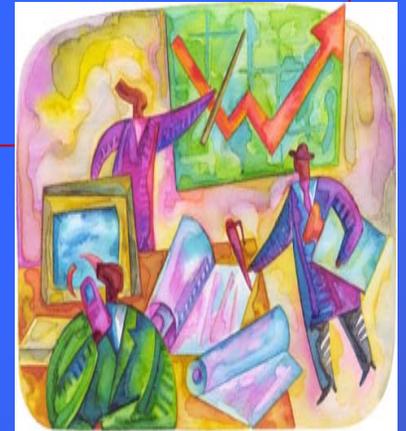


CLIA Update 2008



CLIA Update



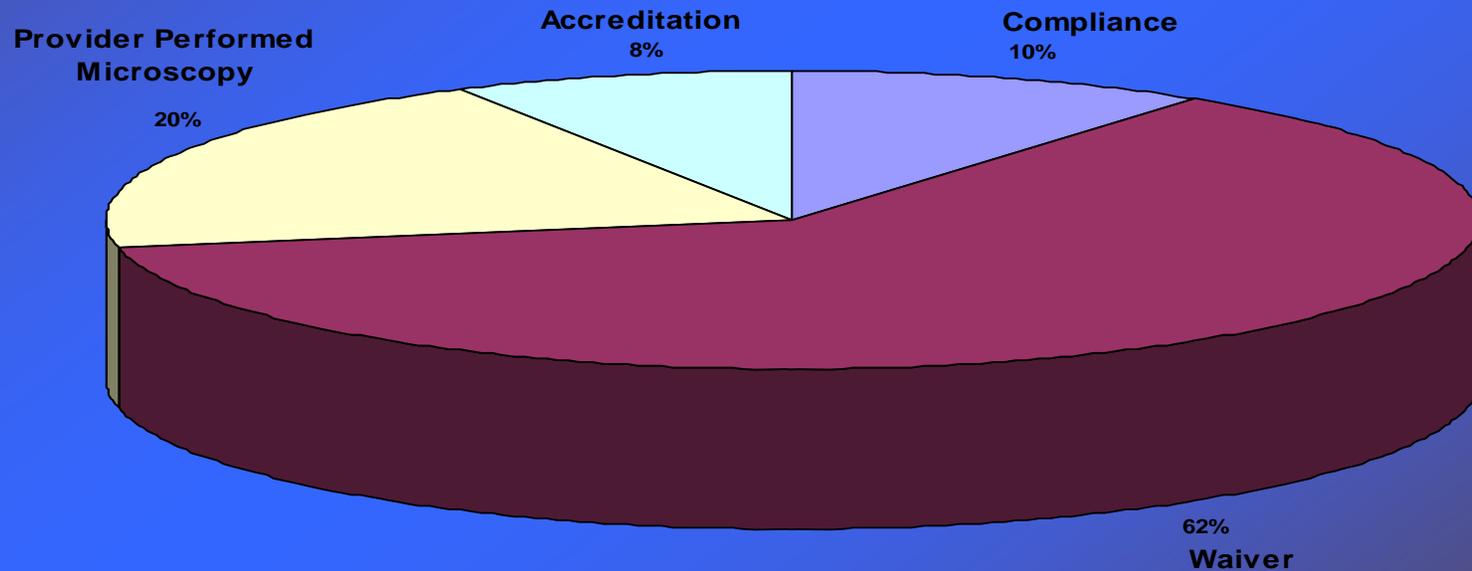
- **Topics for Discussion:**
 - Current Statistics
 - Cytology PT NPRM & Data
 - Oversight of Genetic Testing
 - CMS QC Policy Change
 - CLSI EP-23: Alternative QC for Laboratories
 - PT Referral
 - Complaints
 - Lab Director's Responsibilities
 - Test Report Date
 - GAO Recommendations Follow Up

Current Statistics

- **Total Number of Laboratories: 200,667**
 - Compliance: 19,827
 - Waived: 119,839
 - Provider Performed Microscopy: 38,903
 - Accredited: 16,098
 - Exempt: 6000
 - NY: 2,952
 - WA: 3,065

