

2006 - FINAL Initial Test (10 slides/2 hrs.)

	<u>Pass</u>	<u>%</u>
CT	6085	95%
Path w/o CT	372	83%
Path w/ CT	5437	95%
<u>TOTAL Tested</u>		
12,752	11,894	95%

Cytology PT

2007-FINAL Initial Test (10 slides/2 hrs.)

	<u>Pass</u>	<u>%</u>
CT	6057	97%
Path w/o CT	384	89%
Path w/ CT	5566	97%
<u>TOTAL tested</u>		
12,460	12,007	96%

Cytology PT

Comparison of PT Performance

2005	91% passed
2006	95% passed
2007	96% passed

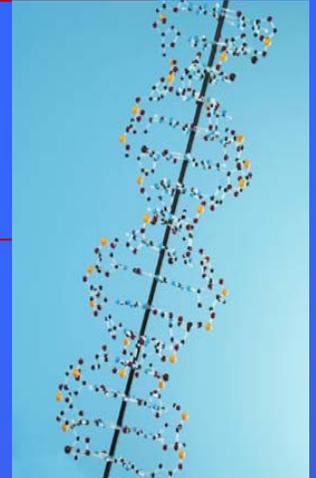


Genetic Testing Oversight

CMS Actions in Lieu of a GT Specialty:

- Provided surveyor education.
- Initiated plan w/ CDC to update PT regulations.
 - Will promote use of formal PT when available.
 - Will evaluate mechanisms for alternative assessment.
- Encouraged public/private partnerships.
- Promoted use/development of prof. standards.
- Hired staff w/ GT expertise.
- Determined existing enforcement is sufficient.

Genetic Testing Oversight



CMS Actions in Lieu of a GT Specialty:

- Seek to enroll more GT labs.
- Monitoring DTC labs ongoing; 117 & counting!
- Expanded CLIA web site w/ certification status.
- Collaborate w/ CDC on MMWR to educate labs.
- Work w/ FDA on test valid. reviews, issues.
- Continue evaluating tests for CLIA coverage.
- Exploring creative survey methods & ensuring consistent, coordinated oversight w/ Partners.

PT Regulation Update

- Plan w/ milestones & est. timeline developed
 - Includes target values, grading criteria, PT providers, labs, PT referral, alternative assessment
 - Requires a proposed rule w/ comment & final
 - No firm ETA
- List of related issues compiled/discussed
- CDC/CMS met a full day in '08 to discuss
- Utilize CLIAC process w/ SMEs from affected parties

PT Regulation Update

- Ongoing teleconf. convened betw. CDC/CMS
- Medicare data reviewed for test frequency
- PT providers' meeting held in Nov.'08
- Evaluating mechanisms for analyte selection.
 - Including genetic tests
- Considering alt. vehicles to publish analyte lists
- CLIAC recommendation to proceed rec'd. '08
- CDC planning WG meeting in 2009.

Changes in QC—“Analytic Systems”--2003

- Verification of performance specifications for mod. complexity tests.
- Clarification of calibration verification (checks).
- QC procedures—2 levels of ext.QC or EQC req'd.
- Initially all 3 were “educational”.
- Pertinent CMS “Brochures” on CLIA web site.

Continue Educational QC, w/ Limited Scope



- *Retain QC (493.1256) as educational !*
 - Effective 12/31/2007
 - CMS labs had 2 ‘educational’ surveys;
 - Should understand & comply.
- **Discontinue as educational/must be met:**
 - Test method verification (493.1253)
 - Maintenance & Function Checks (493.1254)
 - Calibration & Cal. verif. (493.1255)

CMS QC Survey Policy

- Until new QC policies are in place, labs will continue to receive “educational” surveys for *only* QC procedures at 493.1256.
- Labs not meeting QC std, but w/ some QC, receive **letter** urging correction, in lieu of deficiency;
 - *If serious quality issues, QC may be cited.*
- Existing requirements not met continue to be cited on a deficiency statement (CMS-2567).

