Rising Tide Reference Laboratory LLC
495 N US Hwy 17 92 Unit 101
Longwood, FL 32750
Phone Number: (407) 476-1646
Lab Director: Vidhya Narayanan, Ph.D.
CLIA: 10D2276452

Patient:	JOHN DOE	Specimen:	**Urine**	Specimen ID:	**RT138118**
Patient DOB:	**9/10/1992**	Collected:	**11/9/23 3:16 PM EST**	Provider:	**Joe Smith**
Patient Age:	**31**	Received:		Account:	**6588**
Patient Sex:	**Male**	Reported:	**11/9/23 3:26 PM EST**	Facility:	**Rising Tide Demo**

UTI Panel Molecular Antibiotic Resistance Report

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POSITIVES

Bacteria

Acinetobacter baumannii

Resistant Genes

ESBL resistance (CTX-M Group 1)

DISCLAIMER

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Every effort is made to ensure the accuracy of Sanford Guide content. However, current full prescribing information available in the package insert for each drug should be consulted before prescribing any product. The editors and publisher are not responsible for errors or omissions or for any consequences, such as injury, damage, or death, from application of our print and digital content, and make no warranty, express or implied, with respect to the currency, accuracy, or completeness of the contents of this publication. Application of this information in a particular situation remains solely the professional responsibility of the clinician.
The data provided are intended to serve as a general guide to antibacterial usefulness based on package insert, treatment guidelines, published reports, in vitro activity, predominant patterns of susceptibility or resistance and/or demonstrated clinical effectiveness. Variability in resistance patterns due to local or regional differences or as a consequence of clinical setting, e.g., community onset vs. ICU-acquired infection, should be taken into account when using this information because the activity of antimicrobial agents can differ significantly and hence is beyond the scope of this general summary. Susceptibility testing results and your local antibiogram should be consulted in every case.

LEGEND

- **[1] Preferred:** Agent is a first line therapy: reliably active in vitro, clinically effective, guideline recommended, recommended as a first-line agent or acceptable alternative agent in the Sanford Guide.
- **[2] Alternative:** Agent is a potential alternative agent (active in vitro, possesses class activity comparable to known effective agents or a therapeutically interchangeable agents and hence likely to be clinically effective, but second line due to overly broad spectrum, toxicity, limited clinical experience, or paucity of direct evidence of effectiveness).
- **[3] Limited Utility:** Limited utility such that the agent, although clinically effective in some settings or types of infections is not reliably effective in others, or should be used in combination with another agent, and/or its efficacy is limited by resistance which has been associated with treatment failure.
- **[X] Allergy:** Patient has indicated they are allergic to a medication.

Medication Allergies: No medication allergies specified.

Pathogens	Omadacycline	Ciprofloxacin	Delafloxacin	Ofloxacin	Levofloxacin	Moxifloxacin	Prulifloxacin	Minocycline	Tetracycline	TMP-SMX
A. baumannii	2	3	3	3	3	3	3	3	3	3

Patient: JOHN DOE **Specimen ID:** RT138118 **DOB:** 9/10/1992 **Gender:** Male **Race:** Unknown

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Tests

UTI Panel

Bacteria

Bacteroides fragilis Citrobacter freundii Enterobacter cloacae Enterococcus faecalis Escherichia coli Klebsiella aerogenes Klebsiella oxytoca Klebsiella pneumoniae Morganella morganii Mycoplasma genitalium Mycoplasma hominis Prevotella bivia Proteus mirabilis Pseudomonas aeruginosa Serratia marcescens Staphylococcus aureus Staphylococcus epidermidis Staphylococcus saprophyticus Streptococcus pyogenes (Group A Strep) Ureaplasma urealyticum

Fungi

Candida albicans Candida glabrata Candida krusei Candida parapsilosis Candida tropicalis

Resistant Genes

ESBL resistance (CTX-M Group 1) - DETECTED Bactrim resistance (Sul1) Bactrim resistance (Sul2) Carbapenem resistance (KPC) Carbapenem resistance (NDM) Enterococcus faecium Fluoroquinolone resistance (QnrA) Fluoroquinolone resistance (QnrB) Methicillin resistance (mecA) Trimethoprim resistance (DfrA) Trimethoprim resistance (DfrA1) Trimethoprim resistance (DfrA5) Vancomycin resistance (vanA1, vanA2) Vancomycin resistance (vanB)

Intended Use

The detection and identification of specific pathogens and drug resistance markers from individuals exhibiting signs and symptoms of the infectious disease. This test aids in the diagnosis if used in conjunction with other clinical and epidemiological information. This test is a Laboratory Derived (LDT) qualitative nucleic acid multiplex diagnostic test intended for use on an Applied Biosystems™ QuantStudio™ 7 Flex Real-Time PCR System for the simultaneous detection and identification of multiple pathogen nucleic acids in clinical samples obtained from individuals exhibiting signs and symptoms of the infectious disease.

