



American Society for
Clinical Pathology

CLIAC Meeting

Tuesday, June 20, 2006

Atlanta, Georgia

Thomas Bonfiglio, MD, FASCP -- *Medical Director, PT*
Rhonda Metzler, BS, SCT(ASCP) -- *Senior Manager, PT*

Presentation Outline

- I. Introduction – Bonfiglio
- II. Logistics/Changes to 2006 PT Offering – Metzler
- III. Proposed Changes to Regulation – Bonfiglio
- IV. Committee Meeting Update - Bonfiglio

INTRODUCTION

February 27, 2006

- ASCP announces that it has acquired the complete cytology product line of the Midwest Institute for Medical Education (MIME)
- ASCP now offers CMS-approved gynecologic cytology proficiency testing and education.

Comprehensive GYN Cytology Product Line

- ❑ **ASCP GYN PT™**
 - A stand-alone GYN proficiency testing program
- ❑ **ASCP GYN PT and Lab Comparison™**
 - A solution that fulfills all gynecologic cytology proficiency testing and laboratory accreditation requirements (meets CAP accreditation requirements for interlaboratory comparison)
- ❑ **ASCP GYN Assessment™**
 - Gynecologic cytology glass-slide program with detailed educational component
 - Interlaboratory comparison program that meets accreditation requirements (meets CAP accreditation requirements for interlaboratory comparison)

The Society (ASCP) Values Public Health, Patients and the Cytopathology Community

- ASCP believes that patients have a right to be assured that the results of their laboratory tests are accurate; that assurance is a professional responsibility
- Enhance ASCP's ability to meet the cytopathology community's changing needs
- New PT offering will be a collaborative effort to continuously improve the quality of laboratory testing and help members comply with the law

Transparency is Key

Volunteer Oversight is Paramount

- All slides to be used by ASCP had been field validated by the end of 2005.
- Any slides in appeal will be reviewed and/or eliminated.
- The ASCP GYN PT & Assessment Committee will oversee the ongoing field validation process and serve as peer reviewers for each new slide.
- The ASCP GYN PT & Assessment Committee will oversee a blinded referee process and serve as peer reviewers for each new slide.

ASCP GYN PT & Assessment Committee (05/2006)

- Thomas A. Bonfiglio, MD (Chair)
- Ritu Nayar, MD (Co-Chair)
- Fadi W. Abdul-Karim, MD
- Syed Ali, MD
- Karen N. Atkinson, MPA, CT(ASCP)
- Eleni Bourtsos, MD
- Carol A. Filomena, MD, FASCP
- Jamie L. Covell, BS, CT(ASCP)
- Denise V.S. De Frias, MD
- Donna K. Mulford, MS, CT(ASCP)HT, CMIAC
- Dawn Riedy, MD, FASCP
- Alia Salhadar, MD
- Nancy J. Smith, SCT(ASCP)
- Maire A. Duggan, MD
- Robert A. Goulart, MD
- Leigh Ann Cahill, CT(ASCP)
- Andrea E. Dawson, MD
- Mark Dieterich, MD

Proficiency Test Specifics (Metzler)

- Proficiency testing must be performed annually
- The laboratory director can choose 3 dates that best suit attendance for the test and ASCP will accommodate those dates in order of preference
- Grading system and Response Categories for answers are set by Federal CLIA regulations
- 90% is the passing score
- Test consists of 10 glass slides to be completed in 2 hours maximum
 - Customer gets 100% of chosen prep type (ThinPrep, SurePath or Conventional)
- Each slide incorporated into the PT program has been refereed by receiving at least 3 “blinded” independent pathologist reviews with 100% agreement...*Committee elected to have each case refereed by 5 individuals (2 Cytotechnologists and 3 MDs – with a minimum of 3 locations represented)*
- Each abnormal slide has exact biopsy confirmation
- Each slide will have patient age and LMP on the label
- All testing is to be done in an independent manner and individuals may not confer regarding test slide interpretation, nor consult reference materials

Proficiency Test Logistics

The number of slides sets sent to the facility for testing is determined by a calculation related to the number of primary and secondary screeners and the GYN prep-types chosen

Primary Screeners test on un-dotted slide sets

Cytotechnologists are always primary screeners

Pathologists / physicians are primary screeners if they sign out even one Pap test per year by independent evaluation and cannot test as a secondary-screener

Secondary-screening pathologists/physicians may elect to test as a primary screener IF they so desire

Secondary Screeners review dotted slide sets with answers

Most pathologists / physicians are secondary screeners. They receive a randomly selected set of glass slides that have been dotted by their cytotechnologist along with the answer sheet for review, as this mimics normal lab practice.



