# Comments on Mandated Gynecologic Cytology Proficiency Testing

## Clinical Laboratory Improvement Advisory Committee Meeting

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# CLIA ’88 LAW
# CYTOLOGY PT SECTION

- "Periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced an unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions.”

http://www.fda.gov/cdrh/CLIA/pl100-578.pdf

Sec 353 (f)(4)(B)(iv)

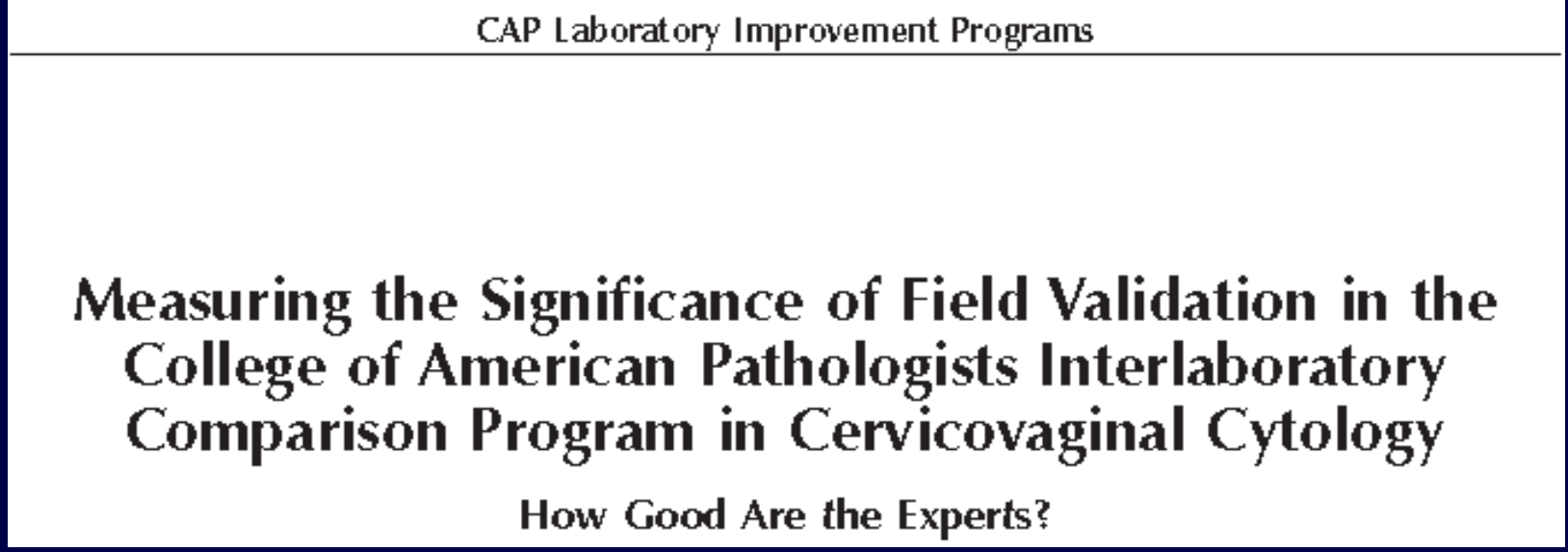
# GYN Cytology PT

- While there have been many reports of individuals successfully taking the PT exam, there have also been many expressions of concern due to cases with ambiguous morphology and/or variable staining quality
- Instances of rare abnormal cells in slides with a reference interpretation of normal have been reported as a cause of missed questions

# GYN Cytology PT

- This is a predictable consequence of the decision to proceed with slides which were not field validated
- The Midwest Institute for medical education (MIME) uses field validated slides in its CytoQuest program and for retesting, but not for initial PT. Field validation of slides used in initial PT is ongoing during 2005[1].
- The risk of spurious results is higher with slides which lack field validation