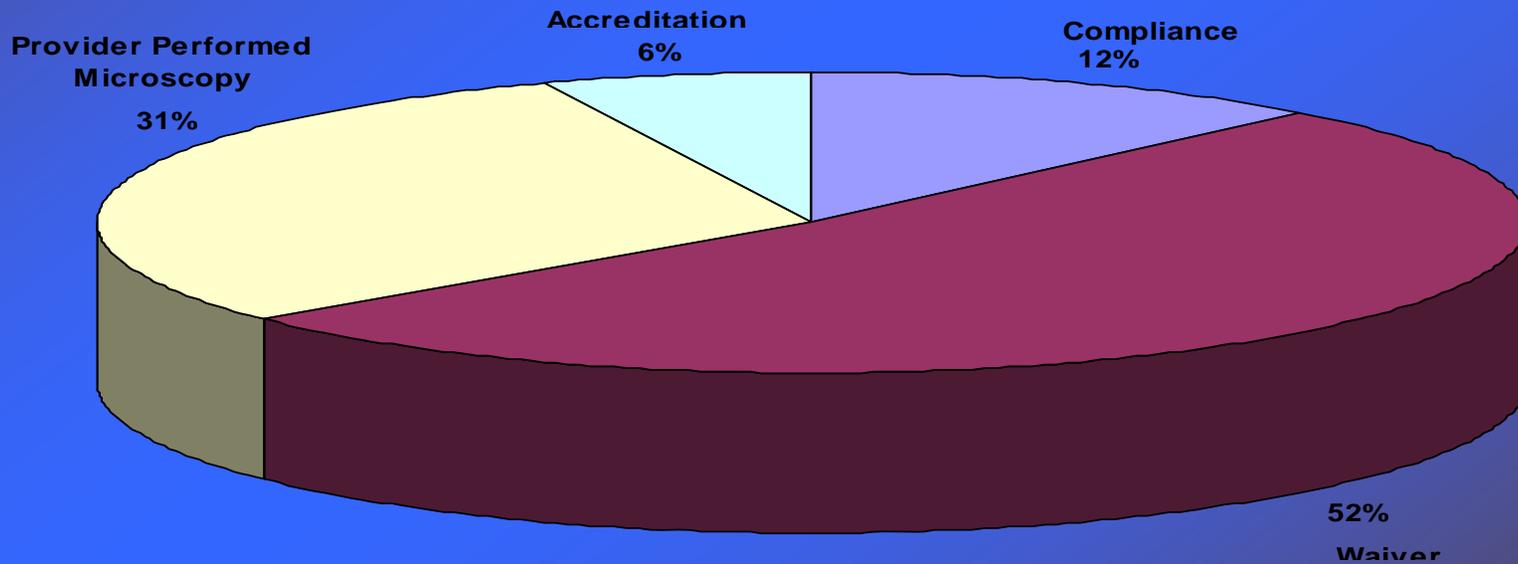
Current Statistics

CLIA Labs by Certificate Type (Non-Exempt Only)



