Clinical Laboratory Improvement Amendments of 1988 (CLIA)

NATIONAL CYTOLOGY PROFICIENCY TESTING

Centers for Medicare & Medicaid Services
Division of Laboratory Services
Survey and Certification Group
May 2008

CLIA
Enacted 1988 / Regulations Issued 1992

- Sets minimum quality standards for all clinical laboratories – based on complexity of tests
- Pap smear accuracy was major concern

3 "pillars" of CLIA include:

- Qualifications of laboratory personnel
- Quality control / quality assurance procedures
- Proficiency testing for persons performing laboratory tests (including cytology)

CLIA
Enacted 1988 / Regulations Issued 1992
RESPONSE

- CLIA Statute does not require specific standards for proficiency tests.

- "The main problem stems from excessive technician workloads and the lack of continuing medical education programs for both technicians and physicians."

  --Senate Report 100-561

Definition of Cytology

The science that deals with the formation, structure, and function of cells.

Importance

- Screening Pap smears detect changes in cervix before they develop into cancer
- Approximately 60,000,000 Pap smears performed (1998-2000) *
- 74% decrease in cervical cancer deaths

* *Unpublished data - NIH/NCI*

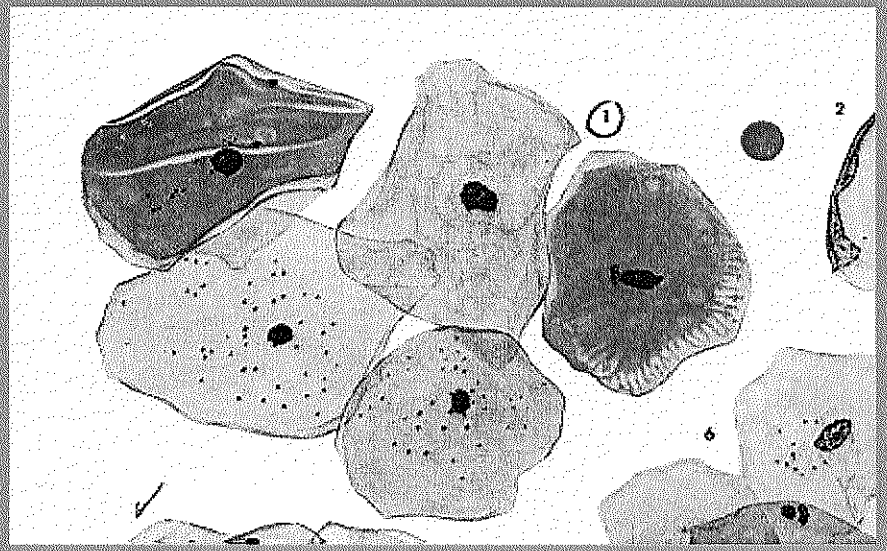
Importance
RESPONSE

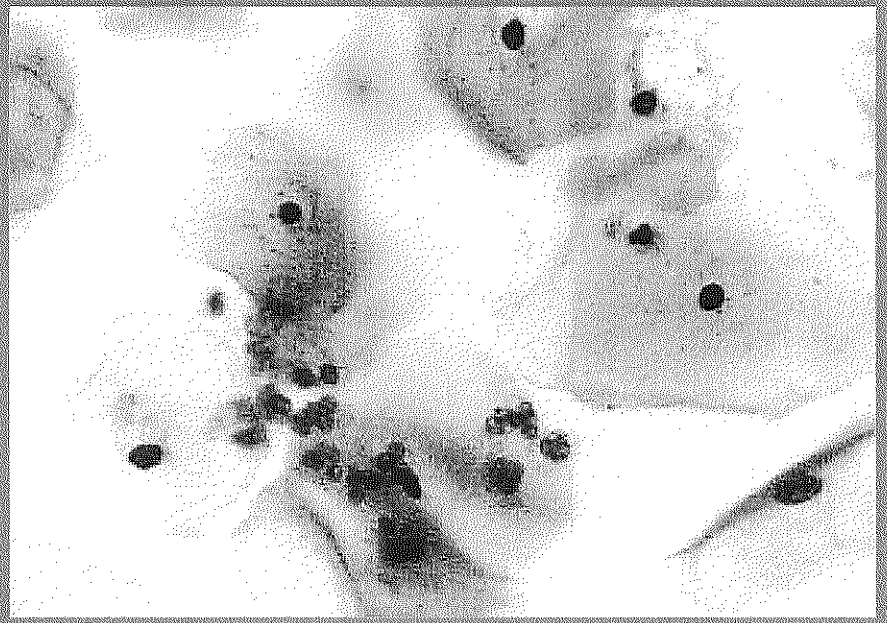
- In 1992, Pap smear only screening technique available – PT model viewed in that context.
- Since then, several new scientific technologies developed for screening, including HPV Typing, computer-assisted screening, digital imaging, and Thin Prep (mono layer of cells).
- 74% decrease in cervical cancer deaths cannot be correlated to the existence of proficiency testing.

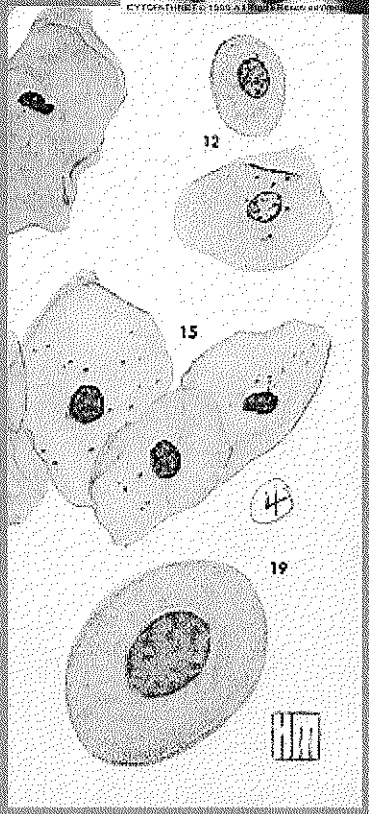
Importance RESPONSE Cont.