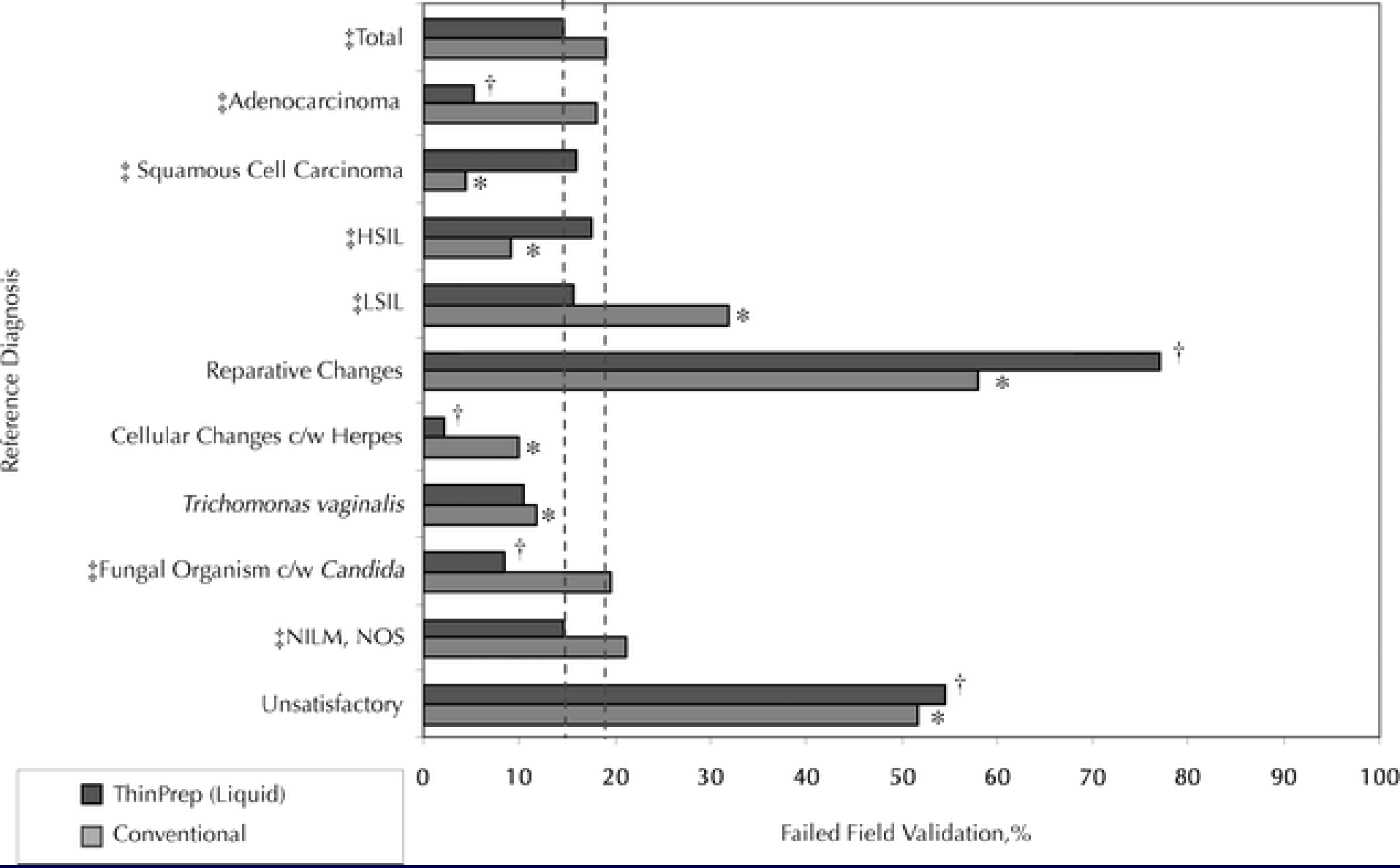
1. Gill, GW It's about MIME The ASC Bulletin. September 2005


CAP Laboratory Improvement Programs

Measuring the Significance of Field Validation in the College of American Pathologists Interlaboratory Comparison Program in Cervicovaginal Cytology

How Good Are the Experts?

- >10,000 cases selected as good examples of various cytodiagnostic entities for circulation after review by and consensus of three expert cytopathologists
- 15 to 19% of cases failed field validation
- Validation criteria stated in article




Renshaw AA, et al Measuring the significance of field validation in the College of American Pathologists Interlaboratory Comparison Program in Cervicovaginal cytology: How good are the experts. *Arch Pathol Lab Med*. 2005;129:609-613

# Gynecologic Cytology: Precision

Renshaw et al. 2003 - CAP Interlaboratory comparison program

Determined rates of exact match with reference interpretation for slides examined between 5 and 24 times

- Three expert cytopathologists at CAP had agreed that the cases were good examples and SILs were confirmed histologically
- 25745 responses on validated slides; 14353 on non validated slides

# Gynecologic Cytology: Precision

- 29.7% of field validated and 28.6% of non-validated HSIL slides had a 100% exact match rate
- 11.8% of field validated and 18.3% of non-validated HSIL slides had <50% exact match rate
- HSIL was one the least reproducible/most difficult interpretations

Renshaw AA, Davey DD, Birdsong GG et al. Precision in gynecologic cytologic interpretation: a study from the College of American Pathologists Interlaboratory Comparison Program in Cervicovaginal Cytology. *Arch Pathol Lab Med*. 2003;127:1413-20.

# GYN Cytology PT

- Can we confidently state to the public that all or most individuals who fail this exam need remediation?
- Can we confidently state to the public that there is a minimal likelihood individuals needing remediation will pass this exam?

# GYN Cytology PT

Despite lack of official sanctions from CMS, potential de facto sanctions exist

- Cost of repeat testing
- Loss of time
- Potential damage to professional reputation including threat of job loss
- Risk/consequences of possible legal discovery currently undefined

# GYN Cytology PT

- We are not opposed to the periodic evaluation of the quality of gynecologic cytology
- The ASC Mission Statement includes advocacy on behalf of patients
- However in its current implementation which focuses exclusively on individuals and does not evaluate the functioning of the overall process in the laboratory, the validity of PT is questionable at best, and it is therefore of questionable public benefit

# GYN Cytology PT

- The formation of a workgroup on gynecologic cytology PT is an excellent suggestion which the ASC will support and would like to participate in