ThinPrep® Pap Test™ Doubles Detection Rate of Pre-Cancerous Lesions in New Study

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THINPREP® PAP TEST™ DOUBLES DETECTION RATE OF PRE-CANCEROUS LESIONS IN NEW STUDY

Teterboro, N.J., and Boxborough, MA, September 15, 1999 – The ThinPrep® Pap Test was found to more than double the detection of high-grade precursors to cervical cancer compared to the conventional Pap smear, according to a study just published in the September 1999 issue of *Archives of Pathology and Laboratory Medicine*. The ThinPrep Pap Test is manufactured and marketed by Cytyc Corporation (Nasdaq: CYTC) of Boxborough, Massachusetts.

The paper was authored by Luis A. Diaz-Rosario, M.D., cytopathologist, and Salim E. Kabawat, M.D., medical director, of the Cambridge, Massachusetts, regional laboratory of Quest Diagnostics Incorporated (NYSE: DGX).

The study, "Performance of a Fluid-Based, Thin-Layer Papanicolaou Smear Method in the Clinical Setting of an Independent Laboratory and an Outpatient Screening Population in New England," focused on a low-risk "typical screening population" which spans a broad range of ages and reproductive histories. The investigators compared the clinical diagnostic performance and specimen adequacy of 56,339 ThinPrep specimens with 74,756 conventional Pap smear cases from similar physician office sources in a corresponding period of the previous year. The ThinPrep specimens were obtained from 151 medical practices in Massachusetts, mostly in the Boston area, and Rhode Island.

The investigators reported a 102.5 percent increase, more than doubling the rate of detection of high-grade squamous intraepithelial lesions (HSIL) with the ThinPrep Pap Test compared to the conventional smear. The authors also reported a 72.7 percent increase in the detection of low-grade squamous intraepithelial lesions (LSIL) with the ThinPrep Pap Test. Biopsy correlation data suggest that the increase in HSIL and LSIL detection represented a true increase in sensitivity for these precursors to cervical cancer.

In addition, the ThinPrep method virtually eliminated a significant drawback of the conventional Pap smear — specimens whose quality is limited by the presence of inflammation or blood or by poor collection procedures in the physician's office. With the ThinPrep Pap Test, the number of specimens categorized as "satisfactory but limited," due to obscuring blood declined by 99.8 percent; poor collection by 99.3 percent; and obscuring inflammation by 94.3 percent. These limitations of interpretation affected 7.8 percent of the conventional smears but only 0.3 percent of the ThinPrep slides.

The authors conclude, "Since the main purpose of Pap smear testing is to detect precancerous intraepithelial lesions, it is obvious from our study that the ThinPrep method positively contributes to the fulfillment of the purpose."

"The Quest Diagnostics study has been instrumental in demonstrating the improved performance of the ThinPrep Pap Test," said Patrick Sullivan, Cytyc's president and chief executive officer. "With a growing list of published studies, including more than 250,000 patients, it is clear that the ThinPrep Pap Test is becoming widely recognized and adopted by the clinical community for cervical cancer screening."

"Since we began offering the ThinPrep Pap Test, we have seen many clients enthusiastically adopt it as a replacement for the conventional Pap smear," said Harvey W. Kaufman, M.D., Vice President and Chief Laboratory Officer of Quest Diagnostics. "As the leading provider of cervical cancer screening, we are committed to making effective new technology available to our clients and patients. This study demonstrates the effectiveness of this new technology in a large clinical laboratory setting."

Cytyc Corporation develops, manufactures, and markets the ThinPrep® System for medical diagnostic applications. The ThinPrep System consists of the ThinPrep® 2000 Processor and related reagents, such as PreservCyt®, filters, and other supplies. Since introduction, Cytyc has manufactured more than 1,000 ThinPrep 2000 Processors and 10 million ThinPrep® Pap Tests for cervical cancer screening.

Quest Diagnostics Incorporated, based in Teterboro, New Jersey, is the nation's leading provider of diagnostic testing, information and services to physicians, hospitals, managed care organizations, employers and government agencies with annualized revenues of more than $3 billion. The wide variety of tests performed on human tissue and fluids help doctors and hospitals diagnose, treat and monitor disease. Its Nichols Institute unit conducts research, specializes in esoteric testing using genetic screening and other advanced technologies, and manufactures and distributes diagnostic test kits and instruments. Quest Diagnostics is one of the leading providers of testing to support clinical trials of new pharmaceuticals worldwide. Quest Informatics collects and analyzes laboratory, pharmaceutical and other data to help large health care customers better manage the health of their patients. Additional company information can be found on the Internet at: http://www.questdiagnostics.com.

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