

Statement from the
AMERICAN SOCIETY OF CYTOPATHOLOGY
to the
CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE
Regarding the Pending Cytology Proficiency Testing NPRM
February 15, 2007

I am George Birdsong, M.D., and I am a Pathologist a Emory University School of Medicine, Director of Anatomic Pathology at Grady Memorial Hospital in Atlanta, GA., and a former member of this committee. I am the immediate Past President of The American Society of Cytopathology (ASC), and I am here today representing that organization. The ASC appreciates the opportunity to speak to the distinguished members of the CLIAC.

We wish to address the issue of the pending revisions to the CLIA Proficiency Testing (PT) regulations. We are pleased with the reported request for expedited development of the Cytology PT NPRM. We would like to add our voices to the request that the NPRM be released as soon as possible, and that the proposed regulations adhere to the recommendations of the CLIAC PT Workgroup. Among our concerns with continuing the current testing protocol are the following:

- As indicated at the June, 2006 CLIAC meeting devoted to PT, the statistical reliability of the 10 slide test is suspect. Nevertheless, we have received reports of employers levying severe penalties on individuals after they did not pass a second or even first test. This is very unfair to these individuals given the known statistical variability of a 10 slide test. The unfairness can be mitigated somewhat by updating the testing protocol in accord with the recommendations of the PT workgroup.
- The current protocol is not educational, but the cost has caused some labs to cut their continuing education budgets, particularly for cytotechnologists. Although not as potentially dramatic as a missed precancerous lesion on a Pap test, lack of continuing education is also potentially harmful to patients.
- Cost/benefit aspects of PT are likely more favorable with the PT protocol suggested by the CLIAC PT workgroup. Much has been made, appropriately, of the *rate* of “not passing” the initial PT by pathologists who do not utilize cytotechnologists, but extrapolating the 2005 data (in which absolute numbers were presented) to 2006 suggests that there were approximately 84 such pathologists that did not pass the initial PT out of almost 13,000 (<1%) individuals who took the test. Labs which do not employ cytotechnologists tend to examine relatively low volumes of Pap tests, so the actual number of cases seen in these labs is probably disproportionately small even compared to the number of primary screening pathologists. The individuals flagged by PT for remediation will be more reliably identified with the 20 slide test suggested by the PT workgroup, and the cost savings from less frequent testing will likely exceed the additional expense of the longer test. Thus, the testing protocol suggested by the

workgroup will likely use taxpayers funds more efficiently as well as more reliably identifying those individuals needing remediation.

- If past experience with NPRMs is a reliable guide, it may be 2009 or even later before changes in the regulation actually go into effect. Given the concerns discussed above, we respectfully suggest that the CLIAC urge the leadership of CMS to disseminate the NPRM as soon as possible, preferably as early as possible this year.

The Pap test remains the most successful cancer screening test in medicine despite its known shortcomings. It has been credited with a decrease in the cervical cancer rate of 70-80%, and this track record was established prior to CLIA mandated PT. Good laboratory practices such as most of those mandated in the CLIA regulations are a major contributor to this success. PT requires a significant allocation of laboratory resources, and should be carried out as efficiently as possible.

ASC Vision Statement:

The American Society of Cytopathology defines and promotes excellence in cytopathology striving for the highest quality of patient care.