Quest Diagnostics Launches Molecular Cervical Cancer Test Based on National Institutes of Health's TERC Gene Marker

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May enhance evaluation of cancer risk in the up to 1.5 million women who receive an indeterminate Pap test result each year

MADISON, N.J., Aug. 30, 2012 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic testing, information and services, today announced the availability of a new laboratory test that identifies molecular changes to cervical cells that increase the likelihood a woman may develop cervical cancer. The test is designed to help physicians identify women who are at increased risk of developing malignancy, unless treated, after receiving unclear results for cervical cancer risk from standard screening tests.

"Given that medical guidelines now advise less frequent cervical cancer screening for women, it is more important than ever that testing for this cancer be highly reliable," said Daniel M. Jones, M.D., Ph.D., Medical Director, Cancer Diagnostics Services, Quest Diagnostics. "Testing for abnormalities of the *TERC* gene is based on the most advanced scientific knowledge available of the molecular changes that turn cervical dysplasia into malignancy. It can potentially act like a 'second opinion' for the thousands of women whose Pap and HPV test results produce an indeterminate picture of cancer risk each year."

The Quest Diagnostics Cervical Cancer *TERC* test is based on the human telomerase RNA component (*TERC*) gene marker under a nonexclusive patent license from the National Institutes of Health (NIH). Research by NIH has shown that the *TERC* gene is amplified, indicated by an abnormal number of copies of the gene on chromosome arm 3q, in the precursor cells of cervical cancer and therefore may be useful for risk stratification in Papanicolaou (Pap) screening.

"One of NIH's goals is to collaborate with commercial organizations to transform our scientific discoveries into clinically valuable technologies," said Dr. Mark Rohrbaugh, Director of the Office of Technology Transfer at the NIH. "The widespread availability of the *TERC* test through Quest Diagnostics achieves this goal because it has the potential to improve the prediction of cervical cancer risk for many women. It highlights the potential for successful public-private collaborations to advance the practice of medicine."

In the United States, women are screened for cervical cancer using Pap and/or human papillomavirus (HPV) tests. Neither Pap nor HPV tests provide definitive results for risk for cervical cancer. Pap tests identify and categorize cellular changes according to risk they will become malignant. HPV tests identify infection with HPV, a virus that causes cervical cancer in some women but is cleared by the immune system in others.

The new Quest Diagnostics test is designed as an adjunct to conventional Pap and HPV tests, and is performed on residual samples from Pap tests. It detects abnormal changes to the *TERC* gene and chromosome 3 to provide a risk assessment of progression to cervical cancer in women who receive indeterminate Pap and/or HPV test results. *TERC* results help categorize risk in abnormal Pap tests prior to colposcopy, a procedure to visually inspect cellular changes. Women with the highest risk result may benefit from additional cervical biopsies at colposcopy and more aggressive monitoring and treatment, while women with low-risk *TERC* and HPV results may be less likely to undergo unnecessary follow-up colposcopy and other procedures.

The new test may be particularly helpful in evaluating women whose Pap test shows mild cellular abnormalities known as low-grade squamous intraepithelial lesions (LSIL). Up to 1.5 million women in the United States receive an LSIL result each year. LSIL diagnosis and treatment is associated with higher patient anxiety, morbidity and cost, although many cases never progress to cancer.

Because cervical cancer may not produce symptoms until advanced stages of disease, screening is vital to detect pre-cervical cellular abnormalities. Guidelines issued in 2012 from the American Cancer Society (ACS) recommend that women of normal risk be screened for cervical cancer with a Pap test every three years between ages 21 and 29, and with a Pap and HPV test together every five years between ages 30 and 65. In the past, the ACS and other organizations recommended Pap screening as frequently as every year for normal-risk adult women depending on type of Pap test, age and other factors.

"Cervical cancer used to be a major cause of death in women in the United States, but thanks to screening, physicians can often catch and treat abnormalities before they progress to cancer," said Dr. Jones. "It is important that the medical community continue to promote clinically appropriate testing so we don't backtrack on these gains. With less frequent Pap screening of women, *TERC* testing is an important tool to ensure women are evaluated reliably and receive the proactive treatment that may prevent malignancy."

Quest Diagnostics is believed to be the first laboratory company with national operations and a full menu of Pap, HPV and biopsy cervical cancer tests to offer a testing service based on the *TERC* marker, affording physicians and patients with broad access in the United States. The new test builds on the company's growing menu of advanced molecular tests for cervical cancer. In early 2012, the company began to offer testing services to identify E6/E7 messenger RNA to help physicians identify women infected with HPV who may have a significantly increased risk of cervical cancer.

Quest Diagnostics and Women's Health

Quest Diagnostics is a comprehensive provider of laboratory testing, research and consultation for women's health disorders across the continuum of a woman's life. The company's specialized services include genetic prenatal carrier tests for diseases such as spinal muscular atrophy, cystic fibrosis and Fragile X; cervical cancer and sexually transmitted disease testing; and pregnancy-related genetic counseling for clinicians and parents. The company's scientists also produce original research on women's health issues published in peer-reviewed journals and at scientific conferences.

About Quest Diagnostics

Quest Diagnostics is the world's leading provider of diagnostic testing, information and services that patients and doctors need to make better healthcare decisions. The company offers the broadest access to diagnostic testing services through its network of laboratories and patient service

centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is a pioneer in developing innovative diagnostic tests and advanced healthcare information technology solutions that help improve patient care. Additional company information is available at QuestDiagnostics.com. Follow us at Facebook.com/QuestDiagnostics and Twitter.com/QuestDX.

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