CMS QC Survey Policy

- Accredited labs continue to meet their AOs QC standards.
- CMS is working w/ AOs to standardize inconsistent policies.
 - Through Partners in Laboratory Oversight.

Status Alternative QC Development



- ‘05 CLSI meeting sponsored by lab prof. orgs., gov’t., industry & AOs, discussed **“QC for the Future”**.
 - *Labs need more info from manufacturers.*
 - *One-size-fits-all QC not good for diff. test systems/labs.*
- Two CLSI docs under development for QC.
 - Alternative QC for labs (*Jim Nichols*) & risk management for manufacturers (*Greg Cooper*).
- Interpretive Guidelines will be revised accordingly.
 - CMS hasn’t determined if EQC will remain.

Status Alternative QC Development

- CMS is working w/ CLSI to develop 2 guidance “Evaluation Protocol” documents.
 - Includes reps from labs, industry & gov’t.
 - Utilizes consensus process.
 - Exciting, groundbreaking efforts nearly complete!
 - Encourage AOs to partake
- *Manufacturers’* - using ISO risk mgt. principles.
- *Laboratories’* - to design custom QC for labs.
- CLSI Subcommittee vote—Fall ’08.



PT Referral **WARNING!**



STOP

- Review & learn CLIA PT regs, Subpart H.
- Do not send a PT sample or partial sample to another lab for testing!
 - Be cautious w/ reflex, confirmatory tests, consults & distributed testing.
 - PT is by certificate; don't send to sister lab w/ different certificate number.
- Do not communicate w/ another lab about PT results.
 - Until after PT program deadline & your results ret'd.
 - QA/PT Coordinators: need robust policies & procedures to avoid perception of cheating.

PT Referral **WARNING!**



STOP

- Report to CMS any PT samples received in your lab from another lab during PT event.
- PT includes analytes **NOT listed** in the regulations.
 - If a CMS approved PT provider is utilized to meet alternative assessment/QA requirements.

PT Referral **WARNING!**



STOP

- PT referral results in the most serious CLIA penalties.
 - Loss of CLIA certificate for one year.
 - Includes cancellation of Medicare/Medicaid payment.
 - Lab dir. (LD) can't direct ANY lab for 2 yrs.
 - Listing on CLIA annual Lab Registry—CMS web site.
- CMS prevailed in all appeals to date.
- CMS sent letter to LDs w/ PT FAQs for labs; now on web.
- CMS main office reviews all cases for accuracy, consistency & to facilitate better policy.

Partners In Laboratory Oversight

- AOs, ES, VA, SA & CMS met since '05 2X/yr.
- Established elevated levels of coordination & collaboration; mutual professional respect
- Improved oversight capability & info sharing
- Presented best practices; defined 'serious' deficiency
- Developing data-driven performance measures
 - Comparison of deficiencies across programs ala GAO
- Continue to ID issues; e.g., CW labs, QC, GT, etc.

CMS Waived Test Concerns

- **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”.

