Original

MicroGenDX
qPCR + NGS DNA DIAGNOSTICS
FOR ACCURATE MICROBIAL IDENTIFICATION

**MICROGEN DIAGNOSTICS**
2002 W LOOP 289, SUITE 116 | LUBBOCK, TX 79407
FAX: 1-407-204-1401 | PHONE: 1-855-208-0019

| | | | | | |
|---|---|---|---|---|---|
| PATIENT | Sample Report MG001 | SPECIMEN | Urine 08:30 | PHYSICIAN | Sharma, Rajendra |
| DOB | xx/xx/xxxx | RECEIVED DATE | 07/20/2022 | PHONE | - |
| PATIENT ID | | REPORTED DATE | 07/20/2022 4:17 PM | FAX | - |
| GENDER | Male | COLLECTED DATE | 07/15/2022 | ACCESSION | |

**RESISTANCE GENES DETECTED**

Tetracycline tetM

# LEVEL 1 PCR REPORT

**THIS IS A PRELIMINARY REPORT. NEXT GENERATION SEQUENCING RESULTS ARE PENDING. THE REPORT WILL BE AVAILABLE TYPICALLY IN 3-5 BUSINESS DAYS.**

**ANTIMICROBIALS FOR CONSIDERATION**

| RAPID SCREENING (PCR RESULTS) | | DNA copies per mL | Gram Stain | Respiration | Aminoglycosides+Aminopenicillins e.g. Ampicillin/Gentamicin | Ampicillin/Amoxicillin | Extended spectrum penicillins/Beta-lactamase inhibitors e.g. Augmentin | Fluoroquinolones e.g. Levofloxacin | Fosfomycin | Glycopeptides e.g Vancomycin | Linezolid (Zyvox) | Lipopeptides e.g. Cubicin | Nitrofurantoin e.g. Macrobid | Penicillins e.g. Penicillin | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **BACTERIAL LOAD** | Medium | $10^5$-$10^7$ | | | IV | PO | PO | PO | PO | IV | PO | IV | PO | PO | | | | | |
| Enterococcus faecalis | | 1.39 x $10^6$ | + | FAn | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |

**FUNGI DETECTED**

**ANTIFUNGALS FOR CONSIDERATION**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| None | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |

**LAB REPORT KEY**

| | | | |
|---|---|---|---|
| DNA copies per mL:<br>[NGS] = Detected by Next-Gen Seq. Only<br>Bacterial Load: < $10^5$ = LOW<br>$10^5$ to $10^7$ = MED<br>> $10^7$ = HIGH | Gram Stain:<br>[+] = Positive<br>[-] = Negative<br>[V] = Variable<br>[N] = Not Applicable<br>[U] = Unknown | Respiration:<br>[Ae] = Aerobic<br>[An] = Anaerobic<br>[Fan] = Facultative anaerobic<br>[Unk] = Unknown | Antimicrobial:<br>[V] = Proven to be effective.<br>[R] = Resistance genes detected.<br>[ ]=Empty Fields denote Unknown.<br>[PO]= Available in Oral formulations.<br>[IV] = Intravenous; [TP] = Topical. |



Laboratory Director: Owatha Tatum PhD, HCLD/CC(ABB), MBA

Original

MicroGenDX
qPCR + NGS DNA DIAGNOSTICS
FOR ACCURATE MICROBIAL IDENTIFICATION

MICROGEN DIAGNOSTICS
2002 W LOOP 289, SUITE 116 | LUBBOCK, TX 79407
FAX: 1-407-204-1401 | PHONE: 1-855-208-0019

| | | | | | |
|---|---|---|---|---|---|
| PATIENT | Sample Report MG001 | SPECIMEN | Urine 08:30 | PHYSICIAN | Sharma, Rajendra |
| DOB | xx/xx/xxxx | RECEIVED DATE | 07/20/2022 | PHONE | - |
| PATIENT ID | | REPORTED DATE | 07/20/2022 4:17 PM | FAX | - |
| GENDER | Male | COLLECTED DATE | 07/15/2022 | ACCESSION | |