Methodology

Real-Time PCR was performed on genomic DNA extractions using the UTI and Wound Advanced RT-PCR Detection Kit, analyzed on a QuantStudio™ 7 Flex. The CFU (Colony Forming Units) equivalent ranges were calculated from the Linearity studies performed using titered control DNA for each organism on the panel. Upon data analysis, absence or presence (in low, medium or high prevalence) of the pathogens is determined, based upon whether the amplification is above or below the threshold of detection.

Limitations

Negative results do not preclude an infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out infection, or co-infection with other pathogens not on our panel. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence and radiography) and clinical presentation must be taken into consideration in the final diagnosis.

This test detects the presence of pathogens and must be evaluated with clinical symptoms to diagnose a disease. All tests established and validated by the laboratory are not FDA approved. The detection of viral, fungal and bacterial nucleic acid is dependent upon proper specimen collection, handling, transporting, storage and preparation.

Comments:

No comments.

Rising Tide REFERENCE LABORATORY

Patient: JOHN DOE **Specimen ID:** RT138118 **DOB:** 9/10/1992 **Gender:** Male **Race:** Unknown

Molecular Antibiotic Resistance Report

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Detected Pathogen - Acinetobacter baumannii

+ CTX-M

Our test result identified the presence of bacteria whose genomes include specific genes that, when expressed during patient infections, can reduce antimicrobial efficacy. Interpret genotypic resistance with caution. The sensitivity and specificity of detection of resistant genes varies with the specific method employed. Not all detected genes are active; some can be induced to an active state only after initiation of antibiotic therapy. Further, a given organism may harbor multiple mechanisms of resistance some of which not be detected by the methods in use. For these reasons, there is the possibility of a discordance between the results of genotypic resistance versus phenotypic in vitro antibiotic resistance testing. The patient's clinical response to empiric or specific antibiotic therapy remains the final arbitrator as to the success of a treatment regimen.

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Clinical Setting

- *Acinetobacter baumannii* complex causes a variety of local and systemic infections in both immunocompetent and immunocompromised patients
  - Hospital-acquired opportunistic pathogen, frequent cause of ventilator-associated pneumonia
  - Can cause a variety of other infections: e.g., soft tissue, wounds and bone; UTIs; meningitis; eye infections
  - Any of the above can be associated with bacteremia.

- Resistance is a problem
  - Acinetobacter sp. have among the largest number and variety of resistance mechanisms of all gram-negative bacilli
    - **Roughly 50% of *Acinetobacter baumanii* isolates demonstrate multi-drug resistance (MDR).** In certain locations, substantive % of isolates demonstrate extensive drug resistance and even pan-drug resistance
    - **Resistance mechanisms, alone or in combination, include:**
      - Production of extended spectrum beta-lactamases (ESBLs)
      - Production of AmpC cephalosporinases (rare)
      - Production of serine-, metallo-, and OXA-carbapenemases
      - Production of aminoglycoside-modifying enzymes
      - Change in drug target binding sites, e.g., penicillin binding protein sites and DNA gyrase mutations
      - Presence of efflux pumps
      - Mutant porins proteins with subsequent decreased outer membrane permeability
  - Clinically, reliance is on phenotypic in vitro patterns of resistance. Outside of a research environment, it is not possible to identify which mechanism, or combination of mechanisms, is responsible for the lab's report of antibiotic resistance.
  - For further discussion of drug resistance classes and mechanisms see Gram-negative Resistance, Overview. See Comments for other recent references on evolving treatment considerations and options.

