NEWS RELEASE

HPV Test Misses Twice as Many Women Who Develop Cervical Cancer as Cotesting, Quest Diagnostics Health Trends™ Study Finds

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Largest study of a nationally representative American population demonstrates cotesting outperforms HPV or Pap testing alone in detecting cancer and precancer in women 30 years and older

SECAUCUS, N.J., July 8, 2020 /PRNewswire/ -- A Health Trends™ study from researchers at Quest Diagnostics (NYSE: DGX) and the University of Pittsburgh Medical Center (UPMC) provides new evidence that the HPV screening test is significantly less likely to detect cervical cancer and precancer than cotesting, a method which combines HPV and Pap (Papanicolaou test by liquid based cytology) testing using the same specimen.

The **study** is significant because it is the largest to date to assess the performance of guideline-recommended cervical cancer screening methods in a diverse population of American women in real-world care settings. It reveals stark differences in the performance of the various recommended methods in detecting cancer and precancers in women 30 years of age and older.

Published online today in the American Journal of Clinical Pathology, the peer-reviewed study assesses sensitivity rates of HPV alone, Pap alone and cotesting (HPV and Pap testing together) in detecting cancer and precancer of the cervix in nearly 19 million de-identified cotest results performed by Quest Diagnostics on behalf of 13.6 million women in the United States from 2010 to 2018. Of these cases, 1,259 were diagnosed with cervical cancer – twice the number of diagnosed cancer cases as the next largest study.v

"This Health Trends analysis of a notably large and diverse population firmly validates the critical role of cotesting as a cancer and precancer screening method for women 30 and older," said R. Marshall Austin, MD, PhD, Emeritus Professor of Pathology, University of Pittsburgh Medical Center (UPMC). "It should put to rest any notion that HPV alone achieves the same bar for quality cancer screening."

HPV testing identifies the genetic material of the human papillomavirus virus, which can cause cervical cancer, while Pap identifies cellular changes on the cervix that may be or become cancer. The United States Preventive Services Task Force (USPSTF) recommends screening in women 30-65 years of age every three years with Pap, every five years with cotesting or every five years with primary HPV testing.

Among the key findings:

- HPV and Pap testing alone fails to detect twice as many women who develop cervical cancer as cotesting. Of 1,615 cotests taken at any time prior to a cancer diagnosis, 86.9 percent were positive by cotesting, a non-detection rate (also known as false negative) of about 13.1 percent. By comparison, Pap and HPV testing alone had non-detection rates nearly twice as high: Pap at 26.4 percent and HPV at 28.4 percent.

- Cotesting detected significantly more women who developed biopsy-confirmed adenocarcinomas, a typically aggressive form of cervical cancer, identifying 82.3 percent of this cancer compared to only 61.2 percent by HPV and 59.7 percent by Pap.

- HPV testing fails to identify one in five women who develop cancer when performed within a year of cancer diagnosis. Among women screened within one year of a cancer diagnosis, the non-detection rate for HPV testing alone was 22.5 percent, nearly 1.5 times higher than Pap (14.9%) and four times higher than cotesting (5.9%).

- Cotesting detected more women who developed biopsy-confirmed precancers than HPV or Pap alone, identifying 95.6 percent of these precancers, compared to 92.6 percent by HPV and 77.9 percent by Pap.

According to a report published in January 2020 by the American Cancer Society, cervical cancer is the second leading cause of cancer death nationally in women 20-39 years of age, causing 10 premature deaths per week in this age group.i

"While widespread screening has helped cut cervical cancer mortality by three fourths in the past 80 yearsii, this disease is still far too common," said co-author Harvey W. Kaufman, M.D., Senior Medical Director and Director, Health Trends Research Program, Quest Diagnostics. "Because most cervical cancers develop in the absence of regular screening, ensuring women have access to the most reliable screening method, cotesting, when they are screened is an essential step in lowering mortality from this disease."