| qPCR TESTS FOR BACTERIA | | | FUNGI | STIs | RESISTANCE GENES | |
|---|---|---|---|---|---|---|
| Enterococcus faecalis<br>Staphylococcus aureus<br>Mobiluncus mulieris<br>Ureaplasma parvum | Klebsiella pneumoniae<br>Escherichia coli<br>Gardnerella vaginalis<br>Mycoplasma hominis | Streptococcus agalactiae<br>Mobiluncus curtisii<br>Ureaplasma urealyticum<br>Prevotella bivia | Candida albicans | None | Vancomycin<br>Extended-Spectrum Beta-Lactamase<br>Aminoglycoside<br>Carbapenem<br>Quinolone | Methicillin<br>Beta-lactam<br>Tetracycline<br>Macrolide<br>Bactrim |

Antimicrobial class reported as resistant are based on the detected resistance genes included in the qPCR and the published activity and spectrum of resistance for each gene. Resistance mechanisms other that the included in this panel may confer resistance not detected by the resistance genes included in the panel.

The following genes are included in the panel:

- mecA: methicillin resistance (applies only to Staphylococcus spp.)
- vanA: vancomycin resistance (applies only to Enterococcus spp.)
- CTX-M: Extended Spectrum Beta-lactamase (applies to all Gram-negative organisms)
- KPC, NDM & OXA48: carbapenemases (applies to all Gram-negative organisms)
- ermB: macrolide resistance (applies only to Gram-positive organisms
- qnr & gyrA: quinolone resistance (applies to all organisms)
- tetB & tetM: tetracycline resistance (applies to all organisms)
- aacC6-aph3 & ant-la-aph2: aminoglycoside resistance (applies to all organisms)
- sul I, sul II: bactrim resistance(applies to all Gram-negative organisms except Neisseria, Moraxella, Veillonella, Megasphaera, Acidaminococcus, Negativicoccus, Paracoccus, Syntrophococcus, Pseudomonas)
- TEM, SHV: beta-lactam resistance (applies only to Escherichia coli and Proteus mirabilis)

## Rapid Screening (PCR Results)

MicroGen Diagnostics Rapid Screening testing is used to rapidly analyze samples for the most commonly found bacteria and fungi in clinical samples of many different types. The sample composition is identified by quantitative PCR analysis with a specified panel of microorganisms. Bacterial and fungal amounts per mL (or mg) based upon standard curves for each target specific organism and 16S. All tests are performed in a CAP and CLIA accredited laboratory.

| ANTIBIOTIC CLASSES AND MOST-COMMONLY USED EXAMPLES | | | |
|---|---|---|---|
| CLASS | GENERIC formulations | CLASS | GENERIC formulations |
| Allylamines | Amorolfine; Naftifine | Flucytosine | 5-fluorocytosine (Ancobon) |
| Aminoglycosides | Gentamycin; Tobramycin | Fluoroquinolones | Norfloxacin(PO); Levofloxacin; Oxafloxacin(PO); Ciprofloxacin(PO) |
| Aminoglycosides+Aminopenicillins | Ampicillin/Gentamicin | | |
| Aminopenicillins | Amoxicillin; Ampicillin(PO) | Glycopeptides | Vancomycin; Teicoplanin |
| Antifolates | TMP/SMX | Imidazoles | Ketoconazole(PO); Clotrimazole; Oxiconazole |
| Anti-Pseudomonal Penicillins | Piperacillin; Nafcillin | | |
| Anti-Pseudomonal penicillins/Beta-lactamase inhibitors | Piperacillin/Tazobactam | Lipopeptides | Daptomycin |
| | | Macrolides | Erythromycin; Azithromycin(PO) |
| Anti-tuberculosis | Isoniazid; Rifampin; Streptomycin | Naphthyridones | Nalidixic acid |
| Aztreonam | Azactam | Oxacephems | Moxalactam |
| Carbapenems | Cilistatin/Imipenem; Meropenem | Penicillins | Penicillin G; Penicillin V(PO) |
| Cephalosporins First Gen | Cephalexin(PO); Cefazolin | Polyenes | Natamycin; Amphotericin B |
| Cephalosporins Fourth Gen | Cefepime | Polyenes+Flucytosine | Amphotericin B/5-fluorocytosine |
| Cephalosporins Second Gen | Cefprozil; Cefotetan | Tetracyclines | Doxycycline(PO); Minocycline |
| Cephalosporins Third Gen | Cefixime; Cefdinir; Ceftazidime | Triazoles | Fluconazole(PO); Terconazole |
| Cephamycins | Cefoxitin | Triazoles+Echinocandins | Voriconazole/Anidulafungin |
| Echinocandins | Caspofugin; Micafungin | | |
| Extended spectrum penicillins / Beta-lactamase inhibitors | Amoxicillin / Clavulanate(PO); Ampicillin / Sulbactam | | |

