

## Major CLIA Accomplishments

- Improved laboratory test quality since 1992.*
- Convened Partners in Laboratory Oversight in '04.*
- Converted to new complaint tracking system in '06.*
- Instituted performance stds. & FMS for States.*
- Published enhanced QC stds., corresponding guidance & brochures.*
- Implemented national cytology PT in '05.*
- Continued educational waived lab visits.*
- Initiated performance meas. for accrediting orgs.*

# CMS/CLIA Responses to GAO Report

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# CMS/CLIA Responses to GAO Report

## Background

- Maryland General Hospital debacle.
  - Serious quality/management problems identified by complainant.
  - Poor communication & coordination by oversight agencies.
  - Two Congressional hearings convened.
- GAO audit--Laboratory Quality initiated Jan. '05; concluded Mar. '06; report May '06.



# CMS/CLIA Responses to GAO Report

## GAO Findings/Recommendations:

- CLIA has not improved the quality of laboratory testing;
- Insufficient data exists to demonstrate CLIA's effect;
- Requirements for oversight agencies should be standardized to compare their performance.

# CMS/CLIA Responses to GAO Report

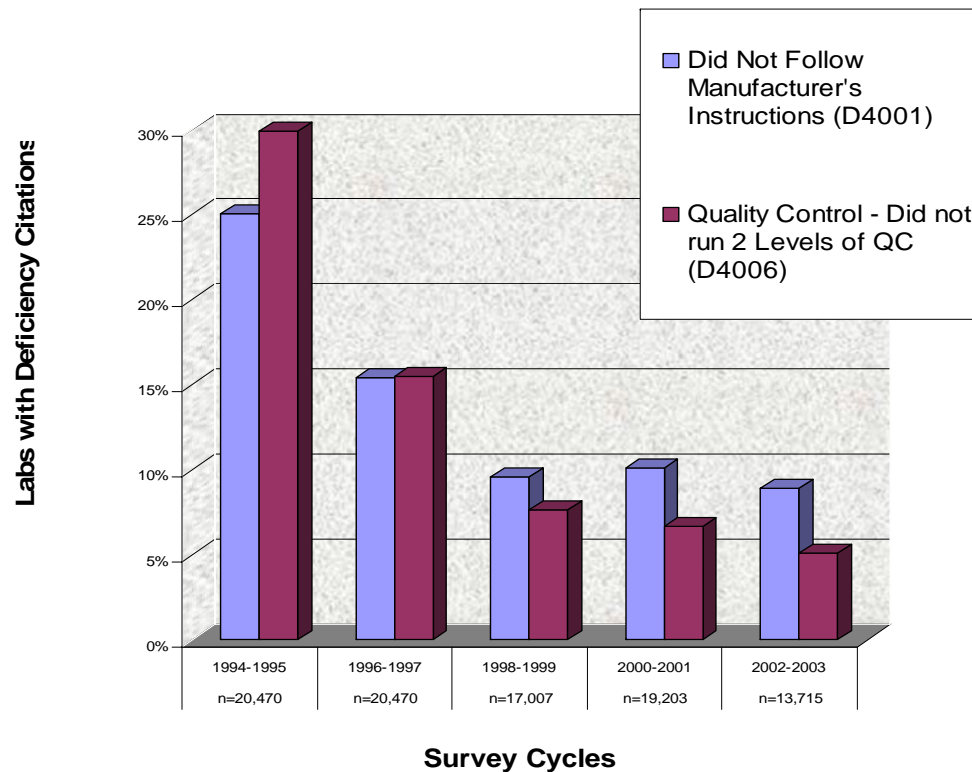
## CMS Response:

- CLIA has improved lab quality. Data reflects:
  - Ongoing improved lab performance for quality-related requirements.
  - Significant numbers of survey deficiencies are identified.
- CMS lost some historical data during a recent system conversion, but has hard copies.
- See next slides.



