Xpert® Xpress MVP

On-demand PCR test for improving women's health by uncomplicating the diagnosis of vaginitis



The Need

Vaginitis is a leading cause of clinic visits by women, with more than 10 million per year in the United States.[1] Limitations with traditional test methods contribute to poor diagnosis, inappropriate treatment, and persistent symptoms.[2] High performing PCR tests are available for large, batch analyzers but have limited practical use for clinicians due to a lag in reportable results, making appropriate same day treatment a challenge.[3]

Challenges remain:

- Detection and differentiation of organisms associated with bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), and trichomoniasis (TV), which all present with similar symptoms
- Mixed and co-infections of BV, VVC, and TV are common, further complicating diagnosis and the guidance of appropriate treatment[4,5]
- Testing options that offer accurate and objective test results to drive timely and appropriate treatment for improved patient management

The Solution

The Xpert® **Xpress** MVP test is a CLIA-waived FDA cleared on-demand PCR test to aid in the diagnosis of vaginal infections in symptomatic women within an hour. This test introduces a simpler algorithm for organisms associated with bacterial vaginosis, combined with the detection of Candida species associated with vulvovaginal candidiasis, and *Trichomonas vaginalis*, from a single sample on Cepheid's easy-to-use GeneXpert® systems.

On-demand molecular testing — an ideal solution:

- Actionable diagnostic aid for bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis within 60 minutes, including potential co-infections
- On-demand results for 4 separate callouts, bacterial vaginosis, *Candida* group,* *C. glabrata/C. krusei*, and *T. vaginalis* from a single sample collection
- Implementing easy-to-use testing with GeneXpert technology
- Approved for women 14 years old and over

The Impact[6]

- The Xpert **Xpress** MVP demonstrates high sensitivity and specificity in detecting the most common causes of vaginitis from clinician and patient-collected samples in both **laboratory-based and point-of-care** settings.
- Xpert **Xpress** MVP is a flexible, easy to use, on-demand test designed with optimized workflow efficiencies for the diagnosis of vaginitis-like symptoms.
- Accurate differential diagnosis with Xpert **Xpress** MVP informs appropriate treatment on time, first time, potentially improving clinical outcomes.

1 Brown H, et al. Improving the Diagnosis of Vulvovaginitis: Perspectives to Align Practice, Guidelines, and Awareness. Population Health Management 2020 23:S1, S-3-S-12

2 Hillier SL, et al. Diagnosis and treatment of vaginal discharge syndromes in community practice settings. Clin Infect Dis. 2021 May 04; 72(9) 1538-1543

3 Gaydos CA, et al. Use of a Rapid Diagnostic for Chlamydia trachomatis and Neisseria gonorrhoeae for Women in the Emergency Department Can Improve Clinical Management: Report of a Randomized Clinical Trial. Ann Emerg Med. 2019 Jul; 74(1) 36-44

4 Gaydos CA, et al. Clinical Validation of a Test for the Diagnosis of Vaginitis. Obstetrics & Gynecology: July 2017 - Volume 130 - Issue 1 - p 181-189 doi: 10.1097/AOG.0000000000002090

5 Schwebke J, et al. Clinical Validation of the Aptima Bacterial Vaginosis and Aptima Candida/Trichomonas Vaginitis Assays: Results from a Prospective Multicenter Clinical Study. J Clin Microbiol 58:e01643-19.

6 Lillis, RA, et al. Clinical Evaluation of a New Molecular Test for the Detection of Organisms Causing Vaginitis and Vaginosis. J Clin Microbiol. 2023 Mar 23;61(3):e0174822. doi: 10.1128/jcm.01748-22. Epub 2023 Feb 28.