## Complete Antibiotic Analysis

ANTIBIOTIC DISCLAIMER: Southwest Regional PCR, DBA MicroGen Diagnostics, LLC assumes no liability to patients with respect to the actions of physicians, health care facilities and other users, and is not responsible for any injury, death or damage resulting from the use, misuse or interpretation of information obtained through this antibiotic report. Therapeutic options listed by the program are based upon national antibiotic susceptibility data and antibiograms. Therapy should not be undertaken without a thorough assessment of the indications, contraindications and side effects of any prospective drug or intervention. Furthermore, the database is curated and derived from incidence and prevalence statistics whose accuracy will vary widely for individual diseases and regions of the country. Changes in endemicity, incidence, and drugs of choice may occur. The list of drugs, infectious diseases and even country names will vary with time. Although we endeavor to include such new information on a timely basis, a delay cannot be avoided. For more information please contact us at 855-208-0019.



Laboratory Director: Owatha Tatum PhD, HCLD/CC(ABB), MBA

Original

MicroGenDX
qPCR + NGS DNA DIAGNOSTICS
FOR ACCURATE MICROBIAL IDENTIFICATION

**MICROGEN DIAGNOSTICS**
**2002 W LOOP 289, SUITE 116 | LUBBOCK, TX 79407**
**FAX: 1-407-204-1401 | PHONE: 1-855-208-0019**

| | | | | | |
|---|---|---|---|---|---|
| **PATIENT** | Sample Report MG001 | **SPECIMEN** | Urine 08:30 | **PHYSICIAN** | Sharma, Rajendra |
| **DOB** | xx/xx/xxxx | **RECEIVED DATE** | 07/20/2022 | **PHONE** | - |
| **PATIENT ID** | | **REPORTED DATE** | 07/20/2022 4:17 PM | **FAX** | - |
| **GENDER** | Male | **COLLECTED DATE** | 07/15/2022 | **ACCESSION** | |

DISCLAIMER: (i)This test was developed and performance characteristics have been determined by Southwest Regional PCR Laboratory dba MicroGen DX. It has not been cleared or approved by the U.S.Food and Drug Administration(FDA), however, the FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. Its use should not be regarded as investigational or for research.This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988(CLIA 88) as qualified to perform high complexity clinical laboratory testing. (ii) A negative result does not rule out the presence of PCR inhibitors, or DNA extraction inhibitors such as lidocaine, in patients' specimens or microbial DNA concentrations below the level of detection of the assay. (iii) This test is performed pursuant to an agreement with Roche Molecular Systems, Inc. (iv) Relative quantitation of swabs refers to analyte load levels of < $10^5$, $10^5$ to $10^7$, and > $10^7$ for low, medium and high respectively. Southwest Regional PCR Laboratory dba MicroGen DX licenses are CLIA 45D1086390 and CAP 7214171.

**ANTIBIOTIC ANALYSIS**

*This antimicrobial recommendation sheet is not based on antibiotic sensitivities but is based on antimicrobial reference guides such as the Johns Hopkins ABX Guide.*