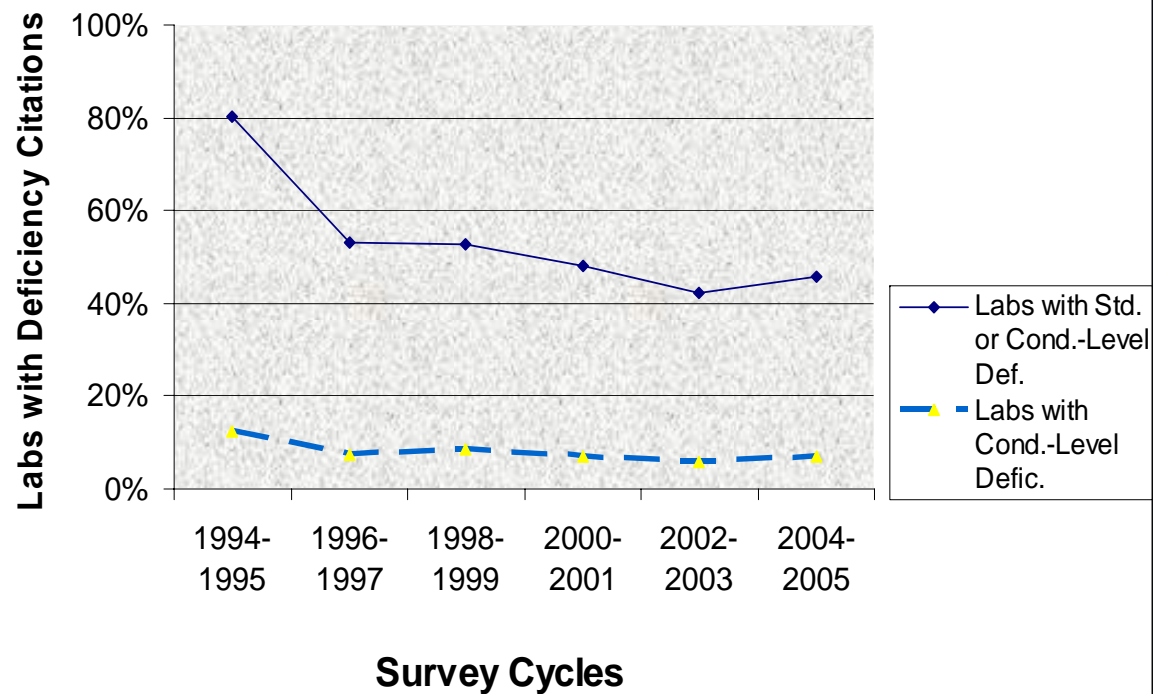
# CMS/CLIA Responses to GAO Report

## Top Quality Control (QC) Deficiencies



# CMS/CLIA Responses to GAO Report

## Labs with Deficiency Citations



# CMS/CLIA Responses to GAO Report

## CMS Actions:

- Complete re-design of existing data system including:
  - Refinements to monitor repeat deficiencies,
  - Labs that have lost accreditation,
  - Enhanced enforcement applications,
  - Specialized monitoring reports &
  - Extensive archiving capabilities.





# CMS/CLIA Responses to GAO Report

## CMS Actions:

- Monitor labs w/ potential for serious problems more closely, consistently.
- Continue to work with Partners in Lab Oversight to develop performance meas. reflecting AOs' *enforcement* of standards.
  - CLIA regs don't require AO stds. be the same; but equivalent (can be more stringent).
  - Validation surveys already monitor AO performance.
- Define serious problems consistently for all oversight orgs.



# CMS/CLIA Responses to GAO Report

## GAO Findings/Recommendations:

- Provide minimal advance notice of surveys to small labs; e.g., physician offices.

# CMS/CLIA Responses to GAO Report

## CMS Response/Actions:

- CMS believes that announced surveys w/ minimal lead time are effective.
  - Unannounced surveys will add significant costs & no benefits.
- CMS will request that no AO have greater than the 2 weeks notice CMS provides.
- CMS may conduct a pilot study to explore possible advantages to unannounced surveys.

# CMS/CLIA Responses to GAO Report

## GAO Findings/Recommendations:

- Maintain an appropriate balance between education & enforcement in CLIA.