Selecting & Training Proctors

- Each facility can choose to have ASCP proctor their exam for an additional fee plus travel expense or
- Choose at least 2 Proctors from their facility, with one being designated as the primary Proctor
- *Proctor Test Administration Instructions* are available online at <http://www.ascp.org> and may be viewed at any time, but should be seriously reviewed by all designated facility Proctors at least 30 days prior to the test date



Excused versus Unexcused Absence

Excused Absence

- ❑ Make-up test with no penalty
- ❑ Make-up test occurs within the calendar year
- ❑ Excused absences may be due to death in the family, natural disaster, illness, hospitalization or other extenuating circumstances as determined by the Laboratory Director or CMS

Unexcused Absence

- ❑ Participant given a failing score of 0%
- ❑ Re-testing must take place within 45 days either at the original testing facility or at ASCP in Indianapolis, IN
- ❑ Two individuals failed in 2005 due to “unexcused absences” (1 MD and 1 CT)

§493.945 (b)(3)(ii)(A)..Response Categories

(A) The four response categories for reporting proficiency testing results and their descriptions are as follows: -----

Category Description

A..... Unsatisfactory for diagnosis due to:

- (1) Scant cellularity.
- (2) Air drying.
- (3) Obscuring material (blood, inflammatory cells, or lubricant).

B..... Normal or Benign Changes--includes:

- (1) Normal, negative or within normal limits.
- (2) Infection other than Human Papillomavirus (HPV) (e.g., Trichomonas vaginalis, changes or morphology consistent with Candida spp., Actinomyces spp. or Herpes simplex virus).
- (3) Reactive and reparative changes (e.g., inflammation, effects of chemotherapy or radiation).

C..... Low Grade Squamous Intraepithelial Lesion--includes:

- (1) Cellular changes associated with HPV.
- (2) (2) Mild dysplasia/CIN-1.

D..... High Grade Lesion and Carcinoma-- includes:

- (1) High grade squamous intraepithelial lesions which include moderate dysplasia/CIN-2 and severe dysplasia/carcinoma in- situ/CIN-3.
- (2) (2) Squamous cell carcinoma.
- (3) (3) Adenocarcinoma and other malignant neoplasms.

Problems noted with Response Categories:

- Receive complaints that other diagnostic categories are not included such as ASC-US, AGUS, and ASC-H since they are diagnoses rendered on a daily basis in laboratory
 - Response: these diagnoses are “gray zones” in cytopathology and would be next to impossible to get 100% consensus on these diagnoses. Adding such diagnostic categories would increase % failures.
- Individuals are not current on new 2001 Bethesda terminology
 - Still believe that the lack of endocervical component renders the pap smear “unsatisfactory for interpretation”
 - Solution: Finding means to educate the laboratorians on current terminology and diagnostic classifications

2005 INITIAL TESTING RESULTS (as of 03/01/06)

Participant Type	Pass	%	Fail	%	Total
Locum	17	81%	4	19%	21
CT	5755	93%	428	7%	6183
Primary MD	306	66%	156	34%	462
Secondary MD	5066	90%	566	10%	5632
TOTALS	11144	91%	1154	9%	12298

2005 1st RETEST RESULTS – 10 SLIDE

(as of 03/01/06)

Participant Type	Pass	%	Fail	%	Total
Locum	2	40%	3	60%	5
CT	397	96%	17	4%	414
Primary MD	85	66%	44	34%	129
Secondary MD	507	92%	45	8%	552
TOTALS	991	90%	109	10%	1100

