

CMS CLIA UPDATE



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Topics for Discussion

- CLSI QC for the Future Meeting-- March 18
- Partners for Laboratory Oversight Meeting
- Certificate of Waiver 2003 Data Summary
- General Accounting Office (GAO) CLIA Audit
- Maryland General Hospital Update
- Implementation of Cytology PT

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- CLSI QC for the Future Meeting

- Questions & issues about EQC and
- CLIA Final regulations for QC.
- Includes reps from industry, labs & gov't.
- Plenary –nationally recognized speakers.
- Breakouts to discuss alternative QC ideas, new technologies, lab issues & other findings.
- Outcome will be QC Plan for the Future.



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- Partners for Laboratory Oversight Mtg.
 - Includes reps from AOs, exempt states, CDC, CMS, SAs with lab regulatory programs, VA.
 - Goal is to improve information sharing & develop more effective survey protocols.
 - Second meeting in Atlanta-highly motivated group.
 - Outcome is a plan to improve communication & to implement a better survey process.
 - Ongoing meetings to share best practices, resolve differences, etc.

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- Maryland General Hospital

- Serious quality issues identified due to a former employee's complaint.
- Highly visible due to public health implications.
- Lab management and lab infrastructure faulty.
- QC records intentionally falsified.
- Has been inspected numerous times and determined to be in compliance.

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- GAO Audit

- GAO is Congressional oversight agency.
- Audit about lab quality oversight requested by Rep. Elijah Cummings of Baltimore.
- Initiated at CMS Jan. 6.
- Evaluating oversight of AOs and SAs.
- Concerned about test quality in waived labs.
- Interviewing CMS, CDC, FDA, SA, AOs, etc.

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Certificate of Waiver (COW) Update

Events transpired since Sept. 2004 CLIAC

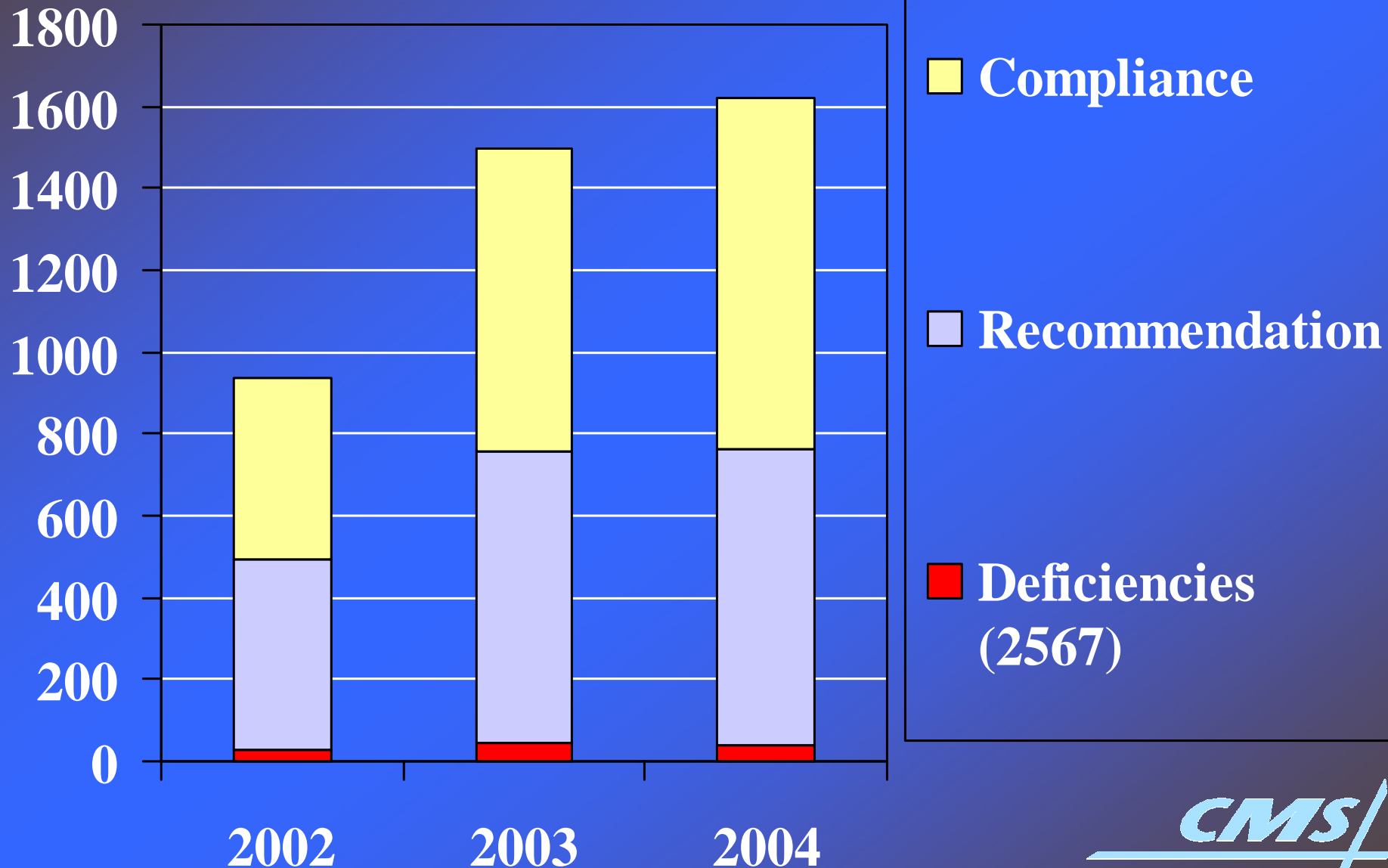
- Reviewed 2003 & 2004 Data
- Verified Data
- Beginning to evaluate data...

