American Society for Clinical Pathology

Statement before the

Clinical Laboratory Improvement Advisory Committee on Workload Recommendations for Automated Pap Test Screening

February 14-15, 2012

Chairman Santrach, members of the Clinical Laboratory Improvement Advisory Committee, my name is Dr. George Birdsong. I am pleased to report today that the American Society of Clinical Pathology (ASCP) has formally endorsed the American Society of Cytopathology's (ASC) Workload Recommendations for Automated Pap Test Screening. As a patient-centric organization, ASCP strongly supports the ASC's efforts to promote the safety of women by adopted evidence-based workload limits for the screening of image-guided Pap tests by cytotechnologists.

The ASCP is a 501(c)(3) nonprofit medical specialty society representing more than 100,000 members. Our members are board certified pathologists, other physicians, clinical scientists, certified medical technologists and technicians, and educators. ASCP is one of our nation's largest medical specialty societies and is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

For the past several years, the ASC has been working to develop evidence-based workload recommendations for cytotechnologists who screen image-guided Pap tests. *The data strongly suggests that current Pap test screening workloads, as currently approved by the Federal Drug Administration (FDA) and reflected in the regulations for the Clinical Laboratory Improvement Amendments of 1988 (CLIA) are too high.* This presents a potential safety risk for women whose Pap tests are reviewed under these conditions.

The current FDA workload limits for automated image-assisted screening methods are 200 slides/day for the ThinPrep Imaging System and 170 slides/day for the FocalPoint GS. These rates are extremely high and may be associated with significant reduction in sensitivity. Recognizing that individual

cytotechnologists productivity may vary, based on recent and current available literature we recommend that the average laboratory cytotechnologist productivity not exceed the ASC-recommended 70 slides/day using the Centers for Medicare and Medicaid Services recommendations for calculating workload (imaged slide only = 0.5 slides, full manual review = 1.0 slides, imaged + manual review = 1.5 slides). This is assuming a manual review rate of imaged slides to be at least 15-20 percent.

With regard to current cytotechnologist screening rates, a study by Balachandia et al (2011)[1] noted that *among laboratories in New York, the overwhelming majority (59/67* [**88 percent**] *reported gynecologic screening rates of less than 50-69 slides per day (emphasis added)*. Only three laboratories reported screening rates in excess of 90 slides per day.

The ASC-recommendations are based upon available research and literature pertaining to gynecologic specimens with image-assisted screening. These workload standards were approved on Augusts 29, 2011, after undergoing extensive review and comment by the American Society for Cytotechnology (ASCT), the Papanicolaou Society of Cytology (PSC), and others. These recommendations have received overwhelming support. ASCP is also pleased that the Cytopathology Education and Technology Consortium (CETC) has come to a consensus on the need for revised workload limits. CETC has also indicated that this issue may benefit from additional study.

ASCP urges CLIAC to adopt the ASC workload standards. We look forward to working with CLIAC, ASC and the FDA to modernize these cytotechnologist workload standards.

[1] **Cytology Workforce Study:** A Report of Current Practices and Trends in New York State. *Indra Balachandran, PhD, SCT(ASCP), CFIAC,1 and Maria Friedlander, MPA, CT(ASCP), CMIAC2. Am J Clin Pathol* 2011;136:108-118