Xpert® Xpress MVP

Product Reference Sheet — US-IVD

Test Reagent Kit	Xpert **Xpress** MVP
Catalog Number	XPRSMVP-10
Technology	Real-time PCR
Targets	**Bacterial Vaginosis*** *Atopobium spp.* *(Atopobium vaginae, Atopobium* novel species *CCUG 55226)* BVAB2 *Megasphaera-1* **Candidiasis** *Candida spp.* *(C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis;* species not differentiated) *Candida glabrata/Candida krusei* species not differentiated)) **Trichomoniasis** *Trichomonas vaginalis*
Batch or On-Demand	On-Demand
Minimum Batch Size	1
Sample Types	**Specimen:** Vaginal swab (both clinician-collected and self-collected in a clinical setting) Swab Transport Reagent included in the Xpert Swab Specimen Collection kit (catalog number SWAB/G-50-US)
Sample Extraction	Automated/integrated
Precision Pipetting	Transfer pipette provided
TAT	Within 60 minutes
Hands-on Time	≤1 minute
Controls: Process	Sample Processing Control
Controls: Probe Function/Detection	Probe Check Control (PCC)

Clinical Performance

	Moderately Complex				CLIA Waived			
	Clinician-collected		Self-collected		Clinician-collected (CVS)		Self-collected (SVS)	
	Sensitivity /PPA (95% CI)	Specificity/ NPA (95% CI)	Sensitivity /PPA (95% CI)	Specificity/ NPA (95% CI)	Sensitivity /PPA (95% CI)	Specificity/ NPA (95% CI)	Sensitivity /PPA (95% CI)	Specificity/ NPA (95% CI)
BV	93.8% 531/566 (91.5%–95.5%)	93.8% 808/861 (92.0%–95.3%)	94.0% 533/567 (91.7%–95.7%)	92.9% 794/855 (90.9%–94.4%)	92.9% 429/462 [a] (90.1%–94.9%)	94.5% 719/761 [b] (92.6%–95.9%)	93.5% 434/464 [c] (90.9%–95.4%)	93.6% 711/760 [d] (91.6%–95.1%)
Candida group^	98.0% 396/404 (96.1%–99.0%)	94.6% 984/1040 (93.1%–95.8%)	97.5% 393/403 (95.5%–98.7%)	92.1% 954/1036 (90.3%–93.6%)	98.1% 360/367 [e] (96.1%–99.1%)	94.9% 820/864 [f] (93.2%–96.2%)	97.8% 359/367 [g] (95.8%–98.9%)	92.9% 804/865 [h] (91.0%–94.5%)
Candida glab-krus Fresh Prospective	93.6% 44/47 (82.8%–97.8%)	99.6% 1392/1397 (99.2%–99.9%)	97.8% 45/46 (88.7%–99.6%)	99.4% 1384/1393 (98.8%–99.7%)	94.1% 32/34 ¡ (80.9%–98.4%)	99.8% 1195/1197 [i] (99.4%–99.9%)	100% 33/33 (89.6%–100%)	99.7% 1195/1199 [k] (99.1%–99.9%)
Candida glab-krus# Contrived	99.0% 98/99 (94.5%–99.8%)	96.4% 27/28 (82.3%–99.4%)	N/A	N/A	99.0% 98/99 (94.5%–99.8%)	96.4% 27/28 (82.3%–99.4%)	N/A	N/A
TV	97.3% 73/75 (90.8%–99.3%)	99.6% 1332/1337 (99.1%–99.8%)	97.3% 72/74 (90.7%–99.3%)	99.8% 1330/1333 (99.3%–99.9%)	98.0% 48/49 [l] (89.3%–99.6%)	99.6% 1155/1160 [m] (99.0%–99.8%)	97.9% 47/48 [n] (89.1%–99.6%)	99.7% 1159/1162 [o] (99.2%–99.9%)

Sample Storage	Samples should be transported at 2–28 °C. Vaginal Swabs placed in transport reagent following collection can be stored for up to 42 days at 2–28 °C prior to testing with the Xpert **Xpress** MVP test
Kit Storage	2–28 °C
Commercial Controls	Refer to Xpert **Xpress** MVP Instructions for Use or contact Cepheid Technical Support

* Detected organisms not reported individually.
^ Target includes *C. albicans, C. tropicalis, C. parapsilosis,* and *C. dubliniensis*
# Contrived specimens were prepared using individual negative clinical vaginal swab specimens.
Refer to most current Instructions for Use 301-8994 and 302-6886 (for GeneXpert Dx and Infinity Systems) for complete details.
US-IVD. *In Vitro* Diagnostic Medical Device.

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