Health Trends study builds on prior research

The new findings confirm **previous Quest Diagnostics research** published in Cancer Cytopathology in 2015, a journal of the American Cancer Society, which found HPV-only cervical screening would not have detected approximately 19 percent of 526 women who developed confirmed cervical cancer. An analysis of data from Magee-Women's Hospital (MWH) of the University of Pittsburgh Medical Center (UPMC) reported a higher percent of positive Pap than HPV tests among 109 cotesting results within 12 months from cancer diagnosis, similar to the present Quest Diagnostics Health Trends study. iii

By comparison, analysis of a regional dataset from Kaiser Permanente Northern California (KPNC) also found that cotesting outperformed other methods, but the authors of that study concluded that "the contribution of cytology to screening is shown to be very small."iv The KPNC data were also limited in its ability to identify cytological abnormalities associated with confirmed adenocarcinomas, an aggressive cancer, as compared to the Quest and MWH data.v

"It is important to reconcile the similar conclusions of Quest Diagnostics and Magee-Women's Hospital with the different findings of Kaiser Permanente in Northern California," said Lee H. Hilborne, MD, Professor of Pathology and Laboratory Medicine at UCLA, Senior Medical Director, Quest Diagnostics. "KPNC has an exemplary care model, but this very strength may limit the usefulness of KPNC data for drawing conclusions about the real-world care experience of most American women who receive care in less integrated practice settings."

"For women who may otherwise not be screened at all, there is no question that cytology or HPV primary are useful screening technologies," said Damian P. Alagia, III, MD, Senior Medical Director of Woman's Health for Quest Diagnostics. "Yet, that should not obscure the fact that cotesting is fundamentally the better screening option for women and is widely available in the U.S."

Study Strengths and Limitations

The strengths of the study include the large, longitudinal, nationally representative sample size and a study population believed to be reflective of adult women in the United States. The study period covers nine years (2010-2018). The study was limited only to women who sought medical care and were referred to laboratory services at Quest Diagnostics. The Quest Diagnostics Health Trends study was deemed exempt by the Western Institutional Review Board.

About Health Trends™

Quest Diagnostics Health Trends™ is a series of scientific reports that provide insights into health topics, based on analysis of objective clinical laboratory data, to empower better patient care, population health management and public health policy. The reports are based on the Quest Diagnostics database of more than 50 billion de-identified laboratory test results, believed to be the largest of its kind in healthcare. Health Trends has yielded novel insights to aid the management of allergies and asthma, prescription drug monitoring, diabetes, Lyme disease, heart

disease, influenza and workplace wellness. Quest Diagnostics also produces the **Drug Testing Index (DTI)**™, a series of reports on national workplace drug positivity trends based on the company's employer workplace drug testing data. **www.QuestDiagnostics.com/HealthTrends**

About Quest Diagnostics

Quest Diagnostics empowers people to take action to improve health outcomes. Derived from the world's largest database of clinical lab results, our diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve health care management. Quest annually serves one in three adult Americans and half the physicians and hospitals in the United States, and our 47,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives. **www.QuestDiagnostics.com**

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i Siegel, R.L., Miller, K.D. and Jemal, A. (2020), Cancer statistics, 2020. CA A Cancer J Clin, 70: 7-30. doi:**10.3322/caac.21590**

ii Cervical cancer statistics. Cancer Research. October 2014. "Cervical cancer deaths have decreased by 74% in the past fifty year). Further: Routine Pat testing with HPV can reduce cervical cancer incidence by up to 80%. Antilla AM, et al. Annals of Oncology 2010;21(3):448-58

iii Austin RM, Onisko A, Zhao C. Enhanced detection of cervical cancer and precancer through use of imaged liquid-based cytology in routine cytology and HPV cotesting. Am J Clin Pathol 2018; 150:385-392.

iv Schiffman M, Kinney WK, Cheung LC, et al. Relative performance of HPV and cytology components of cotesting in cervical screening. J Natl Cancer Inst 2018;110:501-508.

v Adegoke O, Kulasingam S, Virnig B. Cervical cancer trends in the United States: a 35-year population-based analysis. J Woman's Health. 2012;21(10):1031-1037.

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