CMS CLIA UPDATE- COW

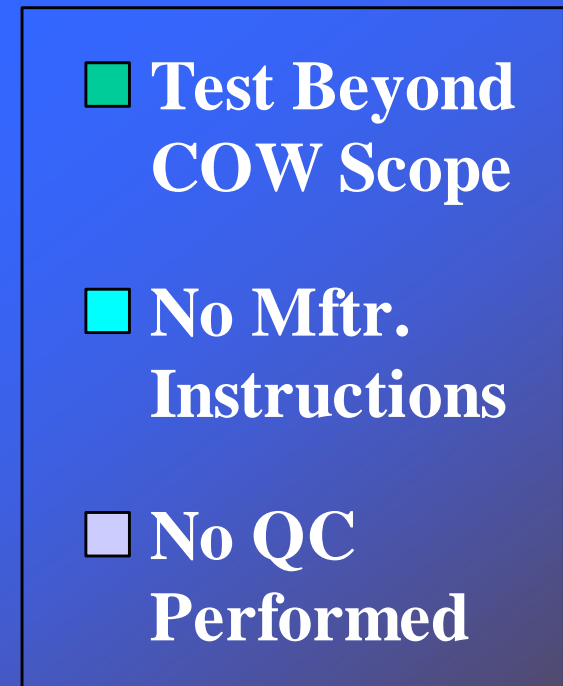
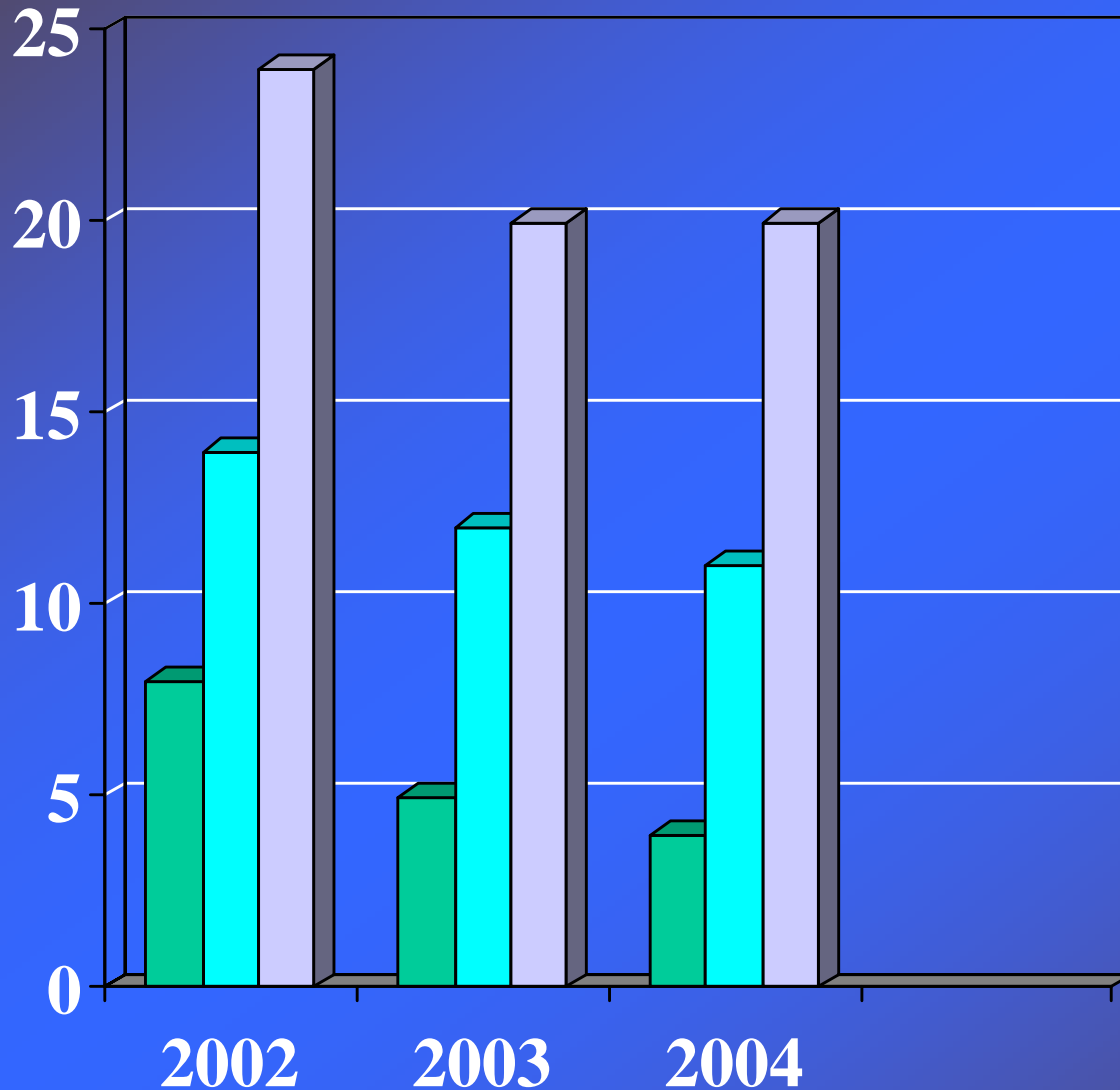
To improve the quality of the 2005 data:

- Enhancements made to database
- Require SA- RO review data before finalized
- Provided surveyor training with periodic updates via e-mail, newsletter, conference call

COW- Survey Actions



COW- Non-Compliance (%)