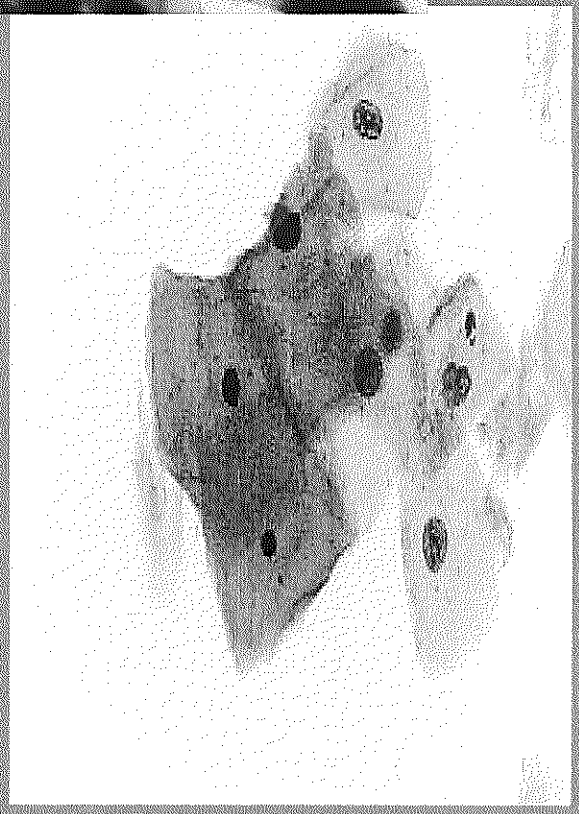
- Screening, follow-up, re-screening important for detection and treatment.
- Given slow progression of disease "repeated screening more effective in detecting abnormalities" (AHRQ, 1999)
- Of women with invasive cervical cancer 60 percent had never been screened or had not been screened in the last five years (Sawaya, 1999)
- Of women with abnormal pap smears 10 percent do not return for follow-up (Sawaya, 1999)