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

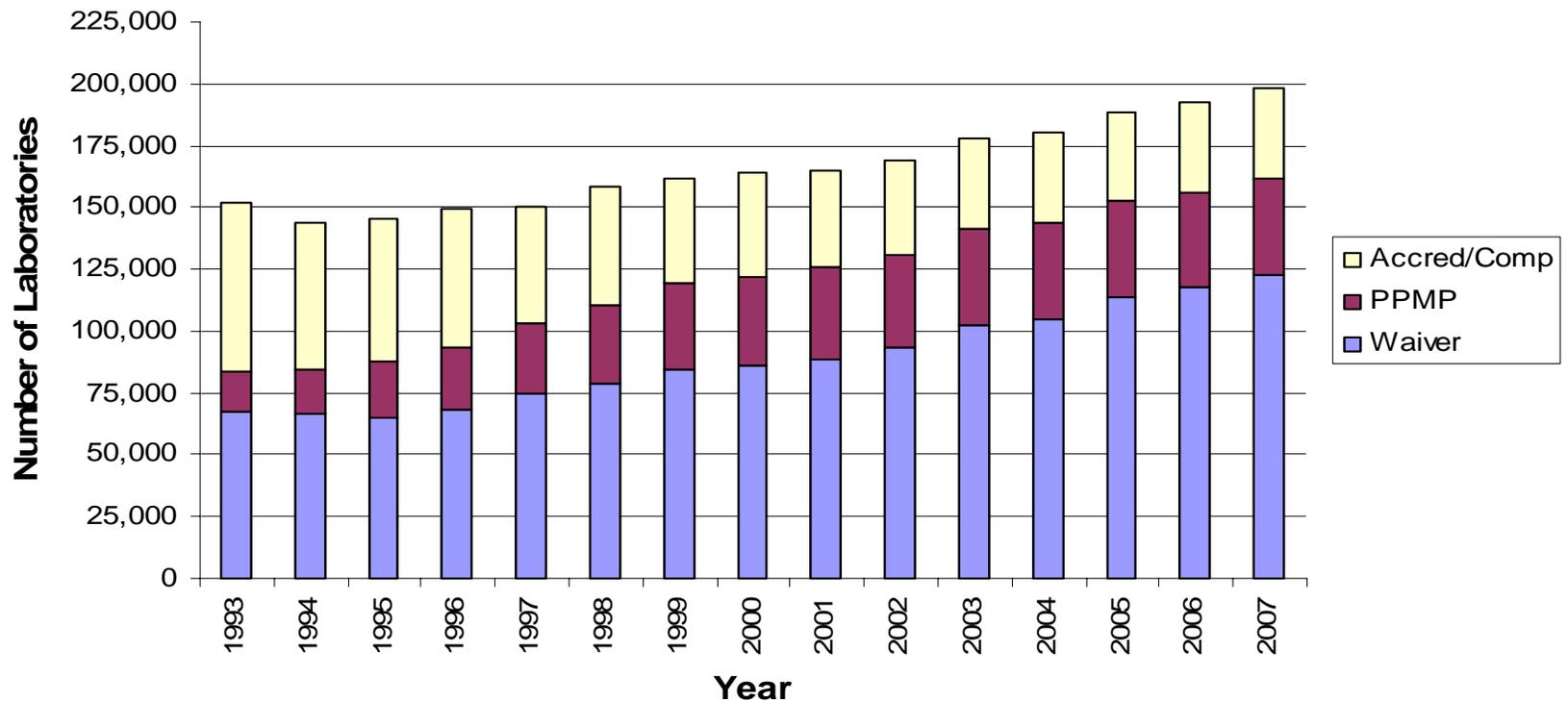


Since 1992.....

- 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 >206,000 laboratories enrolled.

of Non Exempt Labs by Application Type

Non Exempt by Application Type



CMS CERTIFICATE OF WAIVER (CW) PROJECT

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

CMS CERTIFICATE OF WAIVER (CW) PROJECT DATA

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.

CMS CERTIFICATE OF WAIVER (CW) PROJECT DATA

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% 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.

2004 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%)
- CDC & NY studies correspond to CMS’.

(Presentation CLIAC_Waived testing update_Sept 2004.ppt)



Next Steps for Waived Testing.....

- Education is effective.
- CMS developing “Issue” paper w/ multi-faceted recommendations for agency management.
- CMS plans to convene WG w/ Partners.

Where to Find Info:

- CMS CLIA Web site:
 - www.cms.hhs.gov/clia/
 - NEW FEATURE: “Lab Demographic Look- Up”
 - Brochures, state contacts, application, guidelines
- CMS Central Office, Baltimore
 - 410-786-3531
- Judy Yost’s email:
 - Judith.yost@cms.hhs.gov



THE END!!

THANK YOU!!
QUESTIONS???

