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## **Improving consistency in the diagnosis of cervical pre-cancers: Roche CINtec Histology test receives FDA clearance**

- About 50 million women are screened for cervical cancer every year in the United States<sup>5</sup> and nearly all cases of cervical cancer can be attributed to Human Papillomavirus (HPV) infection<sup>6</sup>
- Cervical cancer is highly preventable when screening includes HPV DNA testing
- Roche's CINtec Histology test is the only clinically validated p16 immunohistochemistry test available globally

Roche (SIX: RO, ROG; OTCQX:RHHBY) today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the CINtec<sup>®</sup> Histology test. This test is the only clinically validated p16 biomarker test that, when used in conjunction with hematoxylin & eosin (H&E) staining, helps pathologists determine which women should receive treatment for cervical pre-cancer. This test is a part of the Roche Cervical Cancer Portfolio, which includes the cobas<sup>®</sup> HPV Test and the CINtec *PLUS* Cytology<sup>4</sup> test.

“The CINtec Histology test will help physicians make informed decisions as to the best course of care for patients with high-grade pre-cancerous cervical disease,” said Roland Diggelmann, CEO, Roche Diagnostics. “By improving the consistency of diagnosis across pathologists, it can help ensure the right patients are receiving the best possible treatment for this highly preventable disease.”

As women positive for HPV are at greater risk for having or developing pre-cancerous cervical lesions, cervical cancer screening can help physicians find and treat these pre-cancerous lesions before they develop into invasive cancers. The CINtec Histology test plays a key role when a cervical tissue biopsy is taken as a result of an abnormal cervical cancer screening result, as it provides conclusive visual confirmation of the presence or absence of pre-cancerous lesions. These lesions, if untreated, could eventually lead to cervical cancer.

FDA clearance was based on the results generated in the CERTAIN<sup>1</sup> (Cervical Tissue Adjunctive Analysis) study, which now joins the landmark ATHENA<sup>2</sup> and PALMS<sup>3</sup> trials in demonstrating the effectiveness of the products within the Roche Cervical Cancer Portfolio. Additionally, the use of p16 immunohistochemistry is recommended by the World Health Organization (WHO), the College of American Pathologists (CAP) and the American Society for Colposcopy and Cervical Pathology (ASCCP) to improve the detection of pre-cancerous cervical disease.

### **About the Roche Cervical Cancer Portfolio**

The Roche Cervical Cancer Portfolio enables healthcare professionals to better screen, manage and diagnose women, based on the confidence and clarity of results across a continuum of patient care. The unique combination of molecular, cellular and tissue-based diagnostic tests provides healthcare professionals powerful information to make patient care decisions and minimize unnecessary treatment. Human Papillomavirus (HPV) is the known cause of cervical cancer and is used to identify women at risk. cobas HPV testing is clinically validated for HPV primary screening, ASC-US triage, and co-testing (HPV and Pap cytology) using the cobas 4800 or cobas 6800/8800 Systems<sup>7</sup>. The assays provide specific genotyping information for HPV16 and HPV18, 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. More information about cobas HPV is available at [www.hpv16and18.com](http://www.hpv16and18.com).

Using advanced, dual-biomarker technology to simultaneously detect p16 and Ki-67, the CINtec *PLUS* Cytology<sup>4</sup> test identifies transforming HPV infections, providing greater certainty to clinicians to stratify patients for follow-up or intervention. The CINtec *PLUS* Cytology test is an objective triage solution for managing HPV-positive or abnormal Pap cytology primary screening results and helps address some of the limitations of traditional Pap cytology. The CINtec *PLUS* Cytology test is not available as an *in vitro* diagnostic test in the United States.

The CINtec Histology test is used to confirm the presence or absence of high-grade cervical disease in women who have had a tissue biopsy. The CINtec Histology test uses the p16 biomarker for a more conclusive diagnosis to provide distinctive visual confirmation of pre-cancerous cervical lesions that may be missed by H&E interpretation alone. Both CINtec assays are fully automated on the VENTANA BenchMark IHC/ISH instruments.

### **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. It can take 10 to 15 years or longer for cervical cancer to develop, so knowing a woman's individual risk and finding disease early, before cancer develops, is an important prevention strategy. The World Health Organization (WHO) 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. 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.

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.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. 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 eight years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 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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<sup>1</sup> The landmark CERTAIN (CERvical Tissue AdjunctIve aNalysis) study, with more than 38,000 slide reads, is one of the largest immunohistochemistry clinical studies conducted to date. The CERTAIN study demonstrated significant improvement across all pathologists for identifying cervical pre-cancer when CINtec Histology was used with H&E. This means that more women are likely to receive the appropriate follow-up and treatment.

<sup>2</sup> ATHENA (Addressing THE Need for Advanced HPV Diagnostics)– The cobas HPV Test was clinically validated in the ATHENA trial. ATHENA, the largest U.S. prospective registrational clinical study of its kind, evaluated the performance of the cobas HPV Test in primary screening, ASC-US triage and co-testing in women with normal cytology and is the only study to assess the value of simultaneous HPV16 and HPV18 genotyping in risk assessment of women.

<sup>3</sup> PALMS (Primary ASC-US LSIL Marker Study), which enrolled more than 27,000 women from five European countries, was designed to evaluate the diagnostic performance of the CINtec PLUS Cytology test in detecting precancerous cervical disease compared to HPV testing and more traditional screening methods like Pap cytology.

<sup>4</sup> The CINtec PLUS Cytology test is not available as an *in vitro* diagnostic test in the United States.

<sup>5</sup> Oncology: An Evidence-Based Approach, edited by Alfred E. Chang, Patricia A Ganz, et al. Springer 2007

<sup>6</sup> World Health Organization Fact Sheet 380, September 2013: <http://www.who.int/mediacentre/factsheets/fs380/en/>

<sup>7</sup> HPV testing is not available on the cobas 6800/8800 Systems within the United States.

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