

**Patient:**

**Accession:** NXGMDX-999999  
**Created:** February 03, 2021  
**Patient Gender:** Female  
**Date Of Birth:** September 9, 1999  
**Specimen Type:** Genital vaginal  
**Collection Date:** February 02, 2021

**Receiving Physicians:**  
 Dr. Jones

**Receiving Facilities:**  
 Sample Facility, Grand Rapids MI

**RESULTS SUMMARY:**

Pathogenic organisms detected in this sample are detailed in the table below. These results may be consistent with a diagnosis of bacterial vaginosis. *Lactobacillus spp.* levels are normal. Results should be interpreted in the context of the patient's symptoms.

Presence of *C. trachomatis* is consistent with chlamydia. Presence of *C. trachomatis* is associated with negative pregnancy outcomes. This information may be reported to state or local health agencies as required by state and federal law.

Evidence of antibiotic resistance **was detected** and is reflected in the table below.

Detected Pathogens	Pathogen Type	Copies/µl eq.	Normal Range	Prescribable* Options
<i>Chlamydia trachomatis</i>	STI	<10,000		Doxycycline, Ofloxacin, Ciprofloxacin
<i>Atopobium vaginae</i>	Bacteria	>100,000	<2,000	Metronidazole, Tinidazole, Secnidazole
<i>Gardnerella vaginalis</i>	Bacteria	10,000-100,000	<2,000	Metronidazole, Tinidazole, Secnidazole

\*Prescribable antibiotics are included as prescribing options due to lack of detected antibiotic resistance genes. Physicians should use this as a guide and prescribe antibiotics based upon patient symptoms and medical history, including such factors as allergies, other medications, and pregnancy status.

Sexually Transmitted Infections - Not Detected	Normal Result
<i>Haemophilus ducreyi</i>	Not detected
<i>Herpes Simplex Virus 1</i>	Not detected
<i>Herpes Simplex Virus 2</i>	Not detected
<i>Neisseria gonorrhoeae</i>	Not detected
<i>Treponema pallidum</i>	Not detected
<i>Trichomonas vaginalis</i>	Not detected

Vaginal Flora	Level	Copies/µl	Normal Range
<i>Lactobacillus crispatus</i>	Absent	N/A	>2,000
<i>Lactobacillus gasseri</i>	Absent	N/A	>2,000
<i>Lactobacillus iners</i>	Normal levels	10,000-100,000	>2,000
<i>Lactobacillus jensenii</i>	Low levels	<10,000	>2,000
Summary	Normal Levels		

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<b>Not Prescribable: Antibiotic Resistance Detected</b>	<b>Resistance</b>
<i>Clindamycin, Azithromycin and Erythromycin</i>	<b>Detected</b>
<b>Pathogens Not Detected</b>	<b>Normal Result</b>
<i>Bacteroides fragilis</i>	Not detected
BVAB2	Not detected
<i>Candida albicans</i>	Not detected
<i>Candida dubliniensis</i>	Not detected
<i>Candida glabrata</i>	Not detected
<i>Candida krusei</i>	Not detected
<i>Candida lusitaniae</i>	Not detected
<i>Candida parapsilosis</i>	Not detected
<i>Candida tropicalis</i>	Not detected
<i>Enterococcus faecalis</i>	Not detected
<i>Escherichia coli</i>	Not detected
<i>Megasphaera Type 1</i>	Not detected
<i>Megasphaera Type 2</i>	Not detected
<i>Mobiluncus curtisii</i>	Not detected
<i>Mobiluncus mulieris</i>	Not detected
<i>Mycoplasma genitalium</i>	Not detected
<i>Mycoplasma hominis</i>	Not detected
<i>Prevotella bivia</i>	Not detected
<i>S. agalactiae (Group B Strep)</i>	Not detected
<i>Staphylococcus aureus</i>	Not detected
<i>Ureaplasma urealyticum</i>	Not detected

**METHODS AND LIMITATIONS:**

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DNA is isolated from the sample and array-based qPCR assays simultaneously detect *Atopobium vaginae*, *Bacteroides fragilis*, *Bacterial Vaginosis-Associated Bacterium 2* (BVAB2), *Mycoplasma hominis*, *Gardnerella vaginalis*, *Haemophilus ducreyi*, *Megasphaera Type 1*, *Megasphaera Type 2*, *Mobiluncus curtisii*, *Mobiluncus mulieris*, *Ureaplasma urealyticum*, *Prevotella bivia*, *Enterococcus faecalis*, *Treponema pallidum* (Syphilis), *Candida albicans*, *Candida dubliniensis*, *Candida glabrata*, *Candida krusei*, *Candida lusitanae*, *Candida parapsilosis*, *Candida tropicalis*, *Mycoplasma genitalium*, *Chlamydia trachomatis*, *Trichomonas vaginalis*, *Herpes Simplex Virus 1*, *Herpes Simplex Virus 2*, *Neisseria gonorrhoeae*, *Staphylococcus aureus*, *Streptococcus agalactiae* (Group B Strep), and *Escherichia coli* at analytical sensitivity and specificity >99%. The qPCR data is interpreted using an algorithm developed at NxGen MDx, and the detected presence and/or absence of microbia is reported.

Presence or absence of normal vaginal *Lactobacillus gasseri*, *Lactobacillus iners*, or *Lactobacillus jensenii* is detected using array-based qPCR. Detection of at least one species of lactobacillus is expected in most women with a healthy vaginal microbiome.

Absence of detection does not imply the absence of microorganisms other than those listed. Absence of detection does not exclude the possibility that the target sequence is present below the limit of detection. This assay is designed to detect active outbreaks or primary infections causing current vaginosis symptoms. Latent infections of HSV-1, HSV-2, and *Treponema Pallidum* (Syphilis) may not be detected by this assay.

Array-based qPCR assays are used to detect common molecular antibiotic resistance markers at analytical sensitivity and specificity >99%. The qPCR data is interpreted using an algorithm developed at NxGen MDx, and the detected presence and/or absence of antibiotic resistance markers is reported. Azole antifungal resistance, tetracycline antibiotic resistance, nitrofurantoin antibiotic resistance, and antiviral resistance are not detected by this assay. ACOG or CDC guidelines are displayed for prescribable antibiotics.

This test has not been cleared or approved by the U.S. Food and Drug Administration. However, the FDA has determined that such a clearance or approval is not necessary. The FDA does not require this test to go through premarket FDA review. This test is used for clinical purposes. It should not be regarded as investigational or for research. The laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing. This test was performed at NxGen MDx, located at 801 Broadway Suite 203, Grand Rapids, Michigan-49504. CLIA Number: 23D2059943.

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