# Hologic Announces FDA Approval of APTIMA HPV 16 18/45 Genotype Assay for Use on the TIGRIS System

## First FDA-Approved Genotyping Test to Detect HPV Types 16, 18 and/or 45

***Press Release**: Hologic, Inc.*

BEDFORD, Mass., Oct. 16, 2012 /PRNewswire/ -- Hologic, Inc. (Hologic or the Company) (HOLX), a leading developer, manufacturer and supplier of premium diagnostics, medical imaging systems and surgical products dedicated to serving the healthcare needs of women, today announced that the U.S. Food and Drug Administration (FDA) has approved the Company's APTIMA HPV 16 18/45 Genotype Assay for use on its TIGRIS instrument system.

Hologic's APTIMA HPV 16 18/45 Genotype Assay is the first test FDA-approved for genotyping human papillomavirus (HPV) types 16, 18 and/or 45, which are associated with approximately 80% of all invasive cervical cancers worldwide. Detecting these HPV types provides health care professionals with more information regarding a patient's risk of subsequently developing cervical cancer.

The APTIMA HPV 16 18/45 Genotype Assay is intended to test specimens from women with APTIMA HPV Assay positive results and is approved for two uses:

- Adjunctively with the APTIMA HPV Assay in women 30 years and older in combination with cervical cytology to assess the presence or absence of specific high-risk genotypes 16, 18 and/or 45
- Adjunctively with the APTIMA HPV Assay in women 21 years or older with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to assess the presence or absence of specific high-risk HPV genotypes 16, 18 and/or 45. The results of this test are not intended to prevent women from proceeding to colposcopy.

"The introduction of the APTIMA HPV 16 18/45 Genotype Assay enhances our HPV product offering on the TIGRIS platform," said Rob Cascella, President and Chief Executive Officer of Hologic. "We are pleased to now offer the most comprehensive portfolio of products that address the cervical cancer screening market and we look forward to maintaining our leadership in this important field."

Hologic acquired the APTIMA HPV 16 18/45 Genotype Assay as part of its acquisition of Gen-Probe Incorporated, which was completed on August 1, 2012. The APTIMA HPV Assay received FDA approval in 2011 and was CE marked in 2008.

As is the case with the Company's APTIMA HPV Assay, Cervista HPV HR test, and Cervista HPV 16/18 test, the APTIMA HPV 16 18/45 Genotype Assay is performed from Hologic's ThinPrep liquid cytology specimens, which are routinely collected for pap testing.

The Company expects to begin commercialization of the APTIMA HPV 16 18/45 Genotype Assay during the first quarter of fiscal 2013