

CLIA Update 2007

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CLIA Update

- **Topics for Discussion:**
 - Current Statistics
 - Cytology PT NPRM
 - Electronic Health Records & CLIA
 - State surveyor consistency training
 - Oversight of genetic testing
 - CLSI EP-23: Alternative QC for Laboratories
 - PT Policy



CLIA Update

- Total Number of Laboratories: 198,232
 - Compliance: 20,026
 - Waived: 117,418
 - Provider Performed Microscopy: 38,814
 - Accredited: 15,957
 - Exempt: 6017
 - NY: 2,952
 - WA: 3,065

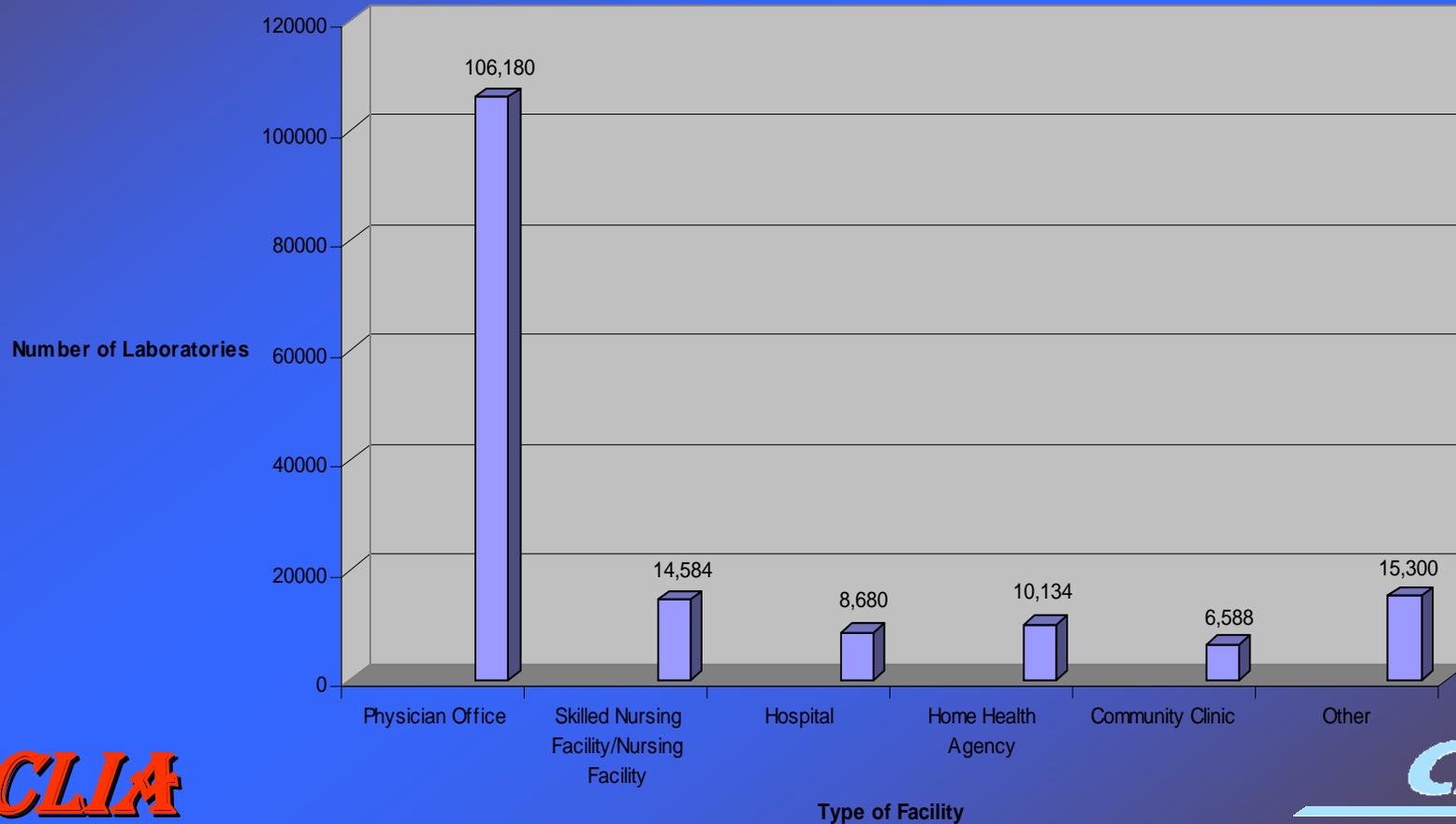


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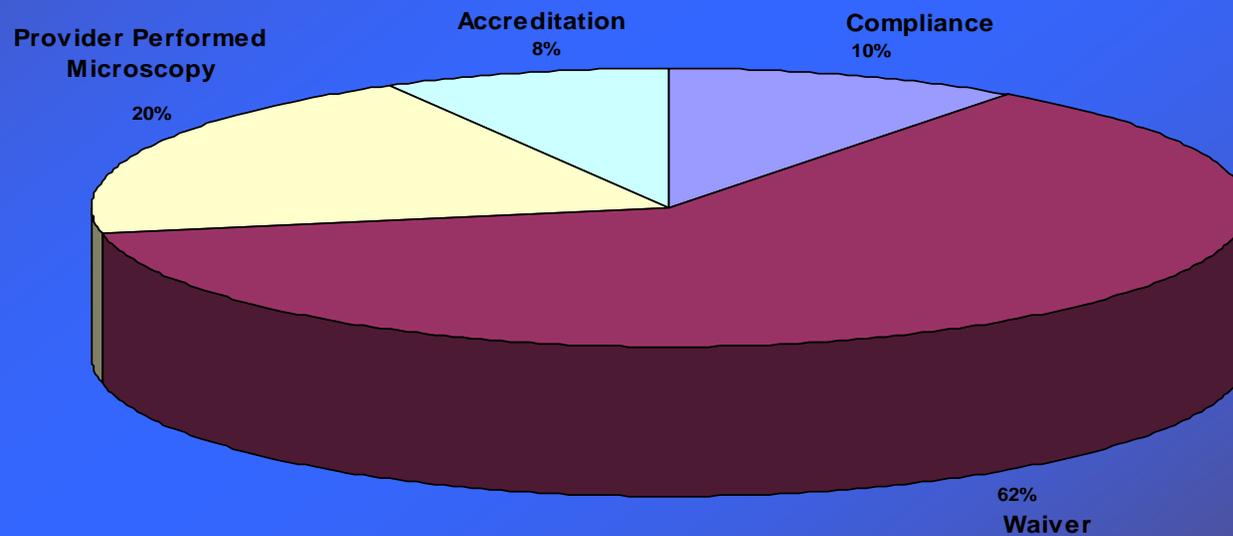
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Total CLIA Laboratories Registered Self-Selected Laboratory Types



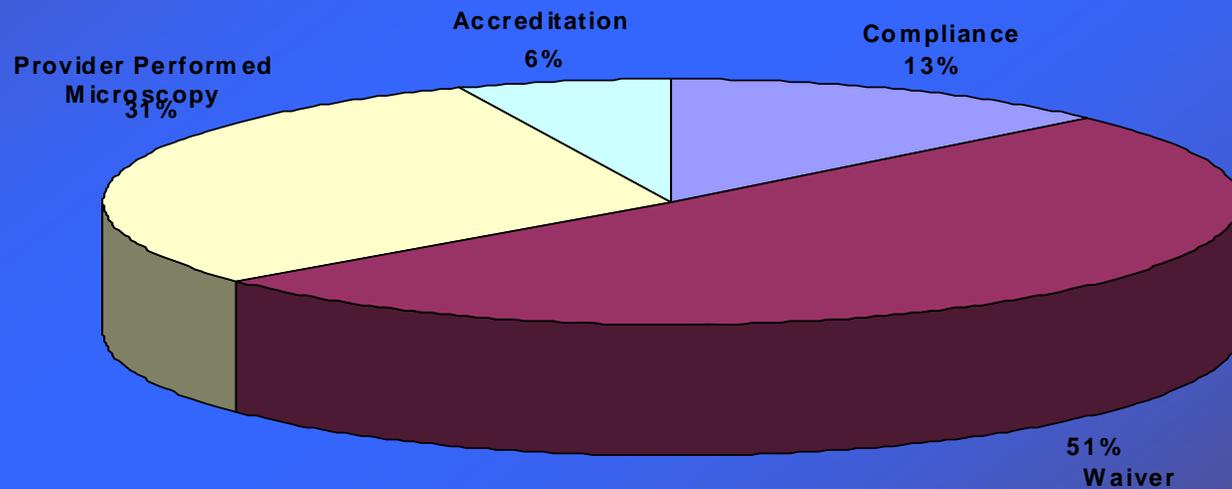
CLIA Update

CLIA Labs by Certificate Type (Non-Exempt Only)