Normal Squamous Cells

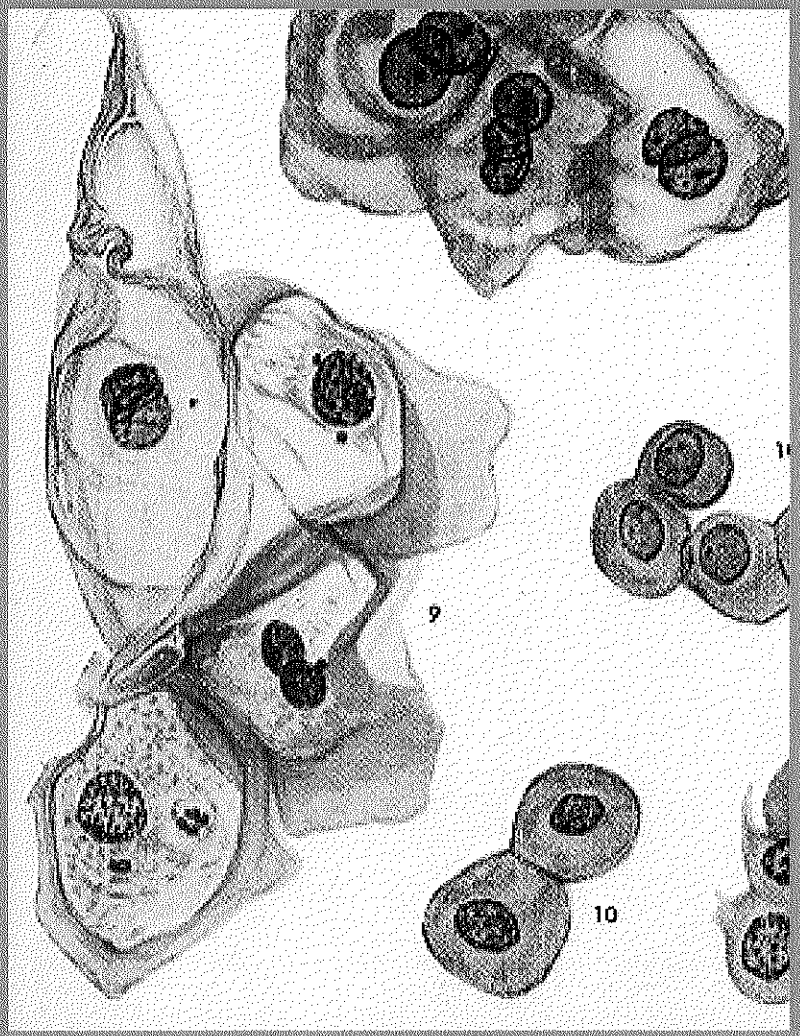


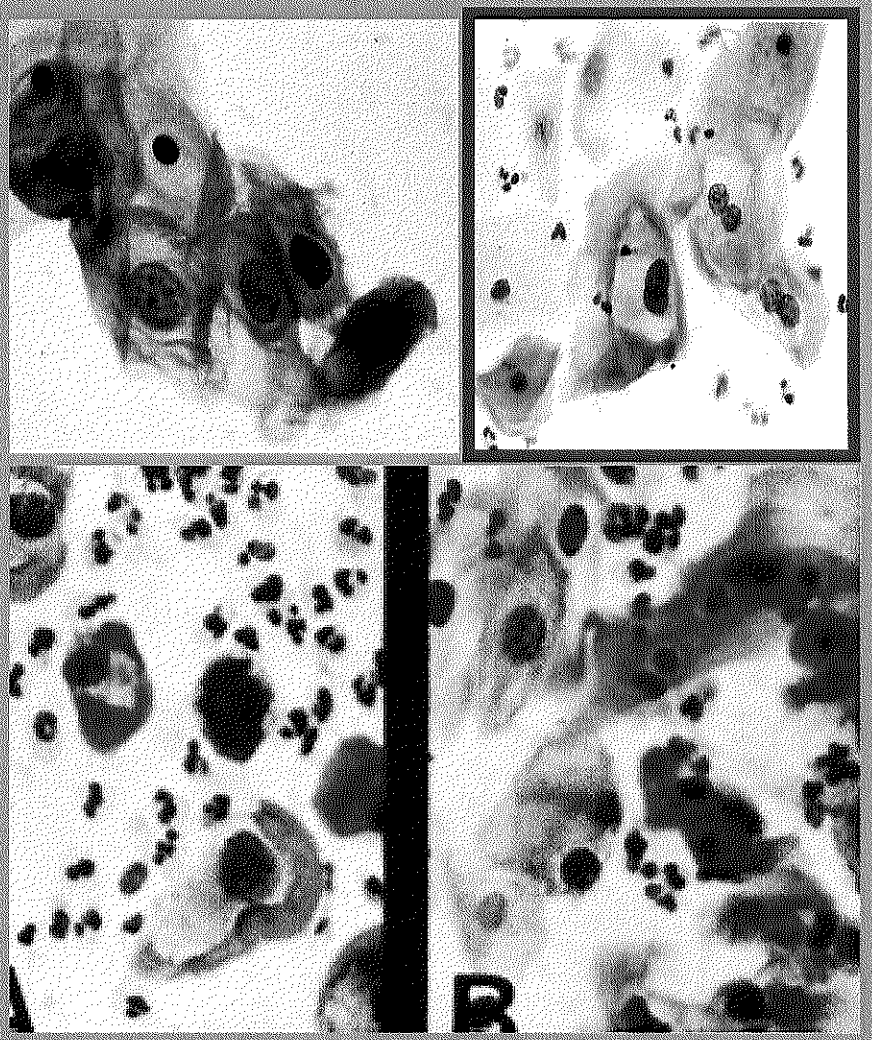






Low Grade Intraepithelial Lesion





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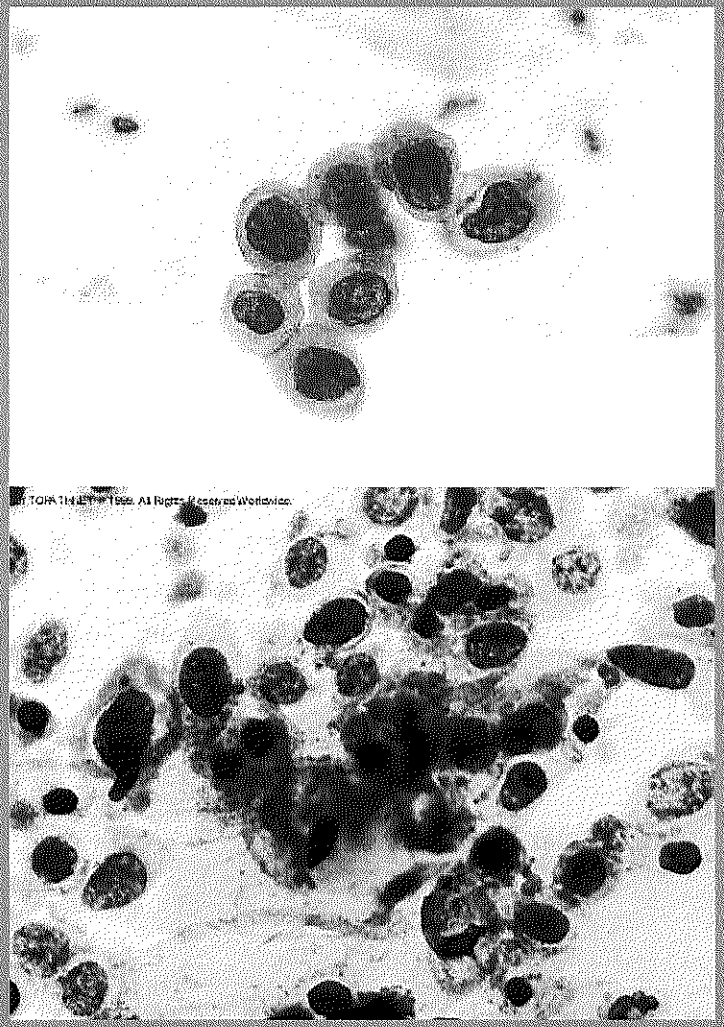
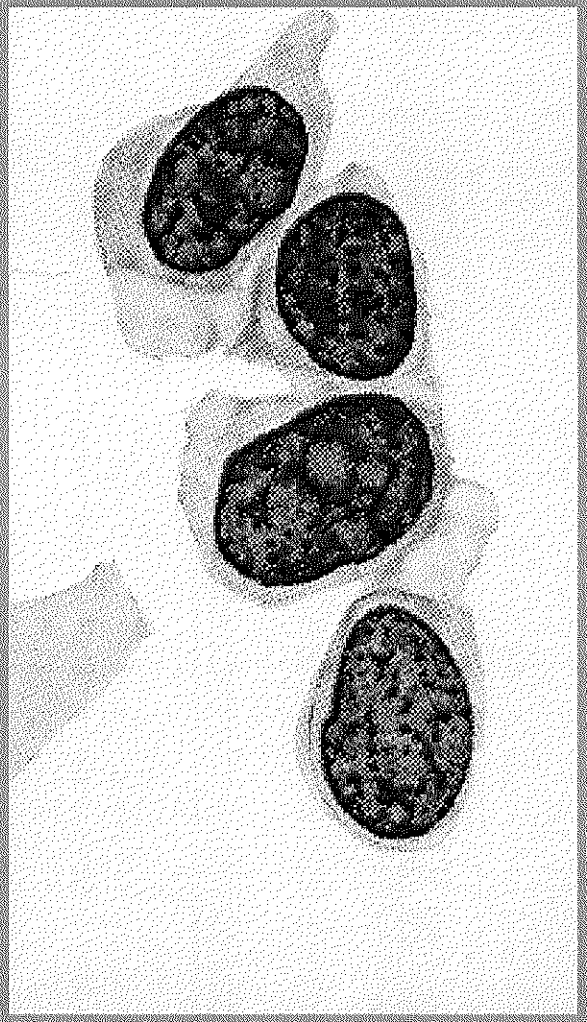
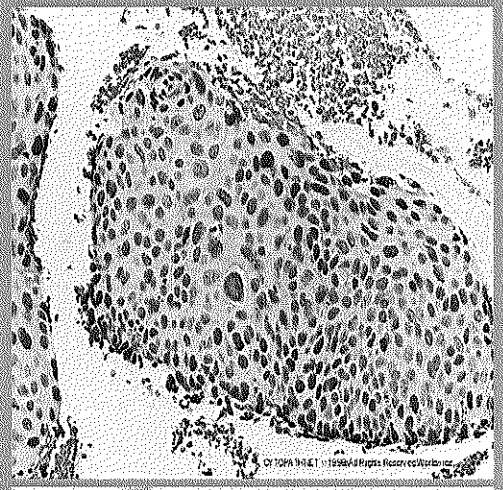
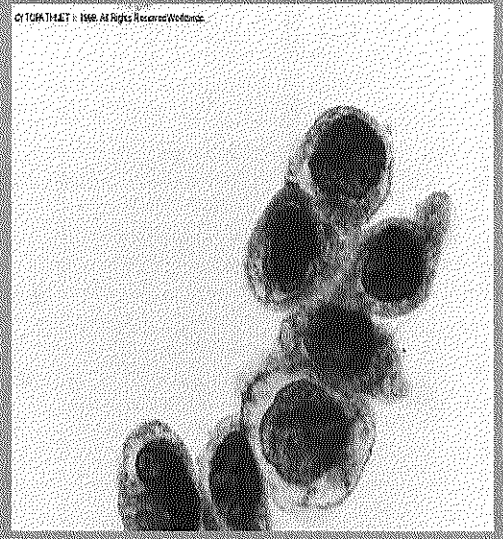
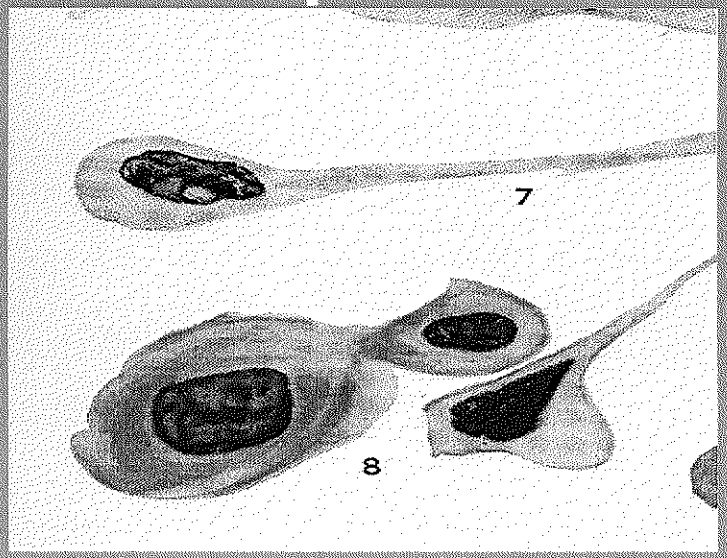