2005 2ND RETEST RESULTS – 20 SLIDE (as of 03/01/06)

Participant Type	Pass	%	Fail	%	Total
Locum	0	0%	0	0%	0
CT	10	91%	1	9%	11
Primary MD	13	81%	3	19%	16
Secondary MD	26	90%	3	10%	29
TOTALS	49	88%	7	13%	56

2005 3RD RETEST RESULTS – 20 SLIDE (as of 03/01/06)

Participant Type	Pass	%	Fail	%	Total
Locum	0	0%	0	0%	0
CT	0	0%	0	0%	0
Primary MD	0	0%	1	100%	1
Secondary MD	3	100%	0	0%	3
TOTALS	3	75%	1	25%	4

Slide Selection Processes:

- Prior to 02/2006 all slides were purchased from US laboratories. Post 02/2006 slides are being donated to ASCP.
- All slides and supporting documentation received must be HIPPA compliant. Required documentation: Patient age, LMP, cytology diagnostic report, and exact tissue confirmation on all abnormals.
- **PRE-REFEREE REVIEW:** All slides are evaluated for quality, screened and dotted by the submitting laboratory/Committee member
- **REFEREE PANEL:** ASCP Referee panel will consist of 2 Committee member Cytotechnologists and 3 Committee member Cytopathologists and/or Pathologists. Slides require 100% consensus amongst 5 panelists. Panelists will conduct blinded reviews of each slide – receiving age and LMP only (37% fell out at this time). **This process meets and EXCEEDS federal regulations.**

Revised 05/06 per Committee

Refereeing Process:

Refereeing is done “blinded”

- Each slide will have:
 - » Age
 - » LMP
 - » NO preliminary diagnosis will be provided
- Slides are to be reviewed as they would be reviewed during a proficiency testing event
 - » Independent review
 - » No textbooks or other reference materials

This process increases the probability of only the best slides making it through with 100% consensus by the 5 panelists

Slide Validation Process:

Slide validation, or field validation, is not a regulatory requirement but is considered an important component in providing a “scientifically defensible process for determining the correct result for each challenge offered by the program” (§493.901(b)(1)(ii)(2))

Current ASCP Validation Standards require PT slides to be performing at 90% or greater to the EXACT response category with a minimum of 40 reads or testing events.

Example Slide Validation Report (w/2 replaced cases)

(This is real data – Identifiers removed – CT & Secondary Path Only)

BOX B		#Labs		Resp Code	A	%A	B	%B	C	%C	D	%D	TOT	Match	DIFF	% Match
1	ProgLine Summary	23	PTT0502	D	0	0	1	2	0	0	53	98	54	53	1	98
2	ProgLine Summary	23	PTT0564	B	0	0	50	93	2	4	2	4	54	50	4	93
3	ProgLine Summary	23	PTT1818	D	0	0	0	0	1	2	53	98	54	53	1	98
4	ProgLine Summary	23	PTT0089	C	0	0	0	0	54	100	0	0	54	54	0	100
5	ProgLine Summary	15	PTT0700	C	0	0	3	8	32	86	2	5	37	32	5	86
5	ProgLine Summary	8	PTT4465	C	0	0	0	0	15	88	2	12	17	15	2	88
6	ProgLine Summary	23	PTT0338	B	3	6	50	93	1	2	0	0	54	50	4	93
7	ProgLine Summary	23	PTT1744	B	0	0	53	98	1	2	0	0	54	53	1	98
8	ProgLine Summary	23	PTT0681	D	0	0	0	0	2	4	52	96	54	52	2	96
9	ProgLine Summary	23	PTT0713	A	53	98	1	2	0	0	0	0	54	53	1	98
10	ProgLine Summary	15	PTT0705	C	0	0	8	22	29	78	0	0	37	29	8	78
10	ProgLine Summary	8	PTT4240	C	0	0	0	0	17	100	0	0	0	17	17	100

Pre-Result De Facto Appeals Process:

- ALL failures go through a “de facto” appeal PRIOR to the release of testing results to lab director and individual.
 - If slide have less than 40 reads, they are put through a minimum of 3 blinded reviews – requiring 100% agreement with tissue confirmed diagnosis and response category. If any disagreement occurs, case is removed from program and individual(s) given credit for their response. Slide labels checked for accuracy
 - Field validation performance report run. If slide is falling below acceptable standard, slide is removed and individual(s) is given credit for their response.

