Media Release

Roche expands access to HPV testing on cobas 5800 molecular system

- **The cobas HPV test has been approved by the FDA for use on the company's newly launched, compact and fully automated cobas 5800 molecular instrument.**
- **Expanding HPV testing on this platform provides labs with a flexible solution to deliver accurate and timely diagnostic results.**
- **Screening for HPV can help identify women who are at risk of developing cervical cancer, so that the disease can be found and treated early.**

INDIANAPOLIS, Nov. 6, 2023 – Roche announced today the recent U.S. Food and Drug Administration (FDA) approval of the cobas® HPV test for use on its next-generation cobas® 5800 molecular instrument. This new approval will broaden access to HPV testing in mid-size and smaller labs in the U.S. to help enable accurate and timely diagnosis of patients who are at risk of developing cervical cancer. With the addition of HPV testing, the cobas 5800 supports critical molecular-testing needs with a broad portfolio of infectious disease, sexual health, respiratory and transplant solutions.

"Roche's continued menu expansion of tests like these for use on the cobas 5800 supports our ongoing commitment to provide access to high-medical-value solutions that can help clinicians deliver the best patient care," said Whitney Green, senior vice president, Molecular & Pathology Lab at Roche Diagnostics. "Expanding access to HPV testing on our new 5800 platform will enable more labs to deliver accurate and reliable results that can lead to the earlier diagnosis of cervical cancer."

The cobas HPV test is indicated for use for routine cervical-cancer screening as per professional medical guidelines, including triage of ASC-US cytology, co-testing (or adjunctive screen) with cytology, and HPV primary screening of women to assess the risk for cervical precancer and cancer. The cobas 5800 supports loading primary-collection vials directly onto the compact system, minimizing hands-on time.

The cobas HPV test, originally introduced in 2011 and clinically validated in large, FDA-registrational trials, ATHENA on the cobas® 4800 and IMPACT on the cobas® 6800/8800, helps healthcare providers identify women at risk for cervical cancer by individually identifying the presence of the DNA of HPV genotypes 16 and 18 – the two genotypes responsible for about 70% of all cervical cancers[1] – and reporting the 12 other high-risk HPV types as a combined result, all in one test and from one patient sample.

About the cobas 5800 System

The cobas 5800 System is a real-time molecular solution built upon the proven technology platform of the cobas® 6800/8800 Systems. The cobas 5800 is designed to provide optimized workflow efficiencies,

[1] Li N, Franceschi S, Howell-Jones R, Snijders PJF, Clifford GM. Human papillomavirus type distribution in 30,848 invasive cervical cancers worldwide: Variation by geographical region, histological type and year of publication. Int J Cancer. 2011;128(4):927–35.

simplicity and timely results to meet the changing demands of labs of all sizes. Labs are able to test multiple assays simultaneously and receive up to 144 results in an eight-hour shift.

The cobas HPV test is now part of the comprehensive menu of assays for use on the cobas 5800, including cobas® BKV, cobas® CMV, cobas® EBV, cobas® HBV, cobas®HBV RNA (RUO), cobas® HCV, cobas® HIV-1, cobas® HIV-1/HIV-2 Qual, cobas® SARS-CoV-2 Qual, cobas® CT/NG, cobas® TV/MG, and cobas®omni Utility Channel (a dedicated open channel). This comprehensive, high-medical-value menu is now available across all of Roche's flagship molecular platforms, including cobas 5800, 6800 and 8800.

About Roche

Founded in Basel, Switzerland, in 1896 as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person, we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognizing our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.
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.

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