nuswab®

New approach to testing for infections of the genital tract

- BACTERIAL VAGINOSIS
- CANDIDA
- CHLAMYDIA
- GONORRHEA
- TRICHOMONAS
- HSV 1/2
- MYCO/UREAPLASMAS

LabCorp
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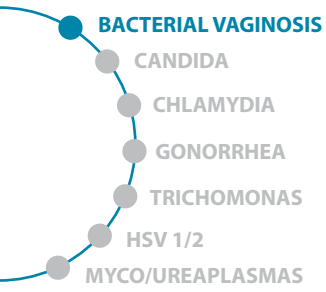
NUSWAB PORTFOLIO

Symptoms resulting from genital tract infections are among the most common reasons patients visit obstetricians and gynecologists.[1]



NuSwab® Bacterial Vaginosis

Result interpretation provides actionable information.

For bacterial vaginosis (BV), merely identifying the presence or absence of bacteria may not differentiate normal levels of bacteria from abnormal levels.[1] Numerous organisms associated with BV are also considered normal vaginal flora. LabCorp's new BV assay identifies bacterial imbalance **quantitatively** using only three marker organisms.

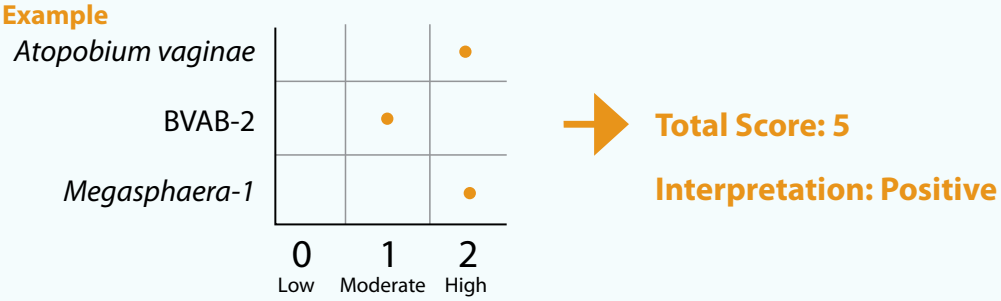
Quantitative markers backed by clinical study

In a clinical study, LabCorp found excellent correlation of three BV markers (*Atopobium vaginae*, Bacterial vaginosis-associated bacterium [BVAB]-2, *Megasphaera*-1) to Nugent Gram stain score and Amsel clinical diagnosis. LabCorp found that additional BV markers studied did not improve overall test performance.

Organisms analyzed for concentrations and scored

Each organism's score translated into a total score.

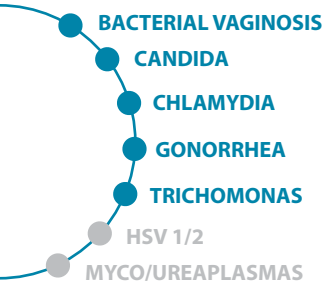
Example



Result interpretation

Provider-friendly interpretation based on total score.

Total Score	Interpretation
3-6	Positive - indicative of bacterial vaginosis.
0-1	Negative - not indicative of bacterial vaginosis.
2	Indeterminate - unable to determine BV status. Additional clinical and laboratory data should be evaluated to establish a diagnosis.

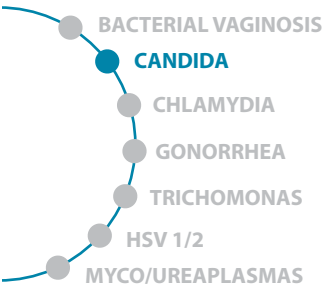


NuSwab® VG and VG+

Targeted profiles, fewer tests

Determining the underlying cause of vaginitis can be difficult.

- NuSwab VG combines tests for BV, *C albicans, C glabrata*, and *Trichomonas*, common causes of vaginitis.[1]
- NuSwab VG+ adds *Chlamydia* and *Gonorrhea* tests to NuSwab VG to aid in the identification of STD coinfection.



NuSwab® *C albicans* and *C glabrata*

Cost-effective testing with actionable results.

Two species of *Candida* comprise approximately 93% to 97%[2,3] of *Candida* species in vulvovaginal candidasis according to two large US studies. LabCorp's new *C albicans* and *C glabrata* test differentiates the two most prevalent species of *Candida*. In addition, *C albicans* and *C glabrata* have different –azole resistance characteristics. This differentiation may help guide appropriate therapy selection.

Target the most prevalent organisms

In two large US clinical studies, *C albicans* and *C glabrata* accounted for approximately 93% to 97%[2,3] of *Candida* species found. Additional *Candida* species testing is available upon request.

Candida Species Prevalence in VVC

Species	Prevalence (n=93,775)[2]	Prevalence (n=429)[3]
C albicans	89.0%	77.3%
C glabrata	7.9%	15.9%
Subtotal	**96.9%**	**93.2%**
C parapsilosis	1.7%	3.9%
C krusei	--	1.6%
C tropicalis	1.4%	1.1%
C lusitaniae	--	0.2%

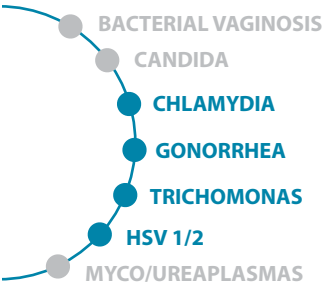
Differentiate species for treatment

C *albicans* and C *glabrata* have different antifungal resistance profiles. C *glabrata* and *C krusei* have been shown to be more resistant to fluconazole. In a large study of –azole susceptibility, approximately 67% of *C glabrata* isolates demonstrated decreased susceptibility.[3,4]

Candida Species with Decreased Susceptibility to Fluconazole[3]

Candida Species	% Resistant	% Susceptible-Dose Dependent	Total % Decreased Susceptibility	Antifungals without Decreased Susceptibility
C glabrata	15.2%	51.8%	67.0%	Flucytosine, Imidazoles, Nystatin
C krusei	Intrinsically resistant	Intrinsically resistant	Intrinsically resistant	Imidazoles, Nystatin

In the same study, *C albicans, C parapsilosis, C tropicalis, C lusitaniae* did not exhibit any significant decreased fluconazole susceptibility.



