Patient:
Sample Report

Accession: NXGMDX-99999
Created: January 26, 2024
Patient Gender: Female
Date Of Birth: August 11, 1981
Specimen Type: Urine
Collection Date: September 12, 2023

Receiving Facilities:
NxGen MDx 801 Broadway Avenue Northwest Suite 203 Grand Rapids MI 49504

Receiving Physicians:
John Smith

RESULT SUMMARY

Pathogenic organisms detected in this sample are detailed in the table below. These results may be consistent with a comorbid diagnosis of **bacterial vaginosis and candidiasis**. Fluconazole sensitivity testing is pending and will be released as a separate report. *Lactobacillus spp.* levels are normal. Results should be interpreted in the context of the patient's symptoms.

No evidence of antibiotic resistance was detected.

Detected Pathogens	Pathogen Type	Copies/µl eq.	Normal Range	Prescribable* Options
Candida Group	Yeast	<10,000	<2,000	Fluconazole, Clotrimazole, Miconazole, Butoconazole, Terconazole
Enterococcus faecalis	Bacteria	<10,000	<2,000	Ciprofloxacin, Linezolid

*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.

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

Pathogens Not Detected	Normal Result
Atopobium vaginae	Not detected
Bacteroides fragilis	Not detected
BVAB Group	Not detected
Candida albicans	Not detected
Candida glabrata	Not detected
Candida krusei	Not detected
Candida parapsilosis	Not detected
Chlamydia trachomatis	Not detected

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Pathogens Not Detected	Normal Result
Escherichia coli	Not detected
Gardnerella vaginalis	Not detected
Haemophilus ducreyi	Not detected
Herpes Simplex Virus 1	Not detected
Herpes Simplex Virus 2	Not detected
Klebsiella pneumoniae	Not detected
Megasphaera Type 1	Not detected
Megasphaera Type 2	Not detected
Mobiluncus spp.	Not detected
Mycoplasma genitalium	Not detected
Mycoplasma hominis	Not detected
Neisseria gonorrhoeae	Not detected
Prevotella bivia	Not detected
S. agalactiae (Group B Strep)	Not detected
Staphylococcus aureus	Not detected
Treponema pallidum	Not detected
Trichomonas vaginalis	Not detected
Ureaplasma urealyticum	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 Bacteria* (BVAB1, BVAB2, and BVAB3), *Mycoplasma hominis, Gardnerella vaginalis* (trivalent pool), *Haemophilus ducreyi, Megasphaera Type 1, Megasphaera Type 2, Mobiluncus spp.* (*M. curtisii* and *M. mulieris*), *Ureaplasma urealyticum, Prevotella bivia, Enterococcus faecalis, Treponema pallidum* (Syphilis), *Candida albicans,* Candida Group (*C. dubliniensis, C. lusitaniae,* and *C. tropicalis*), *Candida glabrata, Candida krusei, Candida parapsilosis, 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%. Presence or absence of normal vaginal flora (*Lactobacillus crispatus, 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. The qPCR data is interpreted using an algorithm developed at NxGen MDx, and the detected presence and/or absence of microbiota is reported.

Fifty-four of the most common antibiotic resistance genes are targeted on the array as well, broken into twelve categories. 23S rRNA (adenine(2058)-N(6))-methyltransferases (*ermA, ermB, ermC*), macrolide efflux MFS transporter (*mefA*), quinolone resistance pentapeptide repeat protein (*qnrA, qnrB, qnrS), Gyrase A* mutations D87N and S83L, trimethoprim-resistant dihydrofolate reductase (*dfrA, dfrA5*), sulfonamide-resistant dihydropteroate synthase (sul1, sul2), Class A extended-spectrum beta-lactamase (CTX-M Groups 1, 2, 8/25, 9; *GES, TEM, PER-1, PER-2, SHV, VEB, KPC*), subclass B1 metallo-beta-lactamase (IMP Groups 1, 2, 7, 16; *NDM, VIM, SPM, CAM*), class C beta-lactamase (*DHA, MOX, CMY, ACC, ACT, FOX, MIR*), Oxacillin-hydrolyzing Class D beta-lactamase (OXA Groups 1, 23, 24, 48, 51, 58), Nitroimidazole Reductase (*nimA, nimB, nimC, nimD*), tetracycline efflux MFS transporter (tetA, tetB), tetracycline resistance ribosomal protection protein (*tetM, tetS*), D-alanine-(R)-Lactate Ligases (*vanA1, vanA2, vanB)* and Methicillin Resistance Genes (*mecA, femA*). Azole antifungal resistance and antiviral resistance are not detected by this assay. ACOG or CDC guidelines are displayed for prescribable antibiotics.

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 vaginitis symptoms. Latent infections of *HSV-1, HSV-2*, and *Treponema Pallidum* (Syphilis) may not be detected by this assay.

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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