# CMS/CLIA Responses to GAO Report

## CMS Response:

- CMS' policy has always been to cite applicable deficiencies when identified, but to provide the lab an understanding of the regulations & resources they may utilize to achieve compliance prior to the imposition of sanctions —*unless there is a threat to patient health & safety.*



# CMS/CLIA Responses to GAO Report

## CMS Response/Actions:

- *Education has achieved the desired result—improved laboratory testing!*
- CMS will conduct comprehensive surveyor training.
- CMS will continue to monitor SA & regional office performance.
- CMS convened a Consistency WG to minimize variability of survey, complaint & enforcement findings.



# CMS/CLIA Responses to GAO Report

## GAO Findings/Recommendations:

- Educational periods for CLIA QC & cytology PT are too long.

# CMS/CLIA Responses to GAO Report

## CMS Response:

- CMS is working w/ CLSI on new QC policies. In the interim, no deficiencies are cited if the lab is doing QC. **If no QC, it is cited.** Labs that don't get citations & haven't met '03 QC regs, rec. a letter describing the stds. not met; this **data is compiled by CMS & monitored.**

**CLIA**

**CMS**  
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# CMS/CLIA Responses to GAO Report

## CMS Response:

- Due to the long lead time until nat'l. cytology PT was available, CMS won't fail individuals if they enroll & are tested according to the regulations.
  - Reg changes are in progress via CLIAC.
  - **Current requirements preclude testing when failures occur at certain intervals to prevent cont'd. patient testing by problem individuals.**
- Consistent with ongoing CMS policy for any new requirements/programs.

**CLIA**

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# CMS/CLIA Responses to GAO Report

## GAO Findings/Recommendations:

- Impose sanctions on labs with repeat deficiencies.

# CMS/CLIA Responses to GAO Report

## CMS Response:

- CMS' policy is to utilize a progressive enforcement approach for successive offenders.
- Not all subsequent citations that are similar are true repeats.
  - Data must be analyzed to confirm.



# CMS/CLIA Responses to GAO Report

## CMS Actions:

- CMS will develop a system & reports to monitor repeat deficiency citations more closely.
- CMS will ensure that appropriate enforcement actions are imposed more consistently when these circumstances are confirmed.



# CMS/CLIA Responses to GAO Report

## GAO Findings/Recommendations:

- Post signs in labs to allow employees to have a mechanism to report complaints.

# CMS/CLIA Responses to GAO Report

## CMS Response:

- CMS receives many complaints & investigates them all.
- CMS has a new, sophisticated complaint data system to track them.
- Most States already have a complaint line in place.

# CMS/CLIA Responses to GAO Report

## CMS Actions:

- CMS placed a notice on the CLIA web site describing how & where to file a complaint.
- CMS added language to the Surveyor Interpretive Guidelines w/ same information.
- CMS will require AOs to submit their complaints to its new data system to provide the 1<sup>st</sup> nat'l. complaint data & to ensure AOs follow up their complaints.



# CMS/CLIA Responses to GAO Report

## GAO Findings/Recommendations:

- Complete AO re-approvals timely.
- Utilize CLIA user fee reserve funds to acquire adequate staffing.



# CMS/CLIA Responses to GAO Report

## CMS Response:

- CMS has approved each AO several times & determined them to be equivalent to CLIA.
- Therefore, CMS is now focusing its oversight on performance; that is, the AOs' *enforcement* of its standards.



# CMS/CLIA Responses to GAO Report

## CMS Actions:

- CMS convened a WG of Partners to develop performance measures for oversight.
- CMS is developing a streamlined AO review process.
- CMS is exploring add'l. CLIA FTEs.



# CMS/CLIA Responses to GAO Report

## GAO Findings/Recommendations:

- Ensure AO validation surveys are independent, not simultaneous.
- Ensure that Federal Monitoring Surveys (FMS) of State surveyors are independent.

# CMS/CLIA Responses to GAO Report

## CMS Response:

- Presently 88% of validation surveys of accredited labs are independent.
- CMS regional surveyors will determine how best to monitor the performance of State surveyors using the outcome-oriented survey protocol.

# CMS/CLIA Responses to GAO Report

## CMS Actions:

- CMS will ensure that all State surveyors have an FMS to ensure optimal performance.
- CMS is conducting comprehensive training for States.

# CMS/CLIA Responses to GAO Report

## GAO Findings/Recommendations:

- The CLIA statute requires PT to be done quarterly, not 3X/year as it is currently—unless the Secretary has scientific or technical reasons why it should be done less frequently.