NuSwab® STD

Convenient, high-quality STD testing

NuSwab STD portfolio gives you the option to test for as many as four common sexually transmitted infections with one vaginal swab collection.

- *Chlamydia* and *Gonorrhea*
- *Trichomonas*
- Herpes (HSV) types 1 and 2

NuSwab® Portfolio

The NuSwab portfolio combines high-quality testing with the convenience of a single-swab collection, providing reliable and actionable information to manage your patients better. The NuSwab test menu offers a targeted approach for clinically appropriate, cost-effective care with profiles that contain fewer, select individual tests without sacrificing the content needed for comprehensive results. **Better information from fewer tests . . . smart testing has arrived.**

	nuswab® VG	nuswab® VG+	nuswab® STD		nuswab® SELECT
Test Number	**180039**	**180021**	**188070**	**183160**	See below
Components	Bacterial vaginosis *Atopobium vaginae* BVAB-2 *Megasphaera-1* *C albicans* *C glabrata* *Trichomonas*	Bacterial vaginosis *Atopobium vaginae* BVAB-2 *Megasphaera-1* *C albicans* *C glabrata* *Trichomonas* *Chlamydia* *Gonorrhea*	*Chlamydia* *Gonorrhea* *Trichomonas* HSV 1/2	*Chlamydia* *Gonorrhea* *Trichomonas*	Bacterial vaginosis (**180060**) *C albicans and C glabrata* (**180055**) *Candida* Six-species Profile (**180010**) *C albicans* *C glabrata* *C tropicalis* *C krusei* *C parapsilosis* *C lusitaniae* *Chlamydia/Gonorrhea* (**183194**) Genital *Mycoplasma* Profile (**180089**) *M genitalium, M hominis, Ureaplasma* spp HSV 1/2 (**188056**) *Mycoplasma genitalium* (**180076**) *Trichomonas* (**188052**)
	180042	**180068**			
	Vaginitis (VG) With *Candida* (Six Species) Bacterial vaginosis *Atopobium vaginae*, BVAB-2, *Megasphaera-1* *C albicans, C glabrata, C tropicalis, C parapsilosis, C lusitaniae, C krusei* *Trichomonas*	**Vaginitis Plus (VG+) With *Candida* (Six Species)** Bacterial vaginosis *Atopobium vaginae*, BVAB-2, *Megasphaera-1* *C albicans, C glabrata, C tropicalis, C parapsilosis, C lusitaniae, C krusei* *Chlamydia, Gonorrhea, Trichomonas*			
Clinical Use	Symptoms of vaginitis/ vaginosis, such as discharge.	Symptoms of vaginitis/ vaginosis and/or patients at risk for coinfection with Ct/Ng.	Screening high-risk patients. Testing patients with symptoms of multiple STDs or coinfections.		Flexibility to order any individual component.
Specimen Type	APTIMA® vaginal (preferred) or unisex swab. Transported at room temperature.				

For the most current information regarding test options, including CPT codes, please consult the Test Menu at **www.labcorp.com.**

LabCorp's policy is to provide physicians, in each instance, with the flexibility to choose appropriate tests to assure that the convenience of ordering test combinations/ profiles does not prevent physicians who wish to order a test combination/profile from making deliberate informed decisions regarding which tests are medically necessary. All the tests offered in test combinations/profiles may be ordered individually using the LabCorp test request form.

Behind Every Test at LabCorp is a Dedicated, Experienced Team of Scientists

The senior scientific directors behind LabCorp's NuSwab portfolio have extensive experience in women's health and oversee laboratories that perform hundreds of thousands of tests annually. These senior directors collectively have more than 100 years of postdoctoral experience in microbiology, immunology, virology, and molecular biology. They have served as active faculty or guest presenters at numerous colleges and universities and authored or coauthored more than 200 publications and abstracts spanning four decades.

References

1. American College of Obstetricians and Gynecologists. Vaginitis. ACOG Practice Bulletin Nº. 72. *Obstet Gynecol.* 2006;107:1195-1206.
2. Vermitsky JP, Self MJ, Chadwick SG, Trama JP, Adelson ME, Mordechai E, Gygax SE. Survey of vaginal-floral *Candida* species isolates from women of different age groups by use of species-specific PCR detection. *J Clin Microbiol.* 2008 Apr;46(4):1501-1503.
3. Richter SS, Galask R, Messer SA, Hollis RJ, Diekema DJ, Pfaller MA. Antifungal susceptibilities of *Candida* species causing vulvovaginitis and epidemiology of recurrent cases. *J Clin Microbiol.* 2005 May;43(5):2155-2162. (studying additional *Candida* and non-*Candida* species)
4. Achkar JM, Fries BC. *Candida* infections of the genitourinary tract. *Clin Micro Reviews.* 2010 Apr;23(2):253-273.

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