Per Committee: Slides with less than 40 reviews will no longer be part of testing process therefore this should not be part of the de facto appeals once all sets are updated.

PT Appeals Process:

ASCP has a written Appeals process approved by CMS.

- **§493.901(b)(2)** A scientifically defensible process for determining the correct result for each challenge offered by the program;
- **§493.901(b)(7)** A process to resolve technical, administrative, and scientific problems about program operations;
- Appeals are only accepted for failures. Individuals cannot appeal a passing score.
- Testing individuals and/or Laboratory Director can submit a written appeal to ASCP that specifies their reason for disputing results.
- Written outcome of the Appeal is provided to the testing individual and/or Laboratory Director, as well as CMS.

Summary of 2005 Appeals:

Total 2005 Testing Events:	2467
Total 2005 Individuals Tested:	12298
Total No. of Appeals Received for 2005:	47 (0.38%)
Total No. of Appeals Completed:	42
Total No. Deemed Valid:	19* (45.2%)
Total No. Denied:	23** (54.8%)

*Of those denied valid:

Two of the wins were due to a typographical error in the data.

Three of the wins were due to proctor irregularities which caused nullification of testing process by MIME/ASCP ("wipe-the-slate clean") per CMS' directive

**Three of those denied were denied because they did not fail, thus did not qualify as an appeal and a fourth one was denied because he wanted to have the grading scale changed for his results due to his years of experience.

Changes Implemented for 2006 ASCP PT Testing

Individuals required to take the first 20-slide re-test (or 2nd retest) now have two options:

Option 1: (NEW) Retest at their facility and pay for an ASCP Proctor to travel to their location

▲ **Convenience**

▼ **Decrease time away from the office**

Option 2: Retest at ASCP's Indianapolis or Chicago office, utilizing ASCP's in-house proctor

Proposed Revisions to the Regulations (Bonfiglio)

CMS and CDC should use:

an **expedited rule making process** that
can be completed as soon as possible....

ASCP meetings with key Senate staff on
HELP Committee indicate desire for CLIAC
to revise regulation as soon as possible.

ASCP urges CLIAC to support revisions that
can be implemented **in this calendar
year.**



New Technologies

- Even though computer-assisted and location-guided screening technologies should be incorporated into the testing protocol, it is currently not feasible from the operational perspective for the ASCP to add this as a testing option at this time (per ASCP GYN PT & Assessment Committee – May 2006).

Testing Intervals

- Less frequent assessment would seem appropriate for the well-trained cytology professional who is working on a regular basis. ASCP is in the process of assessing the data we inherited from the 2005 testing cycle. A comparison of this data with 2006 data may be of value in developing recommendations for assessment intervals.
- Ultimately, the regulation could be revised to allow for a rotation of fulfillment of the testing requirement with education-only PT. Performance on test results should be factored into equation.
- Education component should be consistent with revised CLIA cytology regulation.



Change the Grading Scheme

- The grading scheme proposed under the rules published in 1992 is based on a triage algorithm in use at the time that had been in place since the late sixties
- To reflect developments in the field and be fair, ASCP proposes the following modification to the grading scheme to make it consistent with the current triage algorithm and fair to the participants



Principle

- **Cytology proficiency testing must be scientifically valid and fair**

CLIA Statute mandates that PT programs assess “the clinical relevance of the laboratory examination”

Revisions should be reflective of current practice

Point Values (current)

Pathologist (Technical Supervisor) 10 Slide Test				
Correct Response	Examinee Response			
	A-UNSAT	B-NEGATIVE	C-LSIL	D-HSIL
A-UNSAT	10	0	0	0
B-NEGATIVE	5	10	0	0
C-LSIL	5	0	10	5
D-HSIL	0	-5	5	10