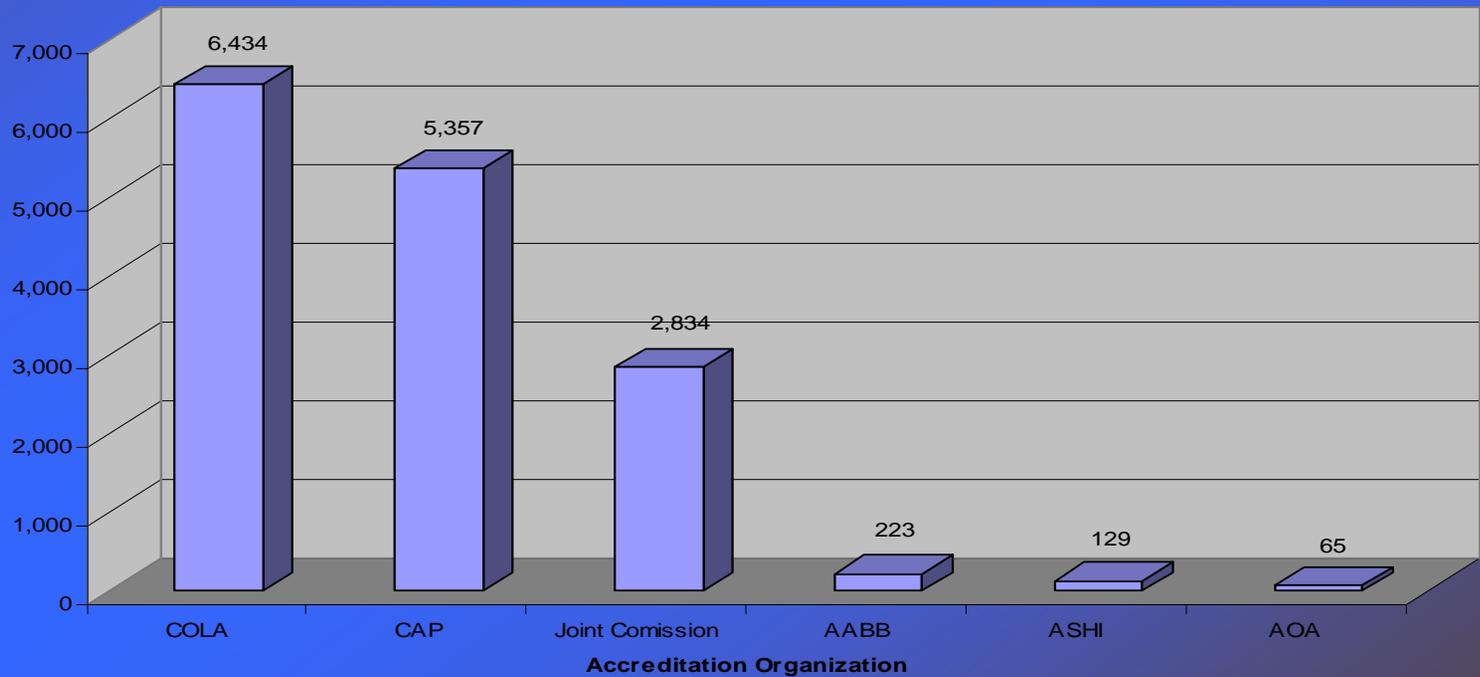
Current Statistics

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



Current Statistics

**Number of CLIA Certificate of Accreditation Laboratories
by Accreditation Organization**



Cytology PT

Regulation:

- Proposed regulation reflects 17 CLIAC recommendations.
- In clearance in HHS;
- Contains questions & solicits comments.
- Comments accepted, both positive & negative!
- Comments then analyzed & final produced.

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	11,654	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 Prelim. Initial Test (10 slides/2 hrs.)

	<u>Pass</u>	<u>%</u>
CT	6052	97%
Path w/o CT	387	89%
Path w/ CT	5544	97%
<u>TOTAL tested</u>		
12,435	11,983	96%

Cytology PT

Comparison of PT Performance

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



Genetic Testing Oversight

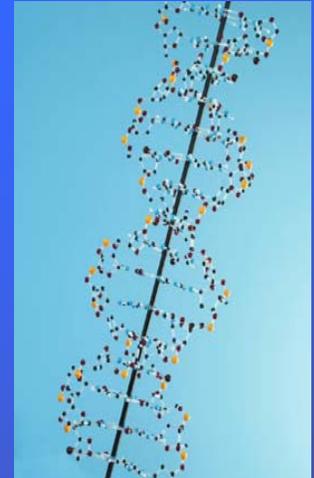
CMS Actions in lieu of a GT Specialty:

- Provided surveyor education.
- Agreed to evaluate PT analyte updates.
 - Will promote use of formal PT when available.
 - Will evaluate mechanisms for alternative assessment.
- Encouraged public/private partnerships.
- Recommended use of professional standards.

Genetic Testing Oversight

CMS Actions in lieu of a GT Specialty:

- Seeks to enroll more GT labs.
- Monitoring DTC labs ongoing.
- Expanding info on CLIA web site.
- Continues to collaborate w/ CDC & FDA.
- Evaluating tests for CLIA coverage.
- Exploring creative mechanisms to survey GT labs.



Changes in QC—“Analytic Systems”--2003

- Verification of performance specifications for mod. complexity tests.
- Clarification of calibration verification (checks).
- QC procedures—2 levels of external QC required.
- Initially all 3 of these were “educational”.
- 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:**
 - 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 receive “educational” surveys for only QC procedures at 493.1256.
- Labs not meeting QC stds. receive a **letter** urging them to correct;
 - Unless there are serious quality issues.
- Existing requirements not met continue to be cited on a deficiency statement (CMS-2567).
 - **Calibration, cal ver. , test method verif., & function checks now in this category!!**

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



- 2005 CLSI meeting sponsored by lab prof. orgs., government, industry & AOs, discussed a plan for “QC for the Future”.
 - *Labs need more info from manufacturers.*
 - *One-size-fits-all QC doesn't work for diff. test systems & methods.*
- Two CLSI docs under development re QC.
 - Alternative QC for labs & risk management for manufacturers.
- Interpretive Guidelines will be revised accordingly.
 - CMS hasn't determined if Options 1-3 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.
 - Utilizing a consensus process.
 - Exciting, groundbreaking efforts.
- *Manufacturers* using ISO risk mgt. principles.
- *Laboratories’* guidance to design custom QC.



