

# Clinical Laboratory Testing Update

Notification Date: June 21, 2023

Effective Date: July 17, 2023

## Methodology Change in Vaginitis Testing at Pathology Laboratory

### Explanation:

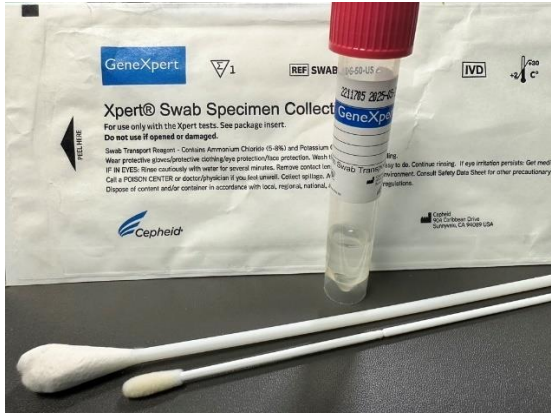


Effective Monday July 17, 2023; The Laboratory/Pathology Clinical Service Group, with support from the Infectious Disease and OB/GYN service groups, will be updating our testing method for bacterial vaginosis from a probe technique to a PCR molecular method developed by Cepheid on the GeneXpert Infinity platform.

This new assay uses a specific algorithm to detect normal vaginal microbiota to determine if a patient has bacterial vaginosis, as well as the ability to detect *Candida albicans*, *Candida glabrata/krusei*, and *Trichomonas vaginalis*.

The sensitivity and specificity are as follows:

	Sensitivity/PPA (95% CI)	Specificity/NPA (95% CI)
<b>Bacterial Vaginosis</b>	93.8% 531/566 (91.5%-95.5%)	93.8 808/861 (92.0%-95.3%)
<b>Candida group (<i>C. albicans</i>, <i>C. tropicalis</i>, <i>C. parapsilosis</i>, and <i>C. dubliniensis</i>)</b>	98.0% 396/404 (96.1%-99.0%)	94.6% 984/1040 (93.1%-95.8%)
<b>Candida glab-krus Fresh Prospective</b>	93.6% 44/47 (82.8%-97.8%)	99.6% 1392/1397 (99.2%-99.9%)
<b>Candida galb-krus Contrived</b>	99.0% 98/99 (94.5%-99.8%)	96.4% 27/28 (82.3%-99.4%)
<b>Trichomonas Vaginalis</b>	97.3% 73/75 (90.8%-99.3%)	99.6% 1332/1337 (99.1%-99.8%)

## Specimen Collection and Test Information:

Epic Order Code	LAB3721	
Epic Name	Vaginitis Panel	
Sunquest Code	AVAGMO	
Collection	<b>Preferred</b>	<b>Acceptable</b>
Collection Supplies	<p>Cepheid Xpert Swab Collection Kit</p>  <p><b>Important:</b> Discard the large swab, do not use for collection. Use the small swab only.</p>  <p>Use – Swab for sample collection Discard – Swab <b>not</b> used for testing</p>	<p>COPAN ESwab</p> 
	Methodology	Cepheid Infinity MVP Real-Time PCR
Performed	24/7	
Analytical Time	60 minutes	
Stability	Refrigerated: 42 days Ambient: 42 days	Refrigerated: 7 days Ambient: 7 days
CPT Code	0352U	
Fee	No Change	
Testing Location	Pathology Laboratory, Microbiology Department	

Questions: Please contact the Clinical Laboratory

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