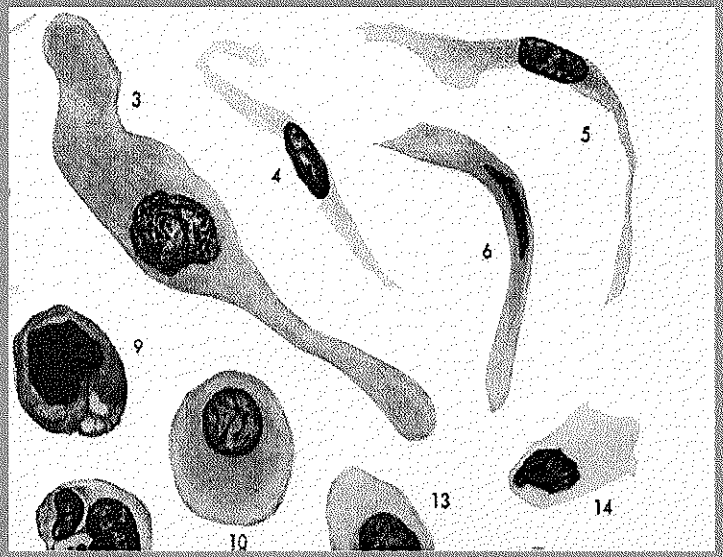


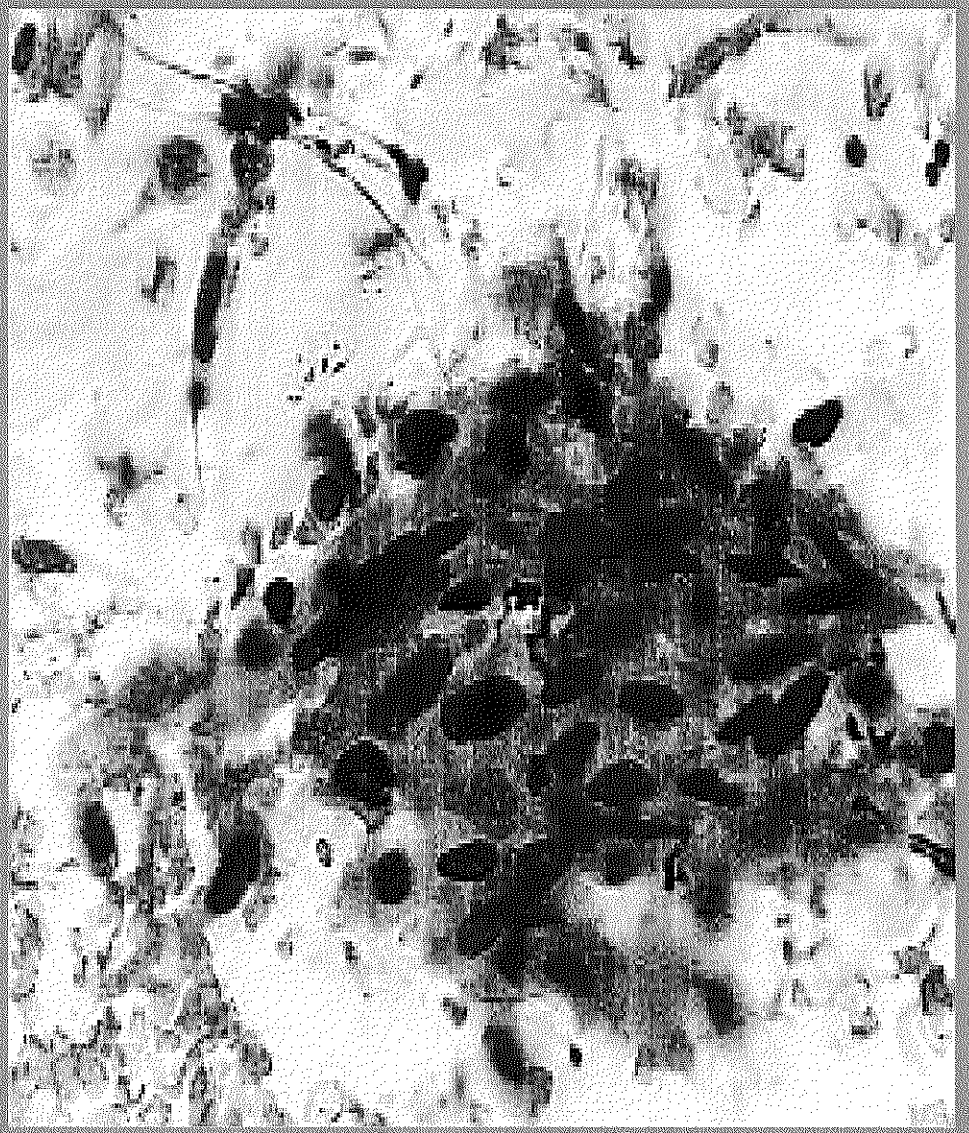




Squamous Cell Carcinoma







The CLIA statute requires:

"Periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations ... with such testing to take place, to the extent practicable, under normal working conditions."