Primary Regimens

- **Treatment options below are for therapy of moderately-severe, or severe infections in patients requiring systemic therapy**
  - Complicated UTI
  - Ventilator associated Bacterial Pneumonia/ Hospital acquired bacterial pneumonia
  - Bacteremia
  - Meningitis: see Comments

Patient: JOHN DOE **Specimen ID:** RT138118 **DOB:** 9/10/1992 **Gender:** Male **Race:** Unknown

Lab reports	Modifying Circumstances	Recommended Regimens	Comments
***Acinetobacter* in sputum or sterile body site, antibiotic susceptibility results pending**	**Local rate of MDR <10-15%**, not critically ill, monotherapy is reasonable	**Empiric therapy** Cefepime 2 gm IV q8h OR Meropenem 2 gm IV infused over 3 hrs and repeat q8h (continuous infusion regimens in clinical trial) OR Ampicillin-sulbactam 9 gm (6 gm amp/3 gm sulb) IV over 4 hrs and repeat q8h	No commercial source for sulbactam alone. High dose: (Eur J Pharm Sci 136:104940, 2019)
	Local rate of MDR >10-15% and/or patient is critically ill, consider combination therapy to increase odds of administering at least one active drug:	**Empiric therapy** Ampicillin-sulbactam 9 gm (6gm amp/3 gm sulb) IV infused over 4 hrs and repeat q8h + Meropenem 2 gm IV infused over 3 hrs and repeat q8h + Polymyxin B 2.5 mg/kg loading dose IV infused over 2 hrs then, starting 12 hrs later, 1.5 mg/kg IV infused over 1 hr q12h	
Susceptibility to multiple antibiotics		Monotherapy with Cefepime, Meropenem, or Ampicillin-sulbactam as above (see Comments)	
Resistance to all cephalosporins, aztreonam, and carbapenems; susceptibility to polymyxins		**Recommend infectious diseases consultation** Cefiderocol 2 gm q8h IV over 3 hrs (see Comments: FDA approved for treatment of complicated UTIs and VABP/HABP)	Another option: combination therapy with one or more of the following if susceptible in vitro (see Comments): Minocycline 200 mg IV x one dose then 100 mg IV q12 h ± Amikacin (more active than gentamicin; check renal function and monitor serum levels) ± Ampicillin-sulbactam 9 gm of sulbactam (6 gm Amp/ 3 gm sulbactam) IV over 4 hr and repeat q8h
Resistance to all antibiotics tested, including polymyxins		No known effective therapy: Recommend infectious diseases consultation Consider Cefiderocol 2 gm q8h IV over 3 hrs (FDA approved for treatment of complicated UTIs & VABP)	See Comments

Alternative Regimens

- **Lab reports susceptibility to multiple antibiotics**
  - Some isolates may be susceptible to:
    - Ciprofloxacin 400 mg IV q8h or Levofloxacin 750 mg IV q24h
    - TMP-SMX 10 mg/kg/day (TMP component) IV divided q8h or q12h
- **Lab reports MDR or extensive drug resistance**
  - Test for in vitro susceptibility to:
    - Aminoglycosides:
      - Amikacin more frequently active in vitro than gentamicin (Antimicrob Agents Chemother 2019; 63: e01154-19)
      - Plazomicin: Aminoglycoside that is stable in presence of enzymes that inactivate gentamicin, tobramycin, and amikacin. Limited observational reports of success vs MDR pathogens.
    - Eravacycline and Omadacycline: Next generation tetracyclines. Better pharmacokinetics than Tigecycline. Active in vitro vs Acinetobacter. No clinical data.

- Combination therapy:
  - **Combination of Meropenem + polymyxin (either Polymyxin B or Colistin) not recommended:**
    - Based on a failed randomized controlled trial (Lancet Infect Dis 2018;18:391-400) of 406 patients with serious infections due to carbapenem-nonsusceptible Gram-negative bacteria, 77% of whom were infected with *Acinetobacter baumannii.*
      - Rate of clinical failure (83% for Colistin and 81% for the combination) and the rate for mortality (46% for Colistin and 52% for the combination) were no better with the combination than with Colistin monotherapy.
        - In subset analysis, patients infected with strains resistant to both carbapenems and colistin, mortality was less with colistin monotherapy despite the in vitro resistance (Clin Infect.Dis 2019;69:769)
      - The results were no better in patients given early empiric therapy with colistin, with or without, meropenem (Clin Infect Dis 2018; 67:1815)
      - The trial was under powered to compare efficacy vs carbapenem-resistant *Klebsiella* and *Pseudomonas aeruginosa* infections

