Media Release

Roche receives FDA clearance for the cobas® BV/CV assay, enabling fast and highly accurate vaginitis diagnosis

- **The new PCR test uses clinician-collected or clinician-instructed, self-collected vaginal swab specimens to simultaneously detect organisms associated with *Bacterial vaginosis* (BV) and *Candida vaginitis* (CV).**
- **This molecular assay can help improve diagnostic accuracy for symptomatic women affected by vaginitis, compared to traditional methods.[1]**
- **The assay expands the sexual-health testing menu on the cobas® 6800/8800 systems, enabling a broad-range of testing from a single sample.**

INDIANAPOLIS, July 24, 2026 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its **cobas®** BV/CV *(Bacterial vaginosis/Candida vaginitis*) assay. This molecular diagnostic test provides results for both *Bacterial vaginosis* (BV) and *Candida vaginitis* (CV) from a single vaginal swab sample. It enables accurate and timely results that can lead to improved patient outcomes and enhanced healthcare efficiencies.

Vaginitis is one of the most common reasons women visit a healthcare provider,[2] with *Bacterial vaginosis* (BV) and *Candida vaginitis* (CV) being two of the most frequent causes of infection.[3] Clinicians have traditionally relied on less precise methods such as microscopy, pH testing and clinical observation to diagnose these conditions, yet these methods lack precision.[4,5,6] Accurate vaginitis diagnosis is a cornerstone of effective treatment, yet misdiagnosis of this condition is close to 50%, raising the risk of recurrence.[7]

“Compared to traditional methods, the **cobas®** BV/CV test can help improve diagnostic accuracy for women affected by vaginitis, addressing a critical need in women’s health,” said Brad Moore, President and CEO, Roche Diagnostics North America. “By expanding our sexual-health portfolio to include comprehensive results for the most common conditions from a single sample, we can streamline care to help patients receive the right treatment faster.”

Bacterial vaginosis impacts approximately 27% of women of reproductive age in North America,[8] while up to 75% of women experience *Candida vaginitis* at least once in their lifetime.[9] Diagnosis of these conditions can be challenging as symptoms are often non-specific, and traditional testing methods, such as microscopy, lack precision. BV and CV infections can cause uncomfortable and sometimes distressing symptoms such as itching, burning, discharge and irritation, and are also associated with an increased risk of having a sexually transmitted infection (STI).[10]

The **cobas**® BV/CV assay, an in vitro diagnostic test, is only available for professional laboratory use based on a clinician's order. The assay utilizes real-time polymerase chain reaction (PCR) technology to accurately identify the specific bacteria and yeast responsible for BV and CV in vaginal samples from symptomatic patients. The test detects DNA targets for organisms associated with BV, including *Gardnerella vaginalis*, *Atopobium vaginae* and *Lactobacillus spp*. It also detects Candida species associated with CV, including *C. albicans, C. glabrata, C. krusei*, *C. parapsilosis, C. tropicalis* and *C. dubliniensis*.

The test aligns with guidelines from the Centers for Disease Control and Prevention, which does not recommend speciation prior to first-line therapy. Additional Candida speciation or susceptibility testing should be performed if there is persistent or recurrent infection defined by three or more episodes of symptomatic CV within one year or documented treatment failure with first-line therapy.

The sample is collected using a clinician-collected or clinician-instructed, self-collected vaginal swab in **cobas**® PCR Media in a healthcare setting. This enables diagnosis from a single sample that can also be used for broader sexual-health testing with the **cobas**® CT/NG (*Chlamydia trachomatis/Neisseria gonorrhoeae*) and **cobas**® TV/MG *(Trichomonas vaginalis/Mycoplasma genitalium*) assays, eliminating the need for additional samples for extended testing.

Roche's Sexual-Health Portfolio

The **cobas**® BV/CV assay further expands Roche Diagnostics' established sexual-health portfolio to provide a full testing menu for sexually transmitted infections. By enabling concurrent testing for BV and CV alongside a broad range of STIs, including *Chlamydia trachomatis*, *Neisseria gonorrhea*, *Trichomonas vaginalis* and *Mycoplasma genitalium*, from the same sample, it enhances the capabilities of the **cobas**® 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. Roche plans to add the **cobas**® 5800 system to the assay via the FDA's Reagent Replacement and Instrument Family Policy. The commercial launch is expected later this year.

About Roche

Roche is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.

Roche was founded in Basel, Switzerland in1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around

the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

For more information, please visit www.roche.com.

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