

**Patient:**  
Sample

**Accession:** NXGMDX-999999  
**Created:** March 12, 2020  
**Patient Gender:** Female  
**Date Of Birth:** September 9, 1999  
**Specimen Type:** Urine  
**Collection Date:** March 12, 2020

**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 are consistent with a diagnosis of urinary tract infection (UTI).

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>Enterococcus faecalis</i>	Bacteria	10,000-100,000	<2,000	Nitrofurantoin, Fosfomycin, Amoxicillin, Ampicillin

\*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.

Not Prescribable: Antibiotic Resistance Detected	Resistance
<i>Clindamycin</i>	Detected

Pathogens Not Detected	Normal Result
<i>Acinetobacter baumannii</i>	Not detected
<i>Candida albicans</i>	Not detected
<i>Citrobacter freundii</i>	Not detected
<i>Enterobacter aerogenes</i>	Not detected
<i>Enterobacter cloacae</i>	Not detected
<i>Enterococcus faecium</i>	Not detected
<i>Escherichia coli</i>	Not detected
<i>Klebsiella oxytoca</i>	Not detected
<i>Klebsiella pneumoniae</i>	Not detected
<i>Morganella morganii</i>	Not detected
<i>Proteus mirabilis</i>	Not detected
<i>Proteus vulgaris</i>	Not detected
<i>Providencia stuartii</i>	Not detected
<i>Pseudomonas aeruginosa</i>	Not detected
<i>S. agalactiae (Group B Strep)</i>	Not detected

Signed by:  
Signed on:  
Accession #: NXGMDX-999999  
Patient DOB:

**SAMPLE Report**  
801 Broadway NW, Suite# 203  
Grand Rapids MI 49504  
Phone: 855-77-NxGen  
Fax: 616-710-4667

Pathogens Not Detected	Normal Result
<i>S. saprophyticus</i>	Not detected

**METHODS AND LIMITATIONS:**

DNA is isolated from the sample and array-based qPCR assays simultaneously detect *Acinetobacter baumannii*, *Candida albicans*, *Citrobacter freundii*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Enterococcus faecalis*, *Enterococcus faecium*, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Morganella morganii*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia stuartii*, *Pseudomonas aeruginosa*, *Staphylococcus saprophyticus*, and *Streptococcus agalactiae* (Group B Strep) 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.

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, and nitrofurantoin antibiotic 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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