Response

- Language leaves rooms for alternative provided for in S. 2510.
- Flexibility allowed for evaluating proficiency of individuals through testing in an educational setting with Pap test challenges that reflect range of cases.
- Accountability/performance tied to lab director, accrediting bodies under CLIA.

Mandatory Enrollment in Cytology Proficiency Testing (PT)

- Every CLIA-certified laboratory that examines gynecologic cytology specimens
  - Cytotechnologists
  - Pathologists

Requirements for Approval as a PT Program

- Private non-profit entity or Federal or State Agency (or designated agent of a State)
- Comply with CLIA regulations
- Apply for approval or reapproval by July 1 of the prior year

Reasons for Implementation Delay

- Testing not done by federal agency
- No approvable application from a national testing program until 2004
- Significant up-front investment needed to recruit slides, attain rating consensus, field validate, set up testing & re-testing system
- Industry discomfort with cytology PT

Reasons for Implementation Delay RESPONSE

- HCFA (now CMS) -CDC struggled from beginning to implement Cytology PT.
- HFCA raised its own issue on regulations.
- HCFA issued RFP for contractor to procure glass slides; but agency received no responses.
- "One difficulty in implementing this program is collecting the requisite number of high-quality glass slides representing the appropriate diagnostic categories."
- "The cost of collecting and referencing the glass slides is very high, and legal and logistical barriers to collection exist as well."
- "For these reasons, it has proven to be an impossible task to collect and reference sufficient glass slides to conduct PT on a national scale."

Comments by Carlyn Collins, 1993 CDC-CAP-CETC Symp.Lab. Medicine, Vol. 25, No. 4 April 1994

CMS-Approved Programs 2008

- State of Maryland Cytology Proficiency Testing Program (1995)
- American Society for Clinical Pathology purchased the Midwest Institute for Medical Education, Inc. program (MIME)) (2005)
- College of American Pathologists (2006)

CMS-Approved Programs 2008 RESPONSE

- Both American Society for Clinical Pathology, an association of 130,000 lab professionals and the College of American Pathologists (CAP) are vendors of the current Cytology PT Program.
- Both organizations oppose the current model and support legislation, S. 2510, the *Cytology Proficiency Improvement Act.*
- Along with the Susan G. Komen Foundation, the AMA, Prevent Cancer Foundation and the Illinois Society of Pathologists.

4 Opportunities to Pass

- Initial test - 10 slides (2 hours)
  - If fail, schedule re-test within 45 days.
- Second test - 10 slides (2 hours)
  - If fail, may continue to screen but results must be checked. Obtain add'l education & then re-test.
- Third test - 20 slides (4 hours)
  - If fail, cease cytology screening, obtain further education (but may continue to perform other duties).
- Fourth test – 20 slides (4 hours)

4 Opportunities to Pass RESPONSE

- "A total of 99.6% of individuals enrolled in the 2006 Pap PT program achieved satisfactory results." Bentz, Joel. Summary of the 2006 College of American Pathologists Gynecologic Cytology Proficiency Testing Program.
- "Statistical considerations have demonstrated that the design of 'short' proficiency tests in cytopathology, including the current federally mandated test, fundamentally is unsound because of the lack of sufficient validity and reliability."
- "Examinees too frequently are misclassified by such short format tests: Competent examinees fail the test in surprisingly high numbers, whereas most of the examinees who have insufficient cytologic skills eventually pass the test after the allowed retakes." Nagy, George K. and Naryshkin, Sonya. The Dysfunctional Federally Mandated Proficiency Test in Cytopathology: A Statistical Analysis.

The CLIA statute requires: RESPONSE

- Cytopathology Education and Technology Consortium (CETC) identified numerous scientific issues:
  - The frequency of testing is excessive.
  - Validation of the test slides is inadequate since it is based on the review of only three pathologists.
  - The scoring system and reporting terminology is believed to be inappropriate and unfair.
  - The test does not consider common and important aspects of modern gynecologic cytology practice such as computer-assisted screening or location-guided screening.
  - Testing is directed at the level of individuals instead of the level of the laboratory as in all other proficiency testing.

