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## **Roche Receives FDA Approval for Use of SurePath Preservative Fluid with cobas HPV Test for Cervical Cancer Screening**

*Roche HPV test is first to be approved for use with the SurePath Preservative Fluid gynecologic cell collection medium commonly used for Pap tests*

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received U.S. Food and Drug Administration (FDA) approval for performing the **cobas**<sup>®</sup> HPV Test from cervical specimens collected in BD SurePath™ Preservative Fluid using the BD SurePath™ vial. In the U.S., a significant number of cervical cancer screening samples are processed using the SurePath vial and preservative fluid. The **cobas** HPV Test is the first HPV (Human Papillomavirus) test approved by the FDA for use with the SurePath collection medium and vial for processing cervical cancer screening samples.

The **cobas** HPV Test, when used with samples collected into SurePath Preservative Fluid, was demonstrated to be safe and effective for cervical cancer screening. The test demonstrated comparable performance similar to specimens collected into ThinPrep PreservCyt Solution, another type of cell collection media.

The FDA approval of SurePath with the **cobas** HPV Test includes triage of ASC-US (Atypical Squamous Cells of Undetermined Significance) Pap cytology results and adjunct testing with Pap cytology for women 30 years of age and older. The SurePath Preservative Fluid is not approved for use with the **cobas** HPV Test as a first-line, primary cervical cancer screening test.

“Until today, no FDA-approved HPV test had been available for laboratories using SurePath Preservative Fluid. We are pleased that the **cobas** HPV Test is the only test in the United States approved for both the ThinPrep and SurePath collection media”, said Uwe Oberlaender, Head of Roche Molecular Diagnostics, Pleasanton, California. “Many labs have a preference in how samples are collected for processing, and this additional approval gives them another clinically validated option for the **cobas** HPV Test.”

### **About the cobas®HPV Test and cobas®4800 System**

Clinically validated by the landmark ATHENA trial, the **cobas** HPV Test provides specific genotyping information for HPV 16 and HPV 18, the highest-risk types, while simultaneously reporting the 12 other high-risk HPV types as a pooled result, all in one test and from one patient sample.

The **cobas** HPV Test is performed on the **cobas** 4800 System, which offers walk-away automation of nucleic acid purification, PCR (polymerase chain reaction) set-up and real-time PCR amplification and detection to help laboratories achieve maximum efficiency. The system also runs Roche tests for CT/NG (chlamydia/gonorrhoea), HSV 1 and 2 (Herpes Simplex Virus), MRSA/SA (methicillin-resistant *Staphylococcus aureus* and *Staphylococcus aureus*) and *C. difficile*, as well as BRAF, EGFR and KRAS mutations. More information about the **cobas** HPV Test is available at [www.hpv16and18.com](http://www.hpv16and18.com).

### **About Human Papillomavirus and Cervical Cancer**

Persistent infection with high-risk Human Papillomavirus (HPV) is the principal cause of cervical cancer in women, with HPV implicated in greater than 99 percent of cervical cancers worldwide. According to the National Cancer Institute, there are more than 12,000 new cases of cervical cancer in the United States annually and 4,210 deaths due to the disease. The World Health Organization estimates there are more than 500,000 new cases of cervical cancer annually.

### **About Roche**

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in *in vitro* diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Roche has been

recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit [www.roche.com](http://www.roche.com).

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