Avenues for Filing Complaints

- GAO expressed concern; Guidance found in--
 - Interpretive Guidelines
 - CMS web site
 - Soon-to-be released “Brochure”
 - CMS letter to professional orgs.
 - States have 800#
 - CMS offices via email, letter, v. mail, fax, etc.
 - Public presentations
- CMS data system tracks & monitors; include AOs later.
- Complainant can be anonymous.
- All complaints accepted & followed up.

PT Referral **WARNING!**



STOP

- Do not send any PT sample or part of a sample to another lab for testing!
- Do not communicate w/ another lab about PT results.
- Report to CMS any PT samples you receive in your lab from another lab during the PT event.
- This 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, whether intentional or not, 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 has prevailed in all appeals to date.
- CMS sending letter to LDs.
 - Contains PT do's & don't's for labs.
- CMS will develop PT Brochure.

Lab Director Info

- CMS regions identified fraudulent CLIA applications.
 - Could bill Medicare for nonexistent testing.
- Qualifications now reviewed prior to data entry.
- May visit unannounced to verify lab's existence.
- CMS created “mandatory” citations; include personnel qualifications.
 - If not met, automatic condition level deficiency.
 - Not “educational”.

CMS' Top 10 Deficiencies— Helpful Hints!

- Don't forget: analytes not listed in the regulations as requiring PT require 2X/yr. accuracy check.
 - Monitor test menu, so as not to miss any!
- You must follow manufacturer's instructions in addition to meeting CLIA QC;
 - CLIA supersedes if more stringent.
- There must be a QA plan in place & followed for ea. phase of testing: general, pre, analytic, post.

CMS' Top 10 Deficiencies— Helpful Hints!

- Test report requires certain elements:
 - Critical w/ advent of EHR & pervasiveness of LIS;
 - includes date report issued on report.
- Avoid using expired reagents:
 - Monitor inventory & workload;
 - Develop & follow purchasing & storage policies.



CMS' Top 10 Deficiencies— Helpful Hints!



- Procedure manual is required for all tests.
 - Have available, follow & LD signed
 - Retain ea. procedure for 2 yrs. following its demise w/ initial & final dates.
- Specimen integrity is vital to producing good results.
 - Have procedures to monitor specimens from collection to result reporting.
- *LD usually cited when serious problems found!*

GAO Report Follow UP

- **Recommendation:** Compare survey findings across survey organizations.
- **Status:** Data collected & compiled; serious deficiency defined via Partners in Lab Oversight; further review planned.
- **Recommendation:** Provide no more than 2 weeks advance notice of surveys.
- **Status:** Done.

GAO Report follow up

- **Recommendation:** Ensure consistency by convening a WG; clarify “educational” surveys via training; provide clear policy.
- **Status:** 2 wk. long state surveyor training courses conducted; multiple policies disseminated; interpretive guidelines being updated; data repts. analyzed ongoing.

GAO Report follow up

- **Recommendation:** Monitor survey deficiencies, including repeat deficiencies.
- **Status:** Entire CLIA data system being upgraded; all entities monitor/track repeat deficiencies & repeat enforcement actions.
- **Recommendation:** Provide more & better options to file a complaint.
- **Status:** On CMS/CLIA web site; letter to orgs.; brochure drafted; complaint system tracks; in guidelines; public presentations.

GAO Report Follow up

- **Recommendation:** Do PT four times/year.
- **Status:** Disagree; current method scientifically valid.
- **Recommendation:** Review AO re-approval aps & interim standards' changes timely.
- **Status:** WG convened; most aps in house are timely; all interim changes approved.
- **Recommendation:** Use CLIA funds to hire staff.
- **Status:** 5 FTE's hired.

GAO Report Follow up

- **Recommendation:** Perform enough federal monitoring surveys of state surveyors to ensure good performance.
- **Status:** Done; annual report created.
- **Recommendation:** Ensure that AO validation surveys are primarily independent instead of simultaneous.
- **Status:** Done (never was a problem!)

Where to Find Info

- CMS Web site:

- www.cms.hhs.gov/clia

- Brochures, state/ regional contacts, application

- CMS Central Office, Baltimore

- 410-786-3531

- Judy Yost's email:

- Judith.yost@cms.hhs.gov



THE END!!

**THANK YOU!!
QUESTIONS???**