Final Results for 2005
Maryland & MIME

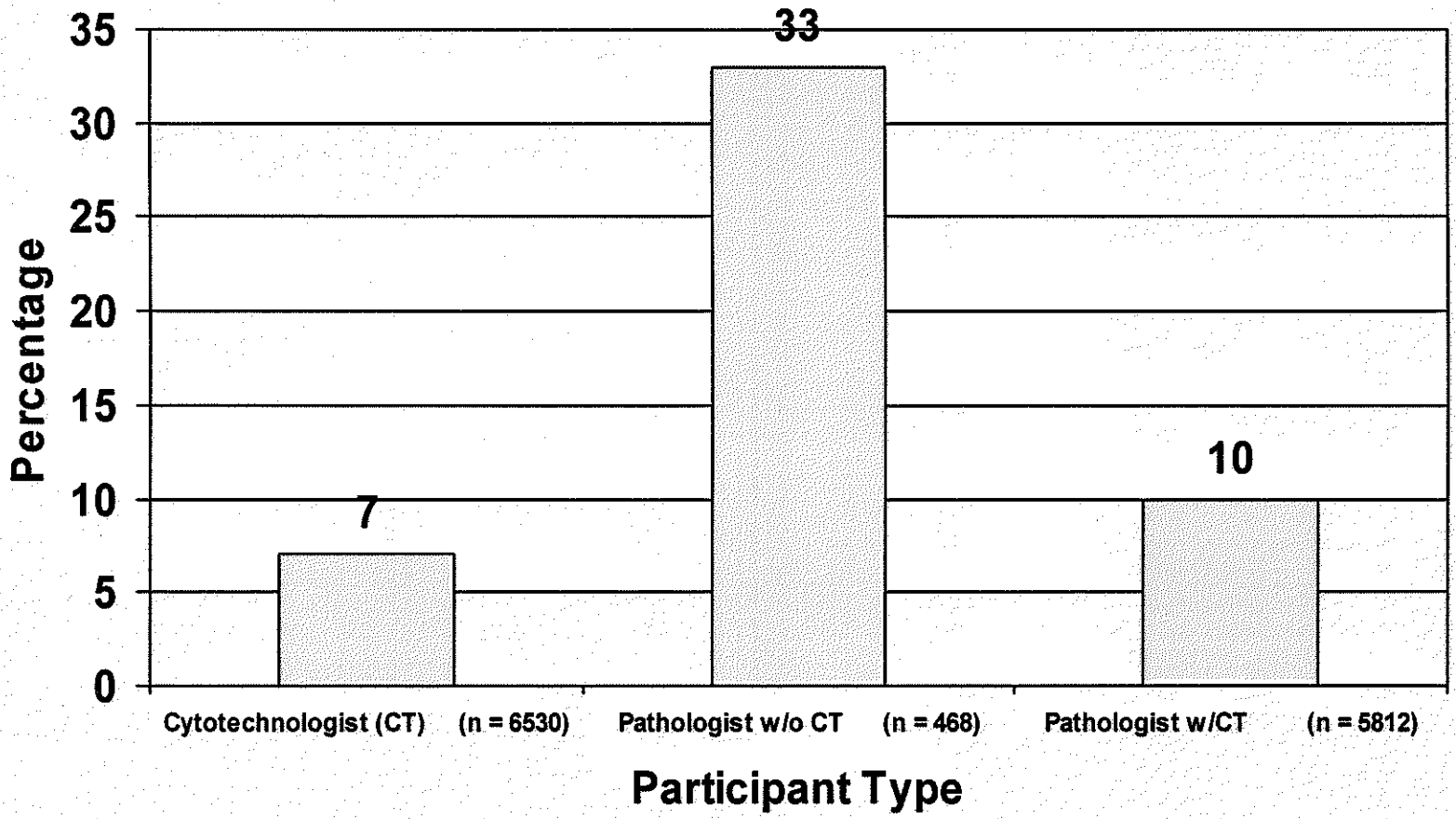
Initial test (10 slides in 2 hours)

Total	Passed	Failed
12,831	11,654 (91%)	1,177 (9%)

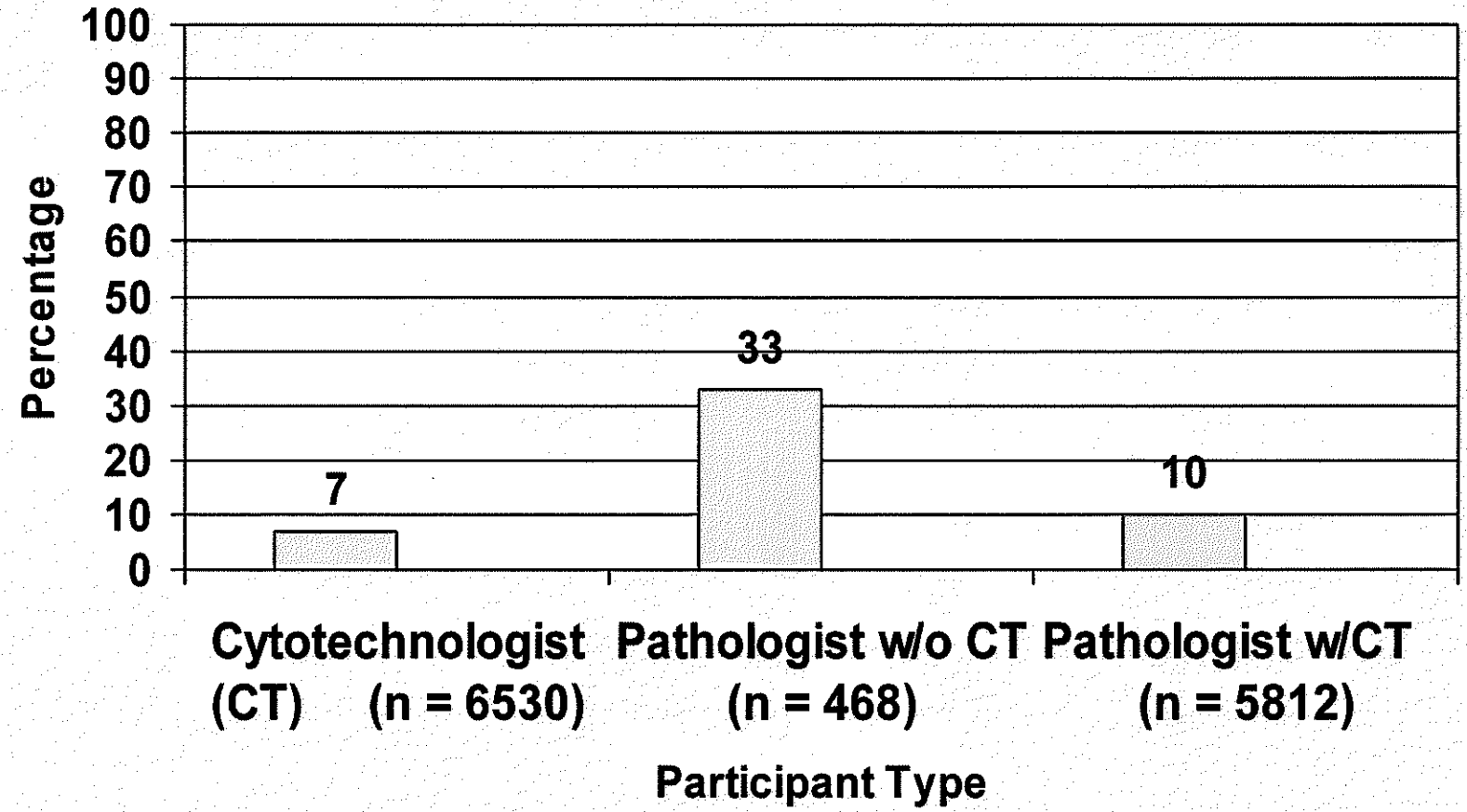
Final Results for 2005 Maryland & MIME RESPONSE