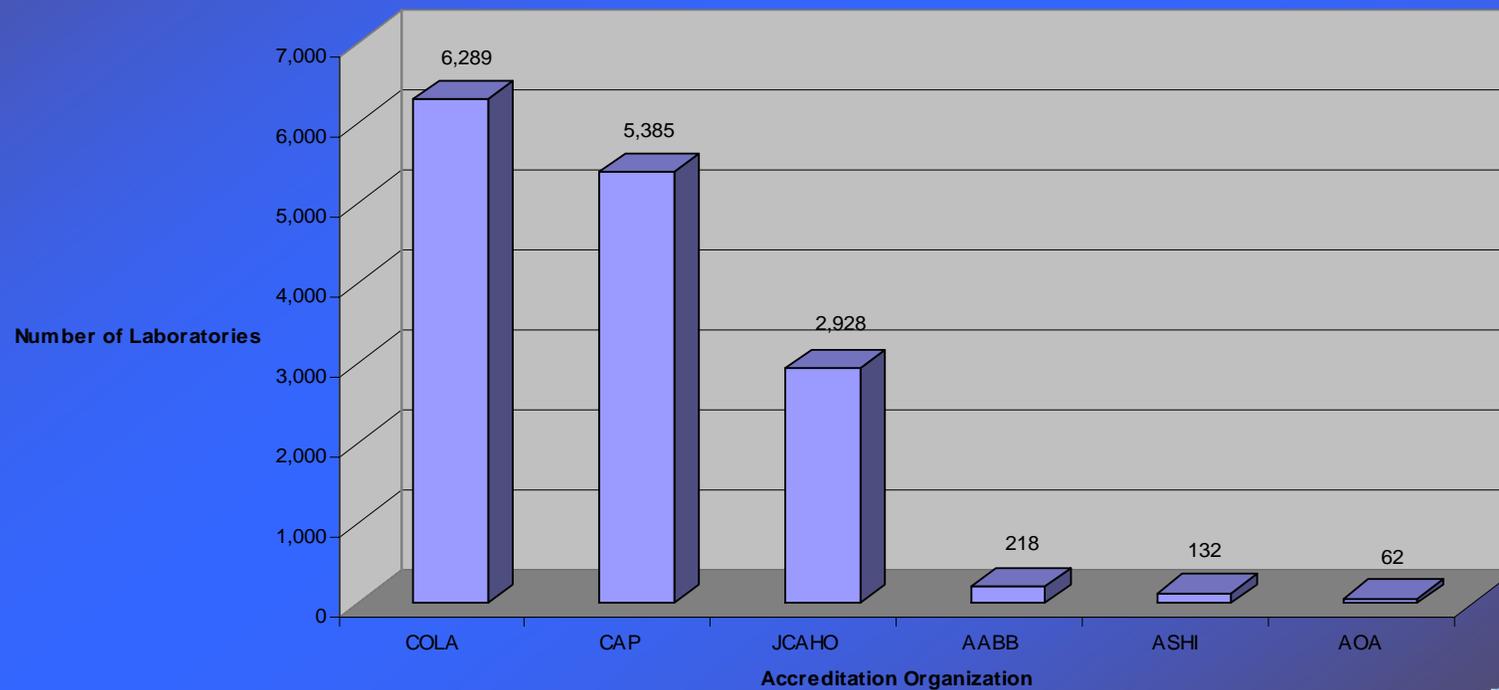
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Physician Office Laboratories by CLIA Certificate Type (Non-Exempt Only)



CLIA Update

Number of CLIA Certificate of Accreditation Laboratories
by Accreditation Organization



