



Advancing Women’s Health with Rapid Diagnostics: bioMérieux files a Dual 510(k) /CLIA Waiver application to the FDA for the BIOFIRE® SPOTFIRE® Vaginitis Panel

Marcy-l’Étoile (France), June 26th, 2026 – bioMérieux, a world leader in the field of *in vitro* diagnostics, has submitted a Dual 510(k)/CLIA Waiver* application to the U.S. Food and Drug Administration (FDA) for the BIOFIRE® SPOTFIRE® Vaginitis (VG) Panel. This automated, multiplex PCR*** test can simultaneously detect the most common causes of vaginitis in 20 minutes, directly at the point of care. With this submission, bioMérieux is intending to expand into women’s and sexual health, bringing rapid and accurate diagnostics closer to patients.**

Most women will experience an episode of vaginitis during their lifetime, often associated with a range of painful symptoms¹. Vaginitis is a broad clinical term encompassing conditions such as bacterial vaginosis, vulvovaginal candidiasis, or trichomoniasis, which may arise from infection or an imbalance of the microbiome. Despite its high prevalence, vaginitis is often misdiagnosed or incompletely characterized using traditional methods which can be subjective or lack sensitivity. Only about half of women diagnosed with vaginitis by non-molecular testing receive appropriate treatment².

Over the past decade, vaginitis testing has evolved with the introduction of molecular diagnostics to improve accuracy and detection of relevant microorganisms, yet significant gaps remain, and long turnaround times can delay treatment decisions and prolong patient discomfort. bioMérieux is now advancing with the BIOFIRE® SPOTFIRE® VG Panel, a rapid and actionable test designed to support patients experiencing symptoms of vaginitis at the point of care.

The BIOFIRE® SPOTFIRE® VG Panel reports 8 results, including bacterial vaginosis, yeast and parasite pathogens,³ with one swab, in about 20 minutes to align within a typical patient’s visit timeframe. The BIOFIRE® SPOTFIRE® VG Panel aims to support timely treatment decisions and deliver a clear and dignified diagnostic experience, which may be associated with improved patient management.

“Not only are the symptoms of vaginitis disruptive and painful, the underlying condition is also associated with other health conditions, including pelvic inflammatory disease, cervical cancer, adverse birth outcomes, and secondary infections. bioMérieux is proud to bring a better diagnostic solution to patients, which can guide healthcare practitioners in prescribing targeted treatment to more quickly alleviate symptoms and potentially reduce the risk of other negative health consequences,” stated Dr. Charles K. Cooper, Executive Vice President, Chief Medical Officer, bioMérieux.

The BIOFIRE® SPOTFIRE® VG Panel represents bioMérieux’s first step into women’s and sexual health testing and expansion of its innovative point-of-care portfolio. Its offering already includes panels for respiratory and sore throat infections, all running on the BIOFIRE® SPOTFIRE® System, an easy-to-use, modular instrument with a small footprint designed to fit in any healthcare setting and already trusted by healthcare professionals worldwide.

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“Today, there is a clear and persistent gap in vaginitis diagnostics — between the need for accurate, comprehensive testing and the reality of delayed or incomplete results in clinical practice. With the BIOFIRE® SPOTFIRE® Vaginitis Panel, bioMérieux is addressing this gap by bringing fast, syndromic molecular testing directly to the point-of-care setting, enabling healthcare practitioners to move from uncertainty to actionable answers within a single patient visit. This is not just an incremental improvement, it’s a strategic step toward closing a long-standing diagnostics gap in women’s and sexual health, fundamentally improving both clinical decision-making and the patient experience,” added Jennifer Zinn, Executive Vice President, Clinical Operations, at bioMérieux.

With the submission to the FDA of a near patient solution dedicated to vaginitis testing, bioMérieux aims to strengthen its leadership in expanding syndromic testing beyond traditional clinical laboratories and into point-of-care settings. This approach enables healthcare professionals to deliver results during the patient visit and to reinforce the role of diagnostics in the global fight against infectious diseases.

Following its submission to the U.S. FDA, the BIOFIRE® SPOTFIRE® VG Panel is also expected to be submitted as a Class C Near Patient Test for CE marking under the IVDR**** in the European Union.

* *Clinical Laboratory Improvement Amendments (CLIA) waiver allows the BIOFIRE® SPOTFIRE® Vaginitis Panel to be used by non-lab professionals at the point of care.*

** *Not available for sale, pending FDA clearance, product subject to change.*

*** *Polymerase Chain Reaction*

**** *In Vitro Diagnostic Regulation*

¹ Workowski KA, Bachmann LH, Chan PA, Johnston CM, Muzny CA, Park I, Reno H, Zenilman JM, Bolan GA. Sexually Transmitted Infections Treatment Guidelines, 2021. *MMWR Recomm Rep.* 2021 Jul 23;70(4):1-187. doi: 10.15585/mmwr.rr7004a1. Erratum in: *MMWR Morb Mortal Wkly Rep.* 2023 Jan 27;72(4):107-108. doi: 10.15585/mmwr.mm7204a5. PMID: 34292926; PMCID: PMC8344968.

² Hillier SL, Macio I, Gallagher R, Meyn L, Beamer M, Zamborsky T, Campbell T, Bunge K, Wiesenfeld HC. Randomized Study of Usual Care vs Xpert® Xpress MVP at the Point of Care for Accurate Diagnosis and Appropriate Treatment of Vaginal Infections. *Sex Transm Dis.* 2026 May 12. doi: 10.1097/OLQ.0000000000002343. Epub ahead of print. PMID: 42117698.

³ **Bacteria:** Bacterial vaginosis - Result informed by an algorithm which assesses the relative abundance of multiple bacteria to provide a binary result. Organisms included are *Fannyhessea (Atopobium) vaginae*, *Bacterial Vaginosis-Associated Bacterium 2 (BVAB2)*, *Lactobacillus crispatus*, *Lactobacillus gasseri/paragasseri*, *Lactobacillus jensenii/mulieris*, *Sneathia sanguinegens/vaginalis (amnii)*

Yeast: *Candida albicans*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, *Candida tropicalis*, *Candida dubliniensis*

Parasite: *Trichomonas vaginalis*

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics since 1963, bioMérieux is present in 46 countries and serves more than 160 countries with the support of a large network of distributors. In 2025, revenues reached €4.1 billion, with over 94% of sales outside of France.

bioMérieux provides diagnostic solutions (systems, reagents, software and services) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are mainly used for diagnosing infectious diseases. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

www.biomerieux.com.



bioMérieux is listed on the Euronext Paris stock market.

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CONTACTS

INVESTORS RELATIONS

bioMérieux

Aymeric Fichet

Tel: +33 (0)4 78 87 20 00

investor.relations@biomerieux.com

MEDIA RELATIONS

Corporate

Romain Duchez

Tel: +33 (0)4 78 87 20 00

media@biomerieux.com

United States

Todd Siesky

Tel: +1 919.791.5822

todd.siesky@biomerieux.com

France

Isabelle de Segonzac (Image 7)

Tel: +33 (0)1 53 70 74 85

isegonzac@image7.fr

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