- In 2005, slides used in the federal cytology proficiency testing program were not field validated.
- The 9% "failure" statistic is misleading. The total number includes pathologists that missed one slide but, subsequently, passed additional examinations.
- "One opportunity for failure"

Initial Test Failure Rate 2005



Initial Test Failure Rate 2005
RESPONSE
DOES NOT CONSTITUTE
FAILING



Final Results for 2006
Maryland, ASCP, CAP

Initial test (10 slides in 2 hours)

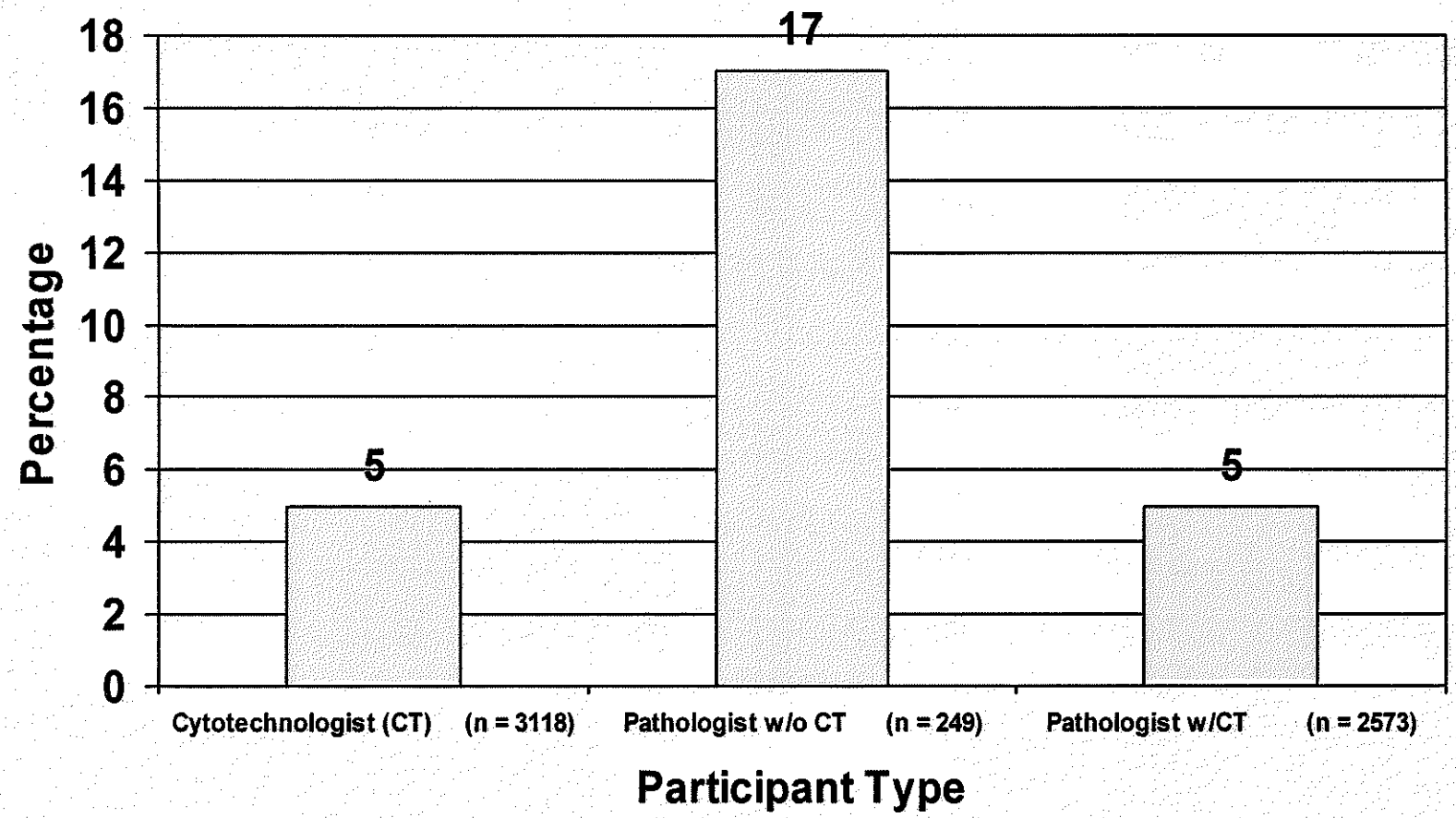
Total	Passed	Failed
12, 572	11,894 (95%)	678 (5%)