# CMS/CLIA Responses to GAO Report

## CMS Response:

- Previously PT was 4X/yr., w/ 3 specimens=12 samples/yr.
- Now PT is 3X/yr., w/ 5 samples= **15 samples/yr.!**
- CDC determined via a probability chart that 3X/yr. w/ 5 samples is **most effective** to identify problems & prevent good lab failures.
- This constitutes scientific & technical rationale to adjust the statute & was approved by CMS/HHS legal counsel.

**CLIA**

**CMS/**  
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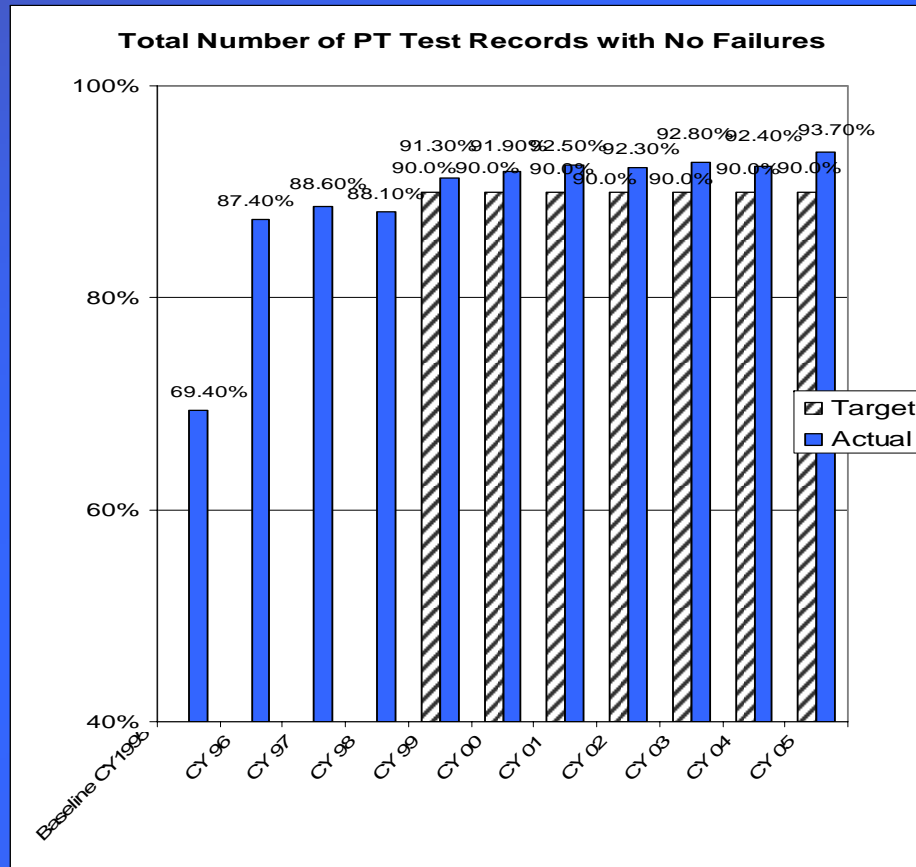
# CMS/CLIA Responses to GAO Report

## CMS Response to GAO:

- *CMS' PT data reflects continuous improved performance since the inception of CLIA.*
- GAO indicated that CLIA had no impact on lab quality.
- See next slide.



# CMS/CLIA Responses to GAO Report



# What Will Labs See in Response to GAO?

- More consistent citations at the appropriate level by CMS surveyors.
  - More follow up on deficiency statements/plans of correction.
  - Progressive, consistent enforcement by CMS regions for true repeat deficiencies.
- Continued educational approach, with deficiencies cited when found.
- Increased mechanisms to file complaints confidentially.
- Continued monitoring of data to improve lab & program performance.

# Where Do I Get More Info??

- CMS Web site:
  - [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia)
- CMS Central office:
  - 410-786-3531
- Judy Yost's email:
  - [Judith.yost@cms.hhs.gov](mailto:Judith.yost@cms.hhs.gov)



# CMS/CLIA Response to GAO Report

Thank You!!  
Questions?????



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