



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* <i>Atopobium spp.</i> <i>(Atopobium vaginae, Atopobium novel species CCUG 55226)</i> BVAB2 <i>Megasphaera-1</i>				Candidiasis <i>Candida spp.</i> <i>(C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis; species not differentiated)</i> <i>Candida glabrata/Candida krusei species not differentiated))</i>				Trichomoniasis <i>Trichomonas vaginalis</i>																																																																					
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	<table><tr><th rowspan="3"></th><th colspan="4">Moderately Complex</th><th colspan="4">CLIA Waived</th></tr><tr><th colspan="2">Clinician-collected</th><th colspan="2">Self-collected</th><th colspan="2">Clinician-collected (CVS)</th><th colspan="2">Self-collected (SVS)</th></tr><tr><th>Sensitivity /PPA (95% CI)</th><th>Specificity/ NPA (95% CI)</th><th>Sensitivity /PPA (95% CI)</th><th>Specificity/ NPA (95% CI)</th><th>Sensitivity /PPA (95% CI)</th><th>Specificity/ NPA (95% CI)</th><th>Sensitivity /PPA (95% CI)</th><th>Specificity/ NPA (95% CI)</th></tr><tr><td>BV</td><td>93.8% 531/566 (91.5%–95.5%)</td><td>93.8% 808/861 (92.0%–95.3%)</td><td>94.0% 533/567 (91.7%–95.7%)</td><td>92.9% 794/855 (90.9%–94.4%)</td><td>92.9% 429/462 ^a (90.1%–94.9%)</td><td>94.5% 719/761 ^b (92.6%–95.9%)</td><td>93.5% 434/464 ^c (90.9%–95.4%)</td><td>93.6% 711/760 ^d (91.6%–95.1%)</td></tr><tr><td>Candida group[^]</td><td>98.0% 396/404 (96.1%–99.0%)</td><td>94.6% 984/1040 (93.1%–95.8%)</td><td>97.5% 393/403 (95.5%–98.7%)</td><td>92.1% 954/1036 (90.3%–93.6%)</td><td>98.1% 360/367 ^e (96.1%–99.1%)</td><td>94.9% 820/864 ^f (93.2%–96.2%)</td><td>97.8% 359/367 ^g (95.8%–98.9%)</td><td>92.9% 804/865 ^h (91.0%–94.5%)</td></tr><tr><td>Candida glab-krus Fresh Prospective</td><td>93.6% 44/47 (82.8%–97.8%)</td><td>99.6% 1392/1397 (99.2%–99.9%)</td><td>97.8% 45/46 (88.7%–99.6%)</td><td>99.4% 1384/1393 (98.8%–99.7%)</td><td>94.1% 32/34 ⁱ (80.9%–98.4%)</td><td>99.8% 1195/1197 ^j (99.4%–99.9%)</td><td>100% 33/33 (89.6%–100%)</td><td>99.7% 1195/1199 ^k (99.1%–99.9%)</td></tr><tr><td>Candida glab-krus[#] Contrived</td><td>99.0% 98/99 (94.5%–99.8%)</td><td>96.4% 27/28 (82.3%–99.4%)</td><td>N/A</td><td>N/A</td><td>99.0% 98/99 (94.5%–99.8%)</td><td>96.4% 27/28 (82.3%–99.4%)</td><td>N/A</td><td>N/A</td></tr><tr><td>TV</td><td>97.3% 73/75 (90.8%–99.3%)</td><td>99.6% 1332/1337 (99.1%–99.8%)</td><td>97.3% 72/74 (90.7%–99.3%)</td><td>99.8% 1330/1333 (99.3%–99.9%)</td><td>98.0% 48/49 ^l (89.3%–99.6%)</td><td>99.6% 1155/1160 ^m (99.0%–99.8%)</td><td>97.9% 47/48 ⁿ (89.1%–99.6%)</td><td>99.7% 1159/1162 ^o (99.2%–99.9%)</td></tr></table>									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 ⁱ (80.9%–98.4%)	99.8% 1195/1197 ^j (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%)
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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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