Final Results for 2006 Maryland, ASCP, CAP RESPONSE

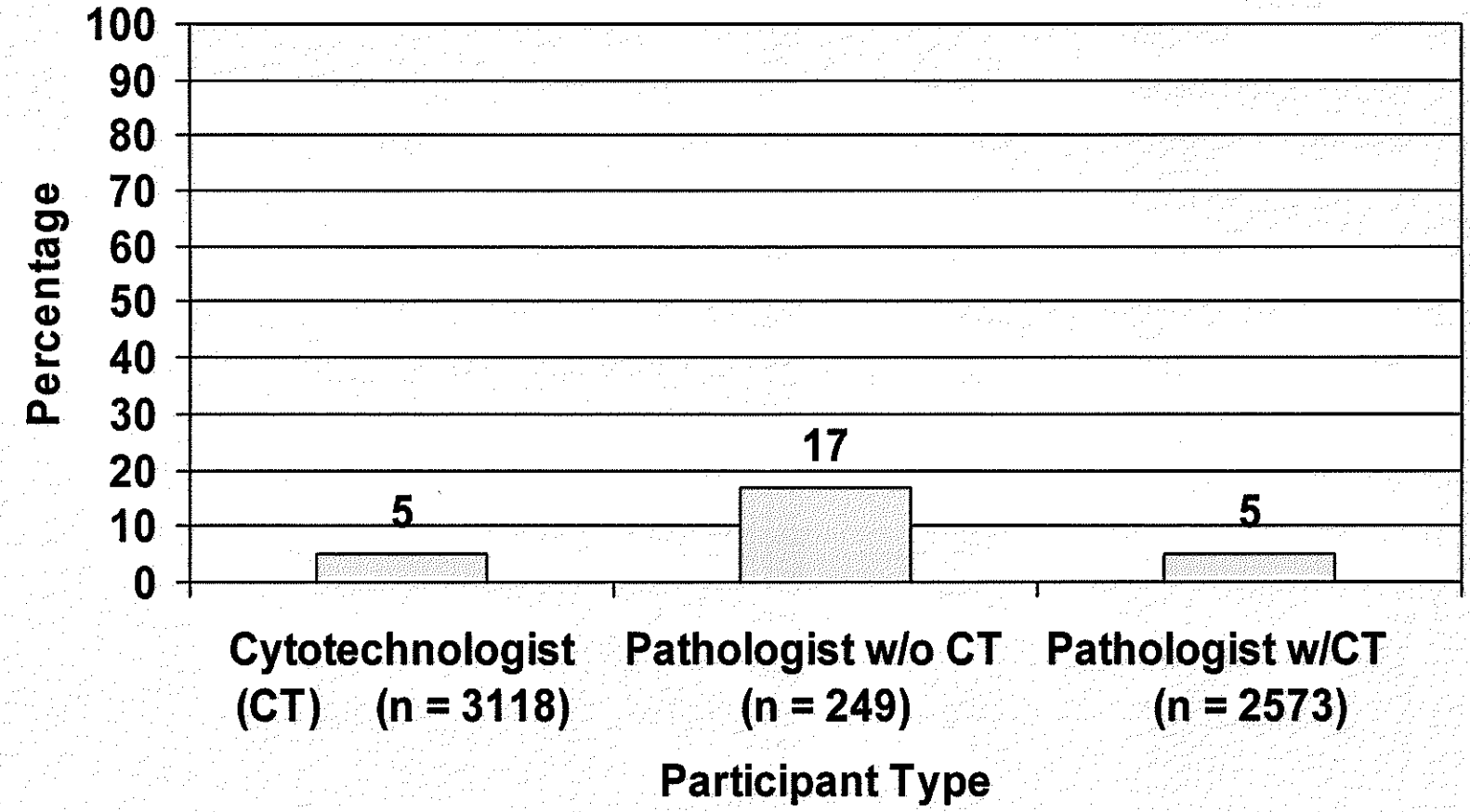
- New vendors provide higher quality slides leading to decline in failure rates.

- Major Conclusion: Statistics may give the impression of improved proficiency among pathologists. In reality, higher quality slides led to more satisfactory results.

Initial Test Failure Rate 2006



Initial Test Failure Rate 2006
RESPONSE



Preliminary Results for 2007 Maryland, ASCP, CAP

Initial test (10 slides in 2 hours)

Total	Passed	Failed
12,435	11,983(96%)	452 (4%)

CLIA
Cytology Proficiency Testing

Frequently Asked Questions

Q: Why are individuals graded vs. the laboratory overall (failing to reflect collaborative decision-making)?

Answer:

- Individual grading is required by statute.
- Most pap smears are read by one person.
- No evidence that collaborative process is used in all labs.
- No assurance labs will follow-up with poor performers if grading is based on "lab as a whole".
- Poor performance may be disguised by the grades of better performers.

Q: Why are individuals graded vs. the laboratory overall (failing to reflect collaborative decision-making)?

BULLET 1 RESPONSE

- CMS: "Individual grading is required by statute."
- FALSE!
- The Secretary of HHS is to establish standards for the **"periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations,** including unannounced and announced on-site proficiency testing of such individuals, **with such testing to take place, to the extent practicable, under normal working conditions."**

Q: Why are individuals graded vs. the laboratory overall (failing to reflect collaborative decision-making)?
BULLET 2 and 3 RESPONSE

- CMS: "Most pap smears are read by one person." "No evidence that collaborative process is used in all labs."
- FALSE!
- Cytopathology Education and Technology Consortium (CETC) Concluded:
  - "In our estimation, **"normal working conditions"** can be reflected in this examination only by allowing the **collaborative, team approach that is a fundamental aspect of the laboratory environment** and most pathology practices. The regulation's premise that individuals **conducting laboratory work are doing so in isolation and making determinations alone is false** for most practitioners."

Q: Why are individuals graded vs. the laboratory overall (failing to reflect collaborative decision-making)?

BULLET 4 RESPONSE

- CMS: "No assurance labs will follow-up on poor performers if grading is based on "lab as a whole."
- **FALSE!**
- CLIA Made Laboratory Director Responsible for Periodic Competency Reassessments.
- **Individual Performance Assessment**: The laboratory director must establish work-load limits for each individual **every 6 months** based upon capabilities and performance using evaluations of 10% negative quality control screens and cytotechnologist-pathologist interpretation correlation data.
- **Documentation of Performance:** The laboratory must evaluate individual performance in comparison to overall performance and document discrepancies and corrective action if appropriate.

Q: Why are individuals graded vs. the laboratory overall (failing to reflect collaborative decision-making)?

BULLET 5 RESPONSE

- CMS: "Poor performance may be disguised by the grades of better performers."
- UNTRUE
- "Short tests will not prevent the frequent failure of competent examinees or the passing of examinees who have less than desirable skill levels."
  - Nagy, George K. and Naryshkin, Sonya. The Dysfunctional Federally Mandated Proficiency Test in Cytopathology: A Statistical Analysis.

Q: What are the consequences of failing cytology proficiency testing?

Answer: (2005-2008)

- For laboratory: no sanctions provided the lab enrolls in a PT program and individuals participate (including re-testing of individuals who fail initial tests).

- For individual: no sanctions except –
  -- after 2nd test failure: education must occur
  -- after 3rd test failure: precluded from screening until achieves a successful score and obtains 35 hours of continuing education

Q: What are the consequences of failing cytology proficiency testing? RESPONSE

- Legislation was not aimed at laboratories. Only requirement is to have all pathologists and cytotechnologists enrolled in PT.
- Laboratories and individuals are mandated to cover the costs associated with taking the test (Unfunded Mandate).
- CMS claims there are no sanctions for individuals except…
  - Precluded from screening until achieve a successful score and obtain 35 hours of continuing education.

Q: Does the PT program account for changes in technology, or is it outdated?

Answer:

- Most laboratories still use glass slide technique
- Automated processes still require manual glass slide reviews
- Terminology for results based on industry-wide standard (Bethesda System - confirmed by 2001 NIH Consensus Conference)

Q: Does the PT program account for changes in technology, or is it outdated?

RESPONSE

- "This isn't your Mother's glass slide…"
- Computer-assisted screening, digital imaging helps locate potentially abnormal areas. "Computer never gets tired."
- Federal testing program fails to include ASCUS "Atypical Squamous Cells of Undetermined Significance."