

Roche launches new PCR test to help improve diagnostic accuracy for women affected by vaginitis in countries following the CE Mark

- **The new PCR test aids in the diagnosis of infectious causes of vaginitis through the detection of bacteria associated with bacterial vaginosis and yeast associated with candida vaginitis.**
- **The test will help improve diagnostic accuracy for millions of women¹ affected by vaginitis annually, delivering more accurate and specific results.**
- **This test offers faster diagnosis by using a single vaginal swab for broader sexual health testing, eliminating the need for an additional sample.**

Basel, 9 December 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the CE Mark for its cobas® BV/CV (Bacterial Vaginosis/Candida Vaginitis) assay to accurately identify specific bacteria and yeast responsible for BV and CV in vaginal samples from symptomatic patients collected using the cobas PCR Media proprietary tube.

Clinicians typically rely on microscopy, pH testing, and clinical observation to diagnose BV and CV, which present with non-specific symptoms. These methods can deliver inaccurate results, leading to delays in treatment or prescription of unsuitable therapies. The cobas BV/CV assay resolves this challenge by delivering accurate and specific results, allowing healthcare professionals to deliver targeted therapies to patients more quickly.

“The cobas BV/CV assay protects women from the risks of delayed or incorrect treatment, leading to faster relief from symptoms and a reduced likelihood of serious future complications,” said Matt Sause, CEO of Roche Diagnostics. “At the same time, it improves efficiency for healthcare services by accurately identifying the most common causes of inflammation or infection in a single test.”

Bacterial vaginosis impacts approximately 25% of women of reproductive age², while up to 75% of women experience candida vaginitis at least once in their lifetime³. Vaginal symptoms are one of the most common reasons women visit the doctor each year. Diagnosis of these conditions can be challenging as symptoms are often non-specific, and traditional testing methods, such as microscopy, lack precision. Causing uncomfortable and sometimes distressing symptoms such as itching, burning, discharge, and irritation, BV and CV infections are also associated with an increased risk of having a sexually transmitted infection (STI).⁴

The global sexual health market segment is valued at CHF 1.1 bn, with an annual growth rate of 11%. Of this market segment, vaginitis is the primary growth driver with a yearly growth rate of 26%.⁵ The cobas BV/CV assay further expands Roche Diagnostics' established sexual

health portfolio. By enabling testing for BV and CV alongside a broad range of sexually transmitted infections, including Chlamydia, Gonorrhoea, Trichomonas, and *Mycoplasma genitalium*, using the same sample, the assay enhances the capabilities of the cobas 5800/6800/8800 systems. This streamlined approach supports sexual health clinics, hospitals, and laboratories by delivering faster, more efficient workflows, while also ensuring that patients benefit from accurate diagnosis and timely care.

The cobas BV/CV assay is now available in countries accepting the CE Mark.

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 recognising our endeavour 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 fifteenth 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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