

VAGINAL PANEL CONTROL

Take control, Molecular control

AMPLIRUN® TOTAL VAGINAL PANEL CONTROL

EXTRACTION & AMPLIFICATION CONTROLS FOR NUCLEIC ACID TESTS

- Multi-panel control set designed to simulate a range of microbiota profiles, from normal flora (*Lactobacillus crispatus* only) to mixed clinical scenarios including *Candida*, *Trichomonas*, *Atopobium vaginae* and bacterial vaginosis-associated microorganisms.
- **Inactivated whole pathogen:** contains the entire genome, monitoring end-to-end molecular workflow.
- **Total control** in a matrix that mimics a **human vaginal swab** sample, including **human epithelial cells** for a more clinically representative extraction
- **Quantified, low positive:** prepared to produce results at a significant clinical concentration.
- **Monodose format and lyophilized presentation:** ensures stability and reduces handling and transport costs.



🎯 PANELS

- 5 panels with different concentrations of microorganisms* simulating clinical conditions

Panel	Simulated profile	Targets
1	Normal flora	<i>Lactobacillus crispatus</i>
2	Normal flora + Candida	<i>Lactobacillus crispatus</i> + <i>Candida albicans</i>
3	Normal flora + BV-associated bacteria	<i>Lactobacillus crispatus</i> + <i>Atopobium vaginae</i>
4	BV profile	<i>Lactobacillus crispatus</i> + <i>Trichomonas vaginalis</i> + <i>Gardnerella vaginalis</i> + <i>Atopobium vaginae</i>
5	BV + Candida profile	<i>Candida krusei</i> + <i>Gardnerella vaginalis</i> + <i>Atopobium vaginae</i>

* Exact concentrations in copies/vial are provided in the Certificate of Analysis

VAGINAL PANEL CONTROL (SWAB)

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Get the vaginitis diagnosis right!

The most frequent vaginitis infectious causes include **Bacterial Vaginosis (BV)**, **Vulvovaginal Candidiasis** and **Trichomoniasis**, and they can occur alone or together.

In BV, the vaginal microbiota changes, often involving a decrease in protective *Lactobacillus* and the presence of BV-associated organisms.

Improper diagnosis can lead to inadequate treatment and recurrent symptoms

47%

Of women with BV received an inappropriate prescription¹

34%

Of women without BV were prescribed antibiotics and/or antifungals¹

Risks of **delayed diagnosis** or **misdiagnosis**

60%

Increased risk of HIV acquisition with BV²

18%

Of women tested positive for BV were coinfecting with a Sexually Transmitted Infection³

Why molecular testing for vaginitis?

- Vaginitis symptoms often appear similar, so **identifying the true cause** is essential for proper treatment.
- Molecular diagnostics enable **highly sensitive and specific pathogen detection**, providing analytically objective and reproducible results.
- Multiplex approach allows the detection of polymicrobial imbalance and co-infections **from a single run**.

Why quality control matters?

In molecular vaginitis testing

- Molecular testing involves multiple steps, so an external control helps **verify the full workflow from extraction to detection**, and can reveal issues that might otherwise go unnoticed.
- Many PCR workflows still rely on **in-house controls** or previously characterized positive specimens, which can be limited, non-standardized, and less stable.

INFORMATION AND RELATED PRODUCTS

Description	Cat. No.	Class	Content
AMPLIRUN® TOTAL VAGINAL CONTROL PANEL	MBTC033-R	RUO	2 x 5 vials
VAGINAL PANEL REALTIME PCR KIT (semiquantitative)	RTPCR005-LPD	CE	48 tests

¹Hillier, Sharon L et al. "Diagnosis and Treatment of Vaginal Discharge Syndromes in Community Practice Settings." *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America* vol. 72,9 (2021): 1538-1543.

²Cohen, CR et al. Bacterial Vaginosis Associated with Increased Risk of Female-to-Male HIV-1 Transmission: A Prospective Cohort Analysis among African Couples". *PLoS Med* 9(6): e1001251. 2012

³Abou Chacra, Linda et al. "Relationship between Bacterial Vaginosis and Sexually Transmitted Infections: Coincidence, Consequence or Co-Transmission?" *Microorganisms* vol. 11,10 2470. 1 Oct. 2023