



AMERICAN SOCIETY FOR  
CYTOTECHNOLOGY

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**Results of Cytotechnologist Survey  
Related to  
Proficiency Testing NPRM  
January 16, 2009**

**American Society for Cytotechnology  
1500 Sunday Drive, Suite 102  
Raleigh, NC 27607  
Phone 800.948.3947  
Fax 919.787.4916  
[www.ASCT.com](http://www.ASCT.com)**

On behalf of the American Society for Cytotechnology (ASCT), representing cytotechnologists, we respectfully request that the Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) consider our comments and suggestions for improvements in the existing Cytology Proficiency Testing (PT) program.

Following the publication of the Notice of Proposed Rule Making, January 16, 2009, ASCT developed an on-line survey directly addressing the key issues for which Center for Medicare Services (CMS) requested input. The survey closed Feb 13, with 315 participants. 66% of the participants are ASCT members and 34% are non members. Although there are no significant differences in the two groups of respondents, we felt that it was important that we prepare two statements, one with only our membership responses and this statement which reflects ALL survey respondents. The ASCT membership response has been sent separately.

In the recent survey of cytotechnologists (ASCT members and nonmembers combined) 75% or more felt very strongly about the following issues. Results of the entire survey are presented in Attachment 1.

**Cytology Challenges and New Technology:**

- CMS should include criteria for pilot testing before any new cytology testing media is approved by CMS.
- Pilot testing will most likely increase the cost of cytology PT.
- Enrollment and participation in an educational program should be required for all cytology laboratories.

**Frequency of Testing:**

- Ten cytology challenges per test are appropriate to test individual performance.

**Number of Challenges:**

- There will definitely be logistical concerns and additional costs associated with administering a proficiency test events with more than 20 cytology challenges.
- The most significant impact on laboratory operations will be a delay in patient testing if the proficiency test requires 20 challenges and 4-hour timeframe for administration. It will also create more stress for laboratory personnel and will require extending the number of testing days in order to accommodate laboratory operations.
- Laboratories would prefer a 2-hour rather than a 4-hour testing period.
- Increasing the number of challenges will most likely increase the PT program's cost to administer the program.
- CMS should use analysis of the answer distance from the target answer to determine the statistical power of cytology PT with 20 challenges and a multinomial, weighted scoring system.

**Response Categories:**

- CMS should include defined criteria in the regulations for "unsatisfactory" challenges.
- CMS should include defined criteria for "unsatisfactory" challenges for all preparation types.
- CMS should NOT add a fifth response category but should keep the current four response categories.

**Cytology Challenge Referencing:**

- CMS should require the three physicians certified in anatomic pathology to independently determine the response category for each cytology challenge.

- CMS should require all PT programs to include cytotechnologists in the review process for referencing cytology challenges, and that it should include both pathologists and cytotechnologists, more specifically, supervisory cytotechnologists.
- CMS should require that there be biopsy confirmation of LSIL (Category C) cytology challenges for PT, as is currently required.

**Validation of Cytology Challenges:**

- The regulations should absolutely require field validation for each cytology challenge before it is included in the test set.
- The regulations should also include specific criteria for initial field validation.
- CMS should require continuous monitoring of each cytology challenge and this requirement should be specified in the regulations. The criteria should be slide performance, slide quality and the number of appeals for that slide.
- It is most likely that these validation requirements will result in additional costs.

**Scoring Scheme:**

- The scoring scheme should be more stringent for pathologists than cytotechnologists based on their level of responsibility, similar to the current scoring scheme. Pathologists should be scored more stringently for “missing” LSIL & HSIL since they make the final interpretation. Having the same scoring scheme for cytotechnologists and pathologists would not meet the requirement of evaluating workplace performance, since the responsibilities in the workplace are quite different for CT and MD. The CT must locate and refer abnormalities and the pathologists must make the final interpretation. With or without change, however, the existing PT does not reflect actual workplace performance. Some of our members suggested that CT’s have three categories – Unsatisfactory, NILM, and Refer to Pathologist. These categories with the answer sheet and dotted slides go to the pathologist for final interpretation. This would be more representative of the level of responsibility in the workplace.

**Retesting and Remediation:**

- CMS should require that all testing be conducted in the laboratory.
- There should be two or three retesting events.

**Appeals Process:**

- The criteria for appeals should include, field validation results, representation of the lesion, quality of preparation, a time period for appeal, and an adjudication panel including MD’s and cytotechnologists.
- PT programs should be required by regulation to provide participants with a description of their appeals process.

**Proctors:**

- There was no strong consensus amongst the respondents regarding proctors. Please see attached survey results.

**General Comments:**

- Many did not feel the Proposed Rule offered any improvements to the current structure and requested there be no change other than a stronger field testing and validation process.
- PT pass rates do not fluctuate from year to year, skills will not be lost if annual testing events were less frequent.
- No data exists to confirm annual testing is valid. PT is about public perception not about test validity.
- Outcome analysis should be done to prove patient safety is enhanced with PT
- Pilot groups taking PT at extended intervals could be compared with groups taking PT annually.

The ASCT appreciates the opportunity to represent all survey respondents in regards to the proposed rule in Proficiency Testing and respectfully submits these comments to CMS. In addition to the survey tool from which this response was compiled, cytotechnologists were provided a tool for individual responses and encouraged to do so.

Attachment 1: Cytotechnologist Proficiency Test Survey

ASCT Executive Council