- Use of other agents
  - **Doripenem** is not approved to treat any type of pneumonia and it is not approved for doses > 500 mg q8h.
  - **Tigecycline** is not recommended due to sub-therapeutic serum concentrations in bacteremia plus increased risk of all cause mortality compared with other agents (Clin Infect Dis 2012 Jun;54(12):1699)
  - **Minocycline IV**:
    - Limited clinical experience (Infect Dis Ther 2017; 6:199)
    - In vitro data (Antimicrob Agents Chemother 2019;63:e01154-19) indicates susceptibility of 67-86 % of clinical isolates
    - In retrospective study of 76 patients, clinical cure and microbiologic eradication in 79% and 82% of those with monomicrobial infection (Antimicrob Agents Chemother 2019;63:e01154-19)
  - **Cefiderocol**
    - Broad range of antibacterial activity against Gram-negatives that produce ESBLs, AmpC cephalosporinases, oxacillinases, serine carbapenemases (KPCs), metallo-beta-lactamases (NDM, VIM)
    - **Inconclusive clinical trial results**
      - **Cefiderocol vs. Best Available Therapy (BAT)**
        - Underpowered, randomized open label study of patients with nosocomial pneumonia, sepsis, complicated UTI, and bacteremia due to carbapenemase producing gram-negative bacilli: 28 day all cause mortality was 9/49 (18.4%) with BAT and 25/101 (24.8%) with cefiderocol therapy (not statistically significant): Lancet Infect Dis 2021; 21: 226
      - **Cefiderocol vs high dose meropenem for treatment of HABP/VABP** due to resistant GNB in randomized double blind trial
        - Cefiderocol 2 gm IV over 3 hr q8h was non-inferior to meropenem 2 gm IV over 3 hr q8h. In 16 patients with meropenem resistant Acinetobacter, day 14 all cause mortality was 0% in 5 patients treated with cefiderocol and 46% in 11 patients treated with meropenem (Lancet Infect Dis 2021; 21: 213)

- References: Evolving treatment considerations and options
  - IDSA treatment guidance (Clin Infect Dis 2022, 74:2089)
  - Semin Respir Crit Care Med 2022, 43:97

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Patient:	JOHN DOE	Specimen:	**Swab**	Specimen ID:	**RT138117**
Patient DOB:	**9/10/1992**	Collected:	**11/9/23 3:15 PM EST**	Provider:	**Joe Smith**
Patient Age:	**31**	Received:		Account:	**6588**
Patient Sex:	**Male**	Reported:	**11/9/23 3:23 PM EST**	Facility:	**Rising Tide Demo**

Wound Care Report

Etiology: Arterial Leg Ulcer
View Overview

References: Assessment | Ankle-Brachial Index Procedure, Figure 3 | Wound Characteristics | Topical Treatment Best Practices

Information is provided as recommendation only. It is the responsibility of institution staff to contact the appropriate person to obtain and implement specific orders. All clinical recommendations are intended to assist with determining the appropriate wound therapy for the patient. Responsibility for final decisions and actions related to care of specific patients shall remain the obligation of the institution, its staff, and the patients' attending physicians. Nothing in this consultation shall be deemed to constitute the providing of medical care or the diagnosis of any medical condition. Consultant will not be liable for any indemnity, costs, fines or other damages arising from the survey/governmental deficiencies.

Wound Panel Molecular Antibiotic Resistance Report

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POSITIVES

High Grade Infection, > 10^6 CFU | Moderate Grade Infection, 5 x 10^4 - 10^6 CFU | Low Grade Infection, 10^4 - 5 x 10^4 CFU

Bacteria

Acinetobacter baumannii - High Grade Infection, > 10^6 CFU — LOW | MED | HIGH

Resistant Genes

Carbapenem resistance (KPC)

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A. baumannii	2	3	3	3	3	3	3	3	3	3

Patient: JOHN DOE **Specimen ID:** RT138117 **DOB:** 9/10/1992 **Gender:** Male **Race:** Unknown

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Tests

Wound Panel

Bacteria

Bacteroides fragilis Bactrim resistance (Sul2) Citrobacter freundii Enterococcus faecium Escherichia coli Fluoroquinolone resistance (QnrB) Klebsiella pneumoniae Morganella morganii Prevotella bivia Proteus mirabilis Pseudomonas aeruginosa Serratia marcescens Staphylococcus aureus Staphylococcus epidermidis Streptococcus pyogenes (Group A Strep) Trimethoprim resistance (DfrA1) Trimethoprim resistance (DfrA5)

Fungi

Candida albicans Candida glabrata Candida krusei Candida tropicalis Enterococcus faecalis

Resistant Genes

Carbapenem resistance (KPC) - DETECTED Bactrim resistance (Sul1) Carbapenem resistance (NDM) ESBL resistance (CTX-M Group 1) Fluoroquinolone resistance (QnrA) Methicillin resistance (mecA) Trimethoprim resistance (DfrA) Vancomycin resistance (vanA1, vanA2) Vancomycin resistance (vanB)

Intended Use

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Comments:

No comments.

Rising Tide REFