

Roche launches human papillomavirus (HPV) self-sampling solution, expanding cervical cancer screening options

- **Every year, over 604,000 women worldwide are diagnosed with cervical cancer and approximately 342,000 die from this preventable disease, caused by infection with Human Papillomavirus (HPV).¹**
- **Nearly nine out of 10 women who die from cervical cancer live in low- and middle-income countries.² For patients living in areas with limited healthcare resources, increasing access to screening and decreasing barriers to sample collection are keys to ultimately preventing this disease.**
- **Roche's HPV self sampling solution expands access to HPV screening options by enabling patients to privately collect their sample while at a healthcare facility.**

Basel, 16 June 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the launch of a human papillomavirus (HPV) self sampling solution in countries accepting the CE mark. This new solution enables a patient to privately collect her sample for HPV screening while at a healthcare facility, following instructions provided by a healthcare worker. The clinically-validated vaginal sample is analysed with the Roche cobas[®] HPV test on a Roche molecular instrument.

Screening for human papillomavirus (HPV) can help identify women who are at risk of developing cervical cancer, so that the disease can be found and treated early before it has a chance to develop. There are many drivers that contribute to women not participating in cervical cancer screening programs, including limited access to testing, past experiences, embarrassment and cultural influences. Roche's self sampling solution helps reduce these barriers by offering women an alternative to more invasive clinician collection procedures, while also providing accurate and reliable results enabling clinicians to make patient care decisions.

"The elimination of cervical cancer is within reach. Reducing barriers to HPV screening by enabling women to self-collect their own specimen for HPV testing is a critical tool in the fight against cervical cancer," said Thomas Schinecker, CEO Roche Diagnostics.

In low- and middle-income countries, women are often diagnosed with cervical cancer at a more advanced stage, where the opportunity for cure is low. By broadening access through removing barriers and enabling screening in additional healthcare environments, Roche highlights its commitment to achieving the World Health Organisation's global strategy to eliminate cervical cancer and reduce the overall mortality rate.³

About the cobas HPV test

The cobas HPV test is indicated for use for routine cervical cancer screening as per professional medical guidelines, including HPV primary screening, co-testing (or adjunctive screen) with cytology, and for triage of women with abnormal cytology, to assess the risk for cervical precancer and cancer. Test performance for this new sampling method demonstrates that self-collected vaginal specimens tested using a molecular technology are fully adequate, and provide results that are comparable to clinician-collected cervical samples.

Cervical cancer screening using the cobas HPV test is clinically validated in large, FDA registrational trials for use on cobas systems, and the assay individually identifies the presence of the DNA of HPV genotypes 16 and 18 – the two genotypes responsible for about 70 percent of all cervical cancers⁴ – and reporting the 12 other high-risk HPV types as a combined result, all in one test and from one patient sample. More information about the cobas HPV tests is available at diagnostics.roche.com/cervicalcancer or cervicalcancer-screening.com.

The fully automated cobas 6800/8800 Systems offer the fastest time to results, providing up to 96 results in about three hours, and 384 results for the cobas 6800 System and 1,056 results for the cobas 8800 System in an eight hour shift. Learn more now: <http://diagnostics.roche.com>.

About Roche

Founded in 1896 in Basel, Switzerland, 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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References

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[2] Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2021;71:209–49. doi:10.3322/caac.21660.

[3] <https://www.who.int/publications/i/item/9789240014107>

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Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD

Phone: +41 61 687 41 47

Karsten Kleine

Phone: +41 61 682 28 31

Nina Mählietz

Phone: +41 79 327 54 74

Nathalie Meetz

Phone: +41 79 771 05 25

Dr. Barbara von Schnurbein

Phone: +41 61 687 89 67

Sileia Urech

Phone: +41 79 935 81 48

Roche Investor Relations

Dr. Bruno Eschli

Phone: +41 61 68-75284

e-mail: bruno.eschli@roche.com

Dr. Sabine Borngräber

Phone: +41 61 68-88027

e-mail: sabine.borngraeber@roche.com

Dr. Birgit Masjost

Phone: +41 61 68-84814

e-mail: birgit.masjost@roche.com

Dr. Gerard Tobin

Phone: +41 61 68-72942

e-mail: gerard.tobin@roche.com

Investor Relations North America

Loren Kalm

Phone: +1 650 225 3217

e-mail: kalm.loren@gene.com