

CLIA UPDATE

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CLIA

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CENTERS for MEDICARE & MEDICAID SERVICES

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Topics for Discussion:

- Partners in Laboratory Oversight
- QC for the Future
- GAO Audit
- Automated Complaint Tracking System
- Current Statistics
- Genetic Testing Proposed Rule
- Certificate of Waiver Project
- Introduction to Cytology PT

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Partners in Laboratory Oversight

- Membership
- Accomplishments
- Current projects
- Future Projects



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QC for the Future

- Background
- CLSI Manufacturers' Guidance Document
 - Risk Management
- CLSI Laboratory Guidance Document
- 2006 CLSI Leadership Conference
- CMS Surveyor Interpretive Guidelines



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GAO Audit

- Background
 - Who, what when, where?
- Status/ETA
- Impact



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Automated Complaint Tracking System (ACTS)

- Receives and tracks all complaints.
- How are complaints handled by CMS?
 - Currently
 - New system
- Advantages
 - Standardized, comprehensive
 - Reliable national data



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Statistics

Total Labs 195,000

Total POLs 106,000

Certificate Type

Compliance 20,000

14,000

Waiver 113,000

53,000

PPM 39,000

32,000

Accredited 16,000

6,000

Exempt

NY (no POLs) 3,000

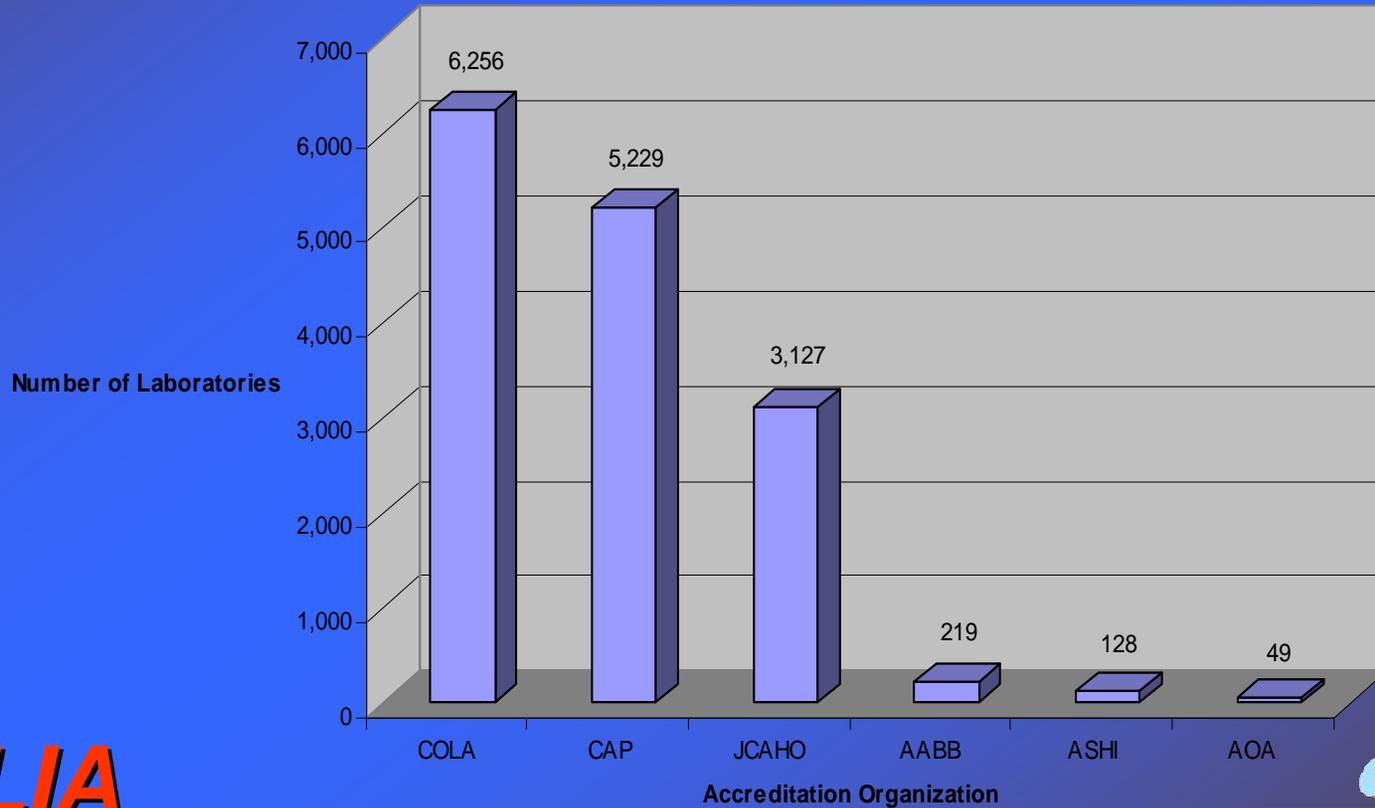
WA 3,000

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Number of CLIA Certificate of Accreditation Laboratories
by Accreditation Organization

