

For Immediate Release

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FDA APPROVES TWO HOLOGIC HPV TESTS

Cervista HPV HR: First FDA approved high-risk HPV test in a decade
Cervista HPV 16/18: First HPV DNA genotyping test approved by the FDA

BEDFORD, Mass., (March 13, 2009) – Hologic, Inc., (Hologic or the Company) (NASDAQ: HOLX), a leading women’s healthcare company dedicated to serving the healthcare needs of women, today announced that the U.S. Food and Drug Administration (FDA) has approved the Company’s premarket approval (PMA) applications for both the Cervista™ HPV HR (high risk) and the Cervista HPV 16/18 tests. Cervista HPV HR, designed to detect the 14 high-risk types of human papillomavirus (HPV) known to cause cervical cancer, is the first HPV DNA test approved by the FDA in more than 10 years. Cervista HPV 16/18 is the first HPV test approved for genotyping for HPV types 16 and 18, known to be associated with approximately 70% of all cervical cancers in the United States.

The Cervista HPV HR test has been approved for two uses:

- To screen patients with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy.
- Used adjunctively with cervical cytology to screen women 30 years and older to assess the presence or absence of high-risk HPV types.

The Cervista HPV 16/18 test has been approved for two uses:

- In women 30 years and older the test may be used adjunctively with the Cervista HPV HR test in combination with cervical cytology to assess the presence or absence of specific high-risk HPV types.
- Used adjunctively with the Cervista HPV HR test in patients with ASC-US cervical cytology results, to assess the presence or absence of specific high-risk HPV types. The results of this test are not intended to prevent women from proceeding to colposcopy.

It is also noted that for both the Cervista HPV HR test and the Cervista HPV 16/18 test, the test results, along with the physician’s assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management.

The Cervista HPV HR clinical trial was one of the largest and most demographically diverse conducted in the United States to date, involving 89 sites and enrolling approximately 4,000 women nationwide. The trial met or exceeded all target endpoints: most importantly, the

Cervista HPV HR test achieved 100% sensitivity for the detection of CIN3, an immediate precursor to cervical cancer.

The Company believes Cervista HPV HR provides a number of benefits over current products. Cervista HPV HR includes an internal control intended to verify adequate cellularity for testing, thus reducing the potential for false negative results. In addition, because it requires a smaller specimen volume, this technology may minimize inconclusive, or indeterminate results, which may lead to fewer patients being called back for repeat testing. More importantly, Cervista HPV HR is designed to minimize false positive results due to a low-risk HPV strain being mistakenly recognized as a high-risk HPV strain, thereby potentially reducing unnecessary clinical management and patient anxiety.

The additional approval of Cervista HPV 16/18 marks the first FDA approved HPV genotyping test available in the United States. The HPV strains identified by this test represent the two most oncogenic and persistent types of HPV, together believed to cause approximately 70% of cervical cancer. Previous studies have shown HPV 16 and 18 are respectively 5.5 times and 4.5 times more likely to cause cancer than all other high-risk HPV types combined.

“We are extremely excited to enter this market with such a unique and strong portfolio of FDA approved molecular tests for HPV DNA,” said Jack Cumming, chairman and chief executive officer of Hologic. “Our state-of-the-art Cervista HPV tests individually and in combination are designed to provide significant advantages over the existing technology and should help solidify our leadership in cervical cancer screening.”

The Cervista HPV HR and Cervista HPV 16/18 tests are based on Invader[®] chemistry, a patented technology owned by Hologic and well established in other areas of molecular testing. Both tests are approved for use utilizing the sample collected with the ThinPrep[®] Pap Test, offering additional convenience for the healthcare provider.

About Human Papillomavirus and Cervical Cancer

HPV is the most common sexually transmitted disease (STD) in the United States and is recognized as the cause of most cervical cancers. To help prevent the onset of disease, the American College of Obstetrics and Gynecology (ACOG) suggests routine Pap and HPV testing for women over the age of 30 to identify women most likely to develop cervical cancer.

About Hologic, Inc.

Hologic, Inc. is a leading developer, manufacturer and supplier of premium diagnostics products, medical imaging systems and surgical products dedicated to serving the healthcare needs of women. Hologic's core business units are focused on breast health, diagnostics, GYN surgical, and skeletal health. Hologic provides a comprehensive suite of technologies with products for mammography and breast biopsy, radiation treatment for early-stage breast cancer, cervical cancer screening, treatment for menorrhagia, osteoporosis assessment, preterm birth risk assessment, mini C-arm for extremity imaging and molecular diagnostic products including reagents for a variety of DNA and RNA analysis applications. For more information, visit www.hologic.com.

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Forward-Looking Disclaimer

This news release may contain forward-looking information that involves risks and uncertainties, including statements about the anticipated effectiveness, benefits and adoption of the use of the Cervista HPV testing products. There can be no assurance that the tests will achieve the detection rates or benefits demonstrated in the studies cited herein. Newly introduced products may contain undetected errors or defects or otherwise not perform as anticipated. Thus there can be no assurance of general adoption of this technology by the medical community. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to the data or statements presented herein to reflect any change in Hologic's expectations or any change in events, conditions or circumstances on which any such data or statements are based. Certain factors that could adversely affect Hologic's business and prospects are described in Hologic's filings with the Securities and Exchange Commission.