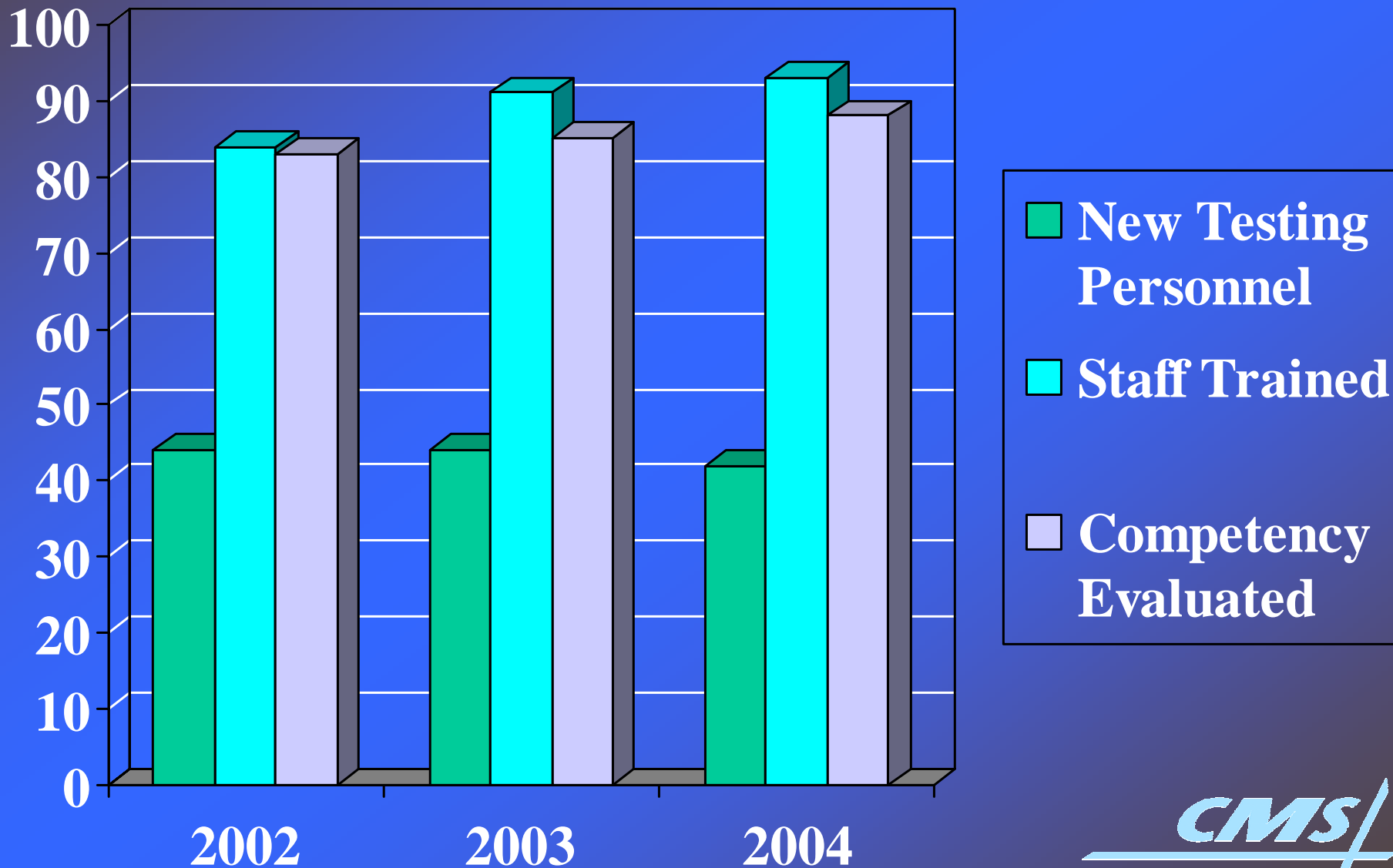
COW- Risk of Harm

Immediate Jeopardy (IJ) identified

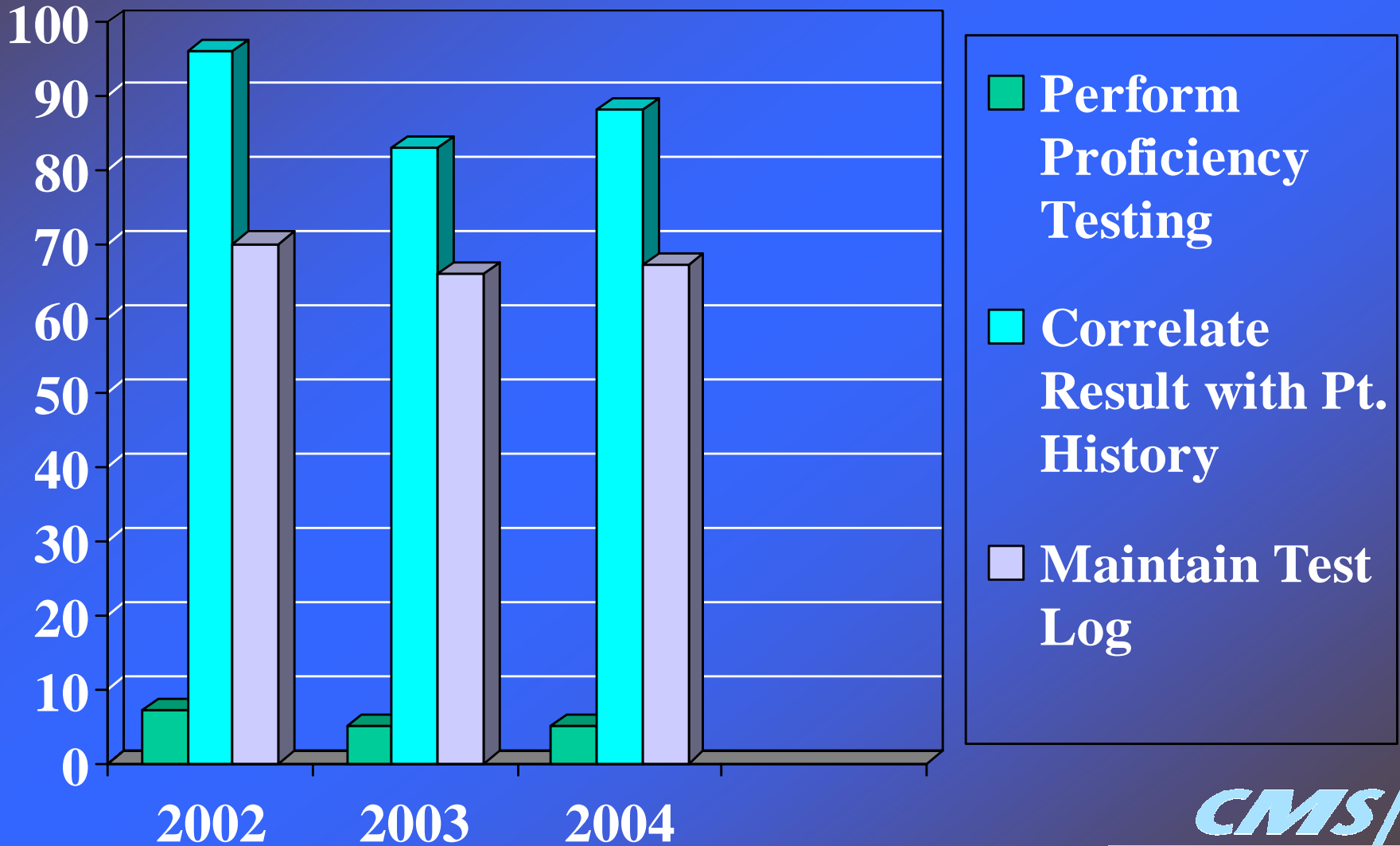
2*	3	2
(897)	(1575)	(1742)
2002	2003	2004

* 1 found from Complaint

COW- Personnel & Training (%)



COW- Good Lab Practices (%)



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Cytology PT-Background

- Incorrect Pap smear results & lack of cytology workload limits--impetus for CLIA '88 law.
- Regulations implementing the law very prescriptive.
- No organization interested in developing a nat'l. program—cost, burden, technology & liability issues.
- CDC made numerous efforts & convened meetings.

Cytology PT-Implementation

- 1994 State of Maryland program approved
- 2004 Midwest Institute for Medical Education, Inc. approved

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- For further information:
 - Visit the CMS/CLIA website at:
 - www.cms.hhs.gov/clia
 - Call CMS CLIA Division at:
 - 410-786-3531
 - Email Judy Yost at:
 - jjyost@cms.hhs.gov



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THE END!!

THANK YOU!!

QUESTIONS???



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