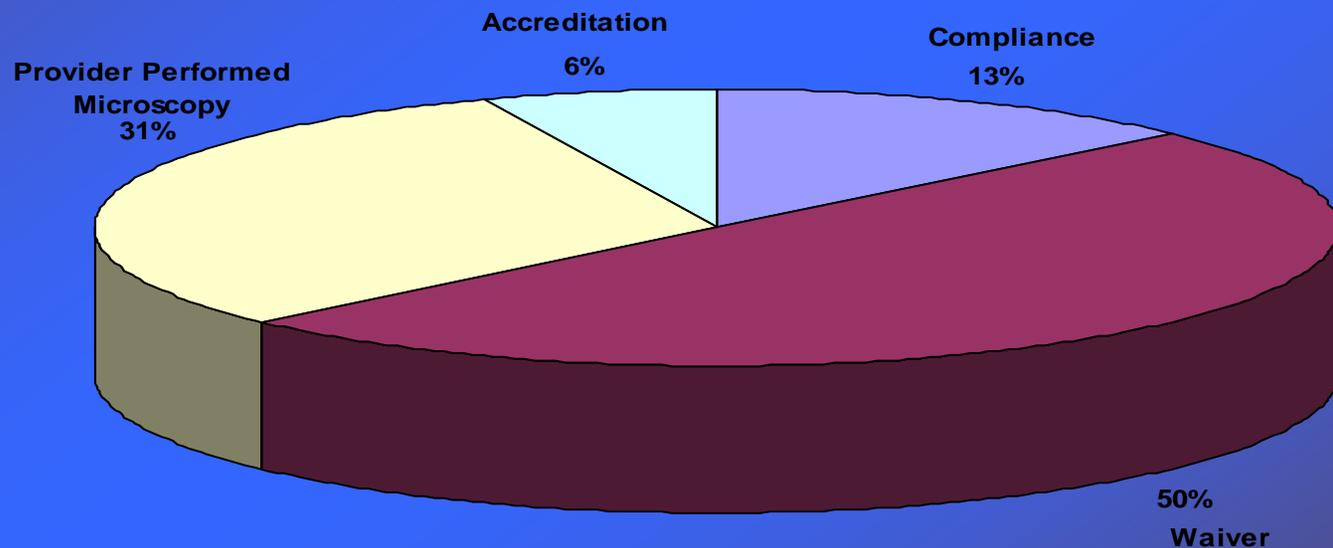


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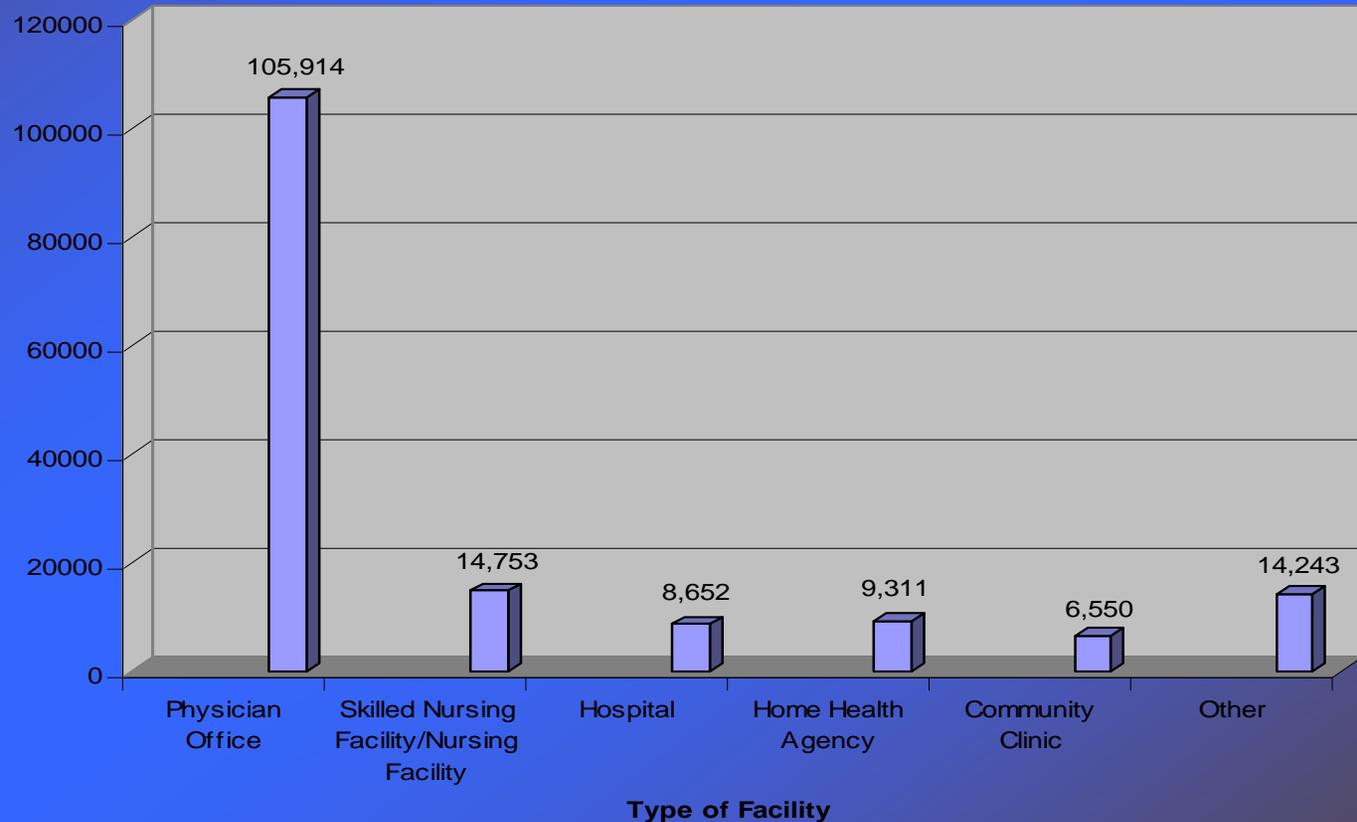
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Physician Office Laboratories by CLIA Certificate Type (Non-Exempt Only)



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Total CLIA Laboratories Registered Self-Selected Laboratory Types



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Genetic Testing Proposed Rule

- In case you were wondering....
- CLIAC & SACGT recommendations
- Some in 2003 QC Rule
- ETA??????
- We need your comments on unresolved issues!!



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Certificate of Waiver Study

- Final year of current approval
- Issue paper to continue
- CMS GPRA goal
- Education facilitates improved performance
 - MMWR document w/ best practices
- Number of CW labs continues to grow
- Technology is revolutionary
- Role of new FDA Guidance



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Cytology PT Introduction.

- 2005--first year of national cytology PT.
- Data reflects the need for the test.
- CMS strongly supports this effort.
- Challenges for the future.
- Educational again for 2006.



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For further information, please visit:

- www.cms.hhs.gov/clia/

Or call CMS Central office at:

- 410-786-3531

Judy Yost's email:

- Judith.yost@cms.hhs.gov



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Thank you!!

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