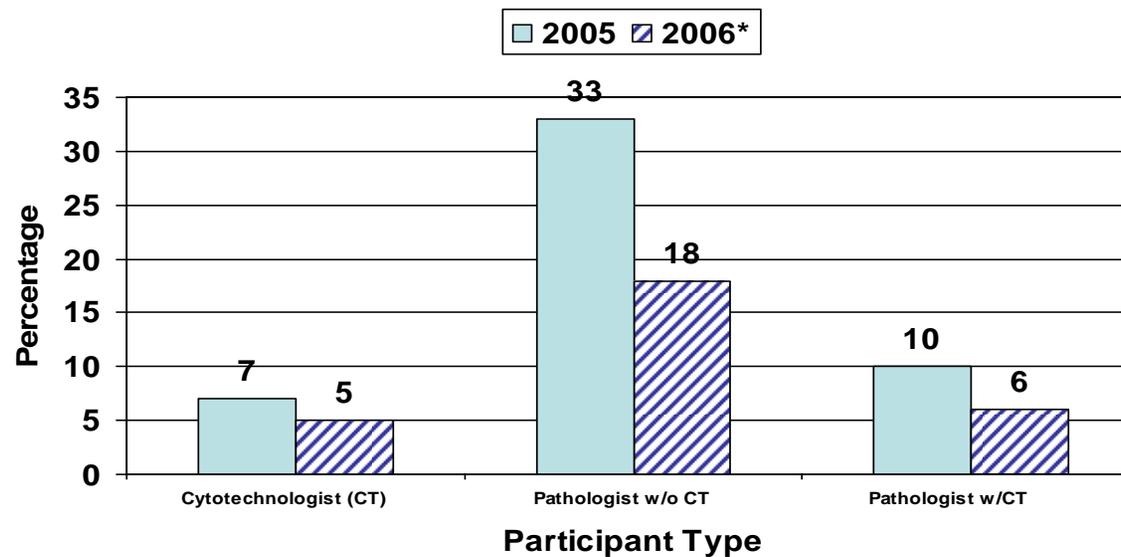
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- Cytology NPRM (Notice of Proposed Rulemaking)
 - Revisions demanded by cytology community, supported by CLIAC;
 - CMS offered numerous opportunities to assist with compliance, listen, educate & communicate;
 - CMS/CDC convened special CLIAC WG & mtg.;
 - CMS collaborating w/ CDC to develop NPRM.
 - Cytopath. representatives propose legislation to derail CLIA statutory provisions for “individual” testing.
 - *Pathologists w/o a cytotech continue to fail > others.*

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Failure Rates First Proficiency Test



* Preliminary 2006 data (January 1- December 5, 2006)

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- Electronic Health Records (EHR)
 - Major initiative of the Secretary of DHHS;
 - Laboratories will be the prototype.
 - CLIA requires accurate, reliable, timely & confidential transmission of patient test results to the “user” or authorized person;
 - Also requires certain elements be included in the report.
 - CMS working w/ attnys. to retain the integrity of CLIA & incur minimal burden for vendors & labs via policies or creative solutions, where possible.

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- State Surveyor Consistency Training:
 - CMS recognized problem;
 - Confirmed by '06 GAO report;
 - CMS conducted comprehensive training '06;
 - Further focused, interactive training in late '07;
 - CMS WG reviewing survey & enforcement data;
 - CMS central office collaborating w/ regional CLIA reps to facilitate consistency; and
 - Providing detailed policies & procedures, regular calls & conferences for regions & States.

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- Oversight of Genetic Testing:

- HHS rec'd. recommendations to augment CLIA from advisory committees;
- In lieu of more regulations, increase awareness & training;
- New regulations won't solve paucity of PT/QC or provide clinical validity reviews;
- Develop creative survey options;
- Educate labs; collect data; and
- Collaborate w/ genetic testing community, government agencies & other experts to facilitate design of PT & QC options.

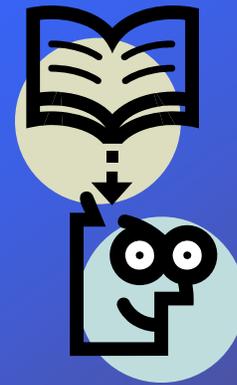


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- **CLSI Evaluation Protocol (EP)- 23**
 - Custom Guidance for alternative QC protocols for laboratories;
 - Based on the lab's unique circumstances:
 - Patient population,
 - Personnel competency,
 - Test systems utilized, and
 - Environmental issues.
 - Development underway by CLSI consensus process w/ nationally recognized experts from industry, gov't. & laboratories.



CLIA Update

- New & Improved CMS PT Policy:
 - Failure to enroll &/or perform successfully are mandatory *condition* level citations.
 - Defines & outlines process for unsuccessful PT; i.e., 2/3 or 2 consecutive failures in a rolling timeframe;
 - Intentional referral or communication of PT results for analytes listed or not in regulations requires automatic loss of CLIA certificate for 1 yr. & LD can't direct for 2 yrs.
 - Affects all sites under LD's responsibility.

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- Where to Find CLIA Info:
 - CMS CLIA Web site:
 - www.cms.hhs.gov/clia
 - CMS Central office in Baltimore:
 - 410-786-3531
 - Judy Yost's email:
 - judith.yost@cms.hhs.gov



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THANK YOU!!!

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THE END!!

Questions???



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