Cepheid®
A better way.

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

Xpert® Xpress MVP

US-IVD. *In Vitro* Diagnostic Medical Device.

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 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]
- Insights for effective triage and patient management
- 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 new, FDA cleared on-demand PCR test to aid in the diagnosis of vaginal infections in symptomatic women within an hour. This test introduces a BV flora specific algorithm for bacterial vaginosis combined with the detection of *Candida* species (*Candida* group and *Candida glabrata/krusei*) 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/krusei*, and *T. vaginalis* from a single sample collection
- Implementing easy-to-use testing with GeneXpert technology

The Impact

The Xpert **Xpress** MVP test, performed on Cepheid's GeneXpert systems, delivers an accurate, simple, and flexible solution for uncomplicating the diagnosis of vaginitis. **It delivers single-test confidence aiding clinicians in diagnosing three distinct conditions from one sample.**

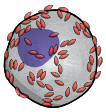
- Easy to use multiplex, real-time PCR panel test
- Less than 1 minute hands-on-time and objective PCR results within 60 minutes
- Detect mixed and diverse vaginal conditions from one sample
- Designed to enable appropriate treatment the first time

Coverage, plus
Accuracy, plus
Peace of mind

That's the **PCR***plus* advantage.
From Cepheid.

Multi-Organism Bacterial Vaginosis Algorithm: Designed to Detect Key Organisms Strongly Associated with BV

BV Flora



Atopobium vaginae
BVAB2
Megasphaera-1

- *Highly associated with BV* [6]
- *Combination offers optimal sensitivity, specificity and accuracy for BV* [6-9]

Gardnerella vaginalis

- *Sensitive but not specific for BV* [6-8]
- *Variable amounts in BV flora*
- *Found in 70% of women without BV* [6-9]

Mobiluncus sp.
Prevotella sp.

- *Variable amounts in BV flora*
- *Low sensitivity for BV* [6]

Normal/Healthy *Flora*

Lactobacillus crispatus
L. jensenii
L. gasseri

- *Type and distribution varies by ethnicity*
- *Limited utility as a negative indicator of BV* [7]

L. iners

- *More common in some ethnicities*
- *Found equality in BV and healthy flora* [9]

Clinical Performance

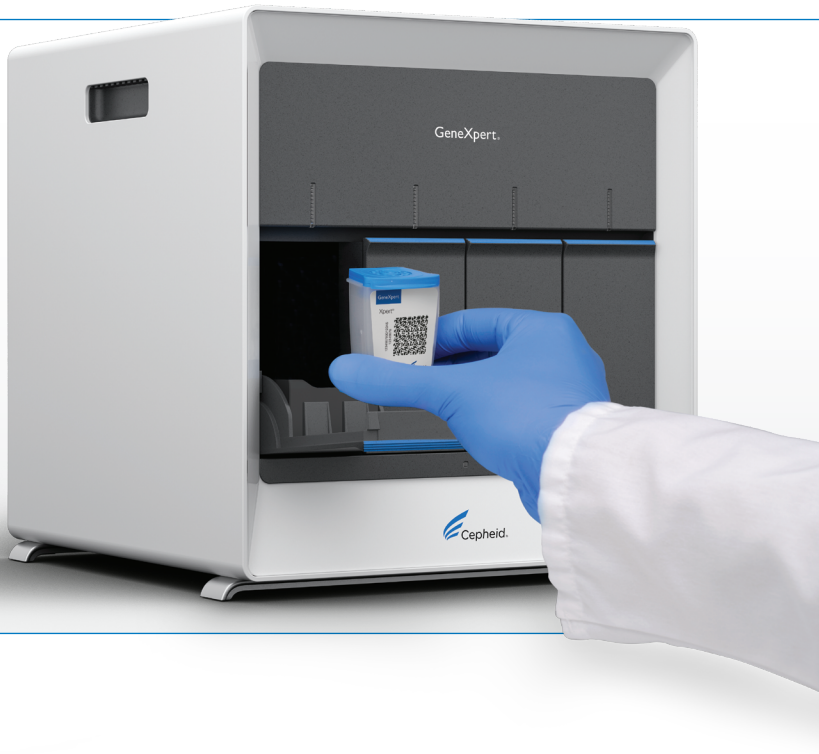
	Clinician-collected		Self-collected	
	Sensitivity/PPA (95% CI)	Specificity/NPA (95% CI)	Sensitivity/PPA (95% CI)	Specificity/NPA (95% CI)
BV	93.8% 531/566 (91.5%-95.5%)	93.8% 808/861 (92.0%-95.3%)	94.0% 533/567 (91.7%-95.7%)	92.9% 794/855 (90.9%-94.4%)
Candida group*	98.0% 396/404 (96.1%-99.0%)	94.6% 984/1040 (93.1%-95.8%)	97.5% 393/403 (95.5%-98.7%)	92.1% 954/1036 (90.3%-93.6%)
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%)
Candida glab-krus^ Contrived	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%)

Workflow: 3 Easy Steps

1 Obtain swab samples in the Cepheid Transport Reagent

2 Transfer sample to cartridge

3 Insert cartridge and start test



Catalog Information

Xpert® **Xpress** MVP	10 tests	XPRSMVP-10
Xpert® Swab Collection Kit	50 swabs	SWAB/G-50-US

US-IVD. *In Vitro* Diagnostic Medical Device.

* Target includes *C. albicans, C. tropicalis, C. parapsilosis,* and *C. dubliniensis.*

^ Contrived specimens were prepared using individual negative clinical CVS and SVS specimens. Refer to table 14 within the package insert for stratified.

References:

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CORPORATE HEADQUARTERS

904 Caribbean Drive
Sunnyvale, CA 94089 USA

TOLL FREE **+1.888.336.2743**
PHONE **+1.408.541.4191**
FAX **+1.408.541.4192**

EUROPEAN HEADQUARTERS

Vira Solelh
81470 Maurens-Scopont France

PHONE **+33.563.82.53.00**
FAX **+33.563.82.53.01**
EMAIL **cepheid@cepheideurope.fr**

www.**Cepheid**.com

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