Cytotechnologist 10 Slide Test				
Correct Response	Examinee Response			
	A-UNSAT	B-NEGATIVE	C-LSIL	D-HSIL
A-UNSAT	10	0	5	5
B-NEGATIVE	5	10	5	5
C-LSIL	5	0	10	10
D-HSIL	0	-5	10	10

Current Model Utilizing all 10-slide testing events in 2005

Participant Type	Pass	%	Fail	%	Total
CT	6043	93.4%	424	7.0%	6467
Primary MD	475	73.1%	175	26.9%	650
Secondary MD	5426	90.4%	573	9.6%	5999
TOTALS	11944	91.1%	1172	8.9%	13116

Reflects all 10-slide testing (1st and 2nd testing events) that occurred from 01/01/05 to 12/31/05

Point Values (proposed per CETC)

Pathologist (Technical Supervisor) 10 Slide Test				
Correct Response	Examinee Response			
	A-UNSAT	B-NEGATIVE	C-LSIL	D-HSIL
A-UNSAT	10	0	0	0
B-NEGATIVE	10	10	0	0
C-LSIL	5	0	10	7.5
D-HSIL	0	0	7.5	10

Cytotechnologist 10 Slide Test				
Correct Response	Examinee Response			
	A-UNSAT	B-NEGATIVE	C-LSIL	D-HSIL
A-UNSAT	10	0	5	5
B-NEGATIVE	10	10	5	5
C-LSIL	5	0	10	10
D-HSIL	0	0	10	10

CETC Model

Participant Type	Pass	%	Fail	%	Total
CT	6227	96.3%	240	4.0% (-3.0%)	6467
Primary MD	509	78.3%	141	21.7% (-5.2%)	650
Secondary MD	5539	92.3%	460	7.7% (-1.9%)	5999
TOTALS	12275	93.6%	841	6.4% (-2.5%)	13116

Reflects all 10-slide testing (1st and 2nd testing events) that occurred from 01/01/05 to 12/31/05; all "participant types" decreased % failures

Alternative Scoring Grid – with the auto-failure removed

		Pathologist (Technical Supervisor) 10 Slide Test			
Correct Response	Examinee Response				
	A-UNSAT	B-NEGATIVE	C-LSIL	D-HSIL	
A-UNSAT	10	0	0	0	
B-NEGATIVE	5	10	0	0	
C-LSIL	5	0	10	5	
D-HSIL	0	0	5	10	

		Cytotechnologist 10 Slide Test			
Correct Response	Examinee Response				
	A-UNSAT	B-NEGATIVE	C-LSIL	D-HSIL	
A-UNSAT	10	0	5	5	
B-NEGATIVE	5	10	5	5	
C-LSIL	5	0	10	10	
D-HSIL	0	0	10	10	

Alternative Scoring Grid – with the auto-failure removed

Participant Type	Pass	%	Fail	%	Total
CT	6200	95.9%	267	4.0% (-3.0%)	6467
Primary MD	499	76.8%	151	23.2% (-3.7%)	650
Secondary MD	5515	92.3%	484	8.1% (-1.5%)	5999
TOTALS	12214	93.1%	902	6.9% (-2.0%)	13116

Reflects all 10-slide testing (1st and 2nd testing events) that occurred from 01/01/05 to 12/31/05; all "participant types" decreased % failures

Additional Committee Updates:

- First meeting of new ASCP GYN PT & Assessment Committee held May 18-21, 2006 in Indianapolis
- Three Subcommittees were formulated:
 - Publications Subcommittee
 - Marketing Subcommittee
 - Testing Violations Subcommittee
- “White Paper” publication most immediate goal for Committee in regards to PT product
- ASCP was requested by CMS & CLIAC Work Group to run testing data against 5 alternative testing grids for Proficiency testing.
 - Data was provided CMS in 05/2006
- Committee recommended that Psychometrician attend all future meetings of the ASCP GYN PT & Assessment Committee to ensure that statistical-driven discussions & decisions are statistically sound.
- Committee elected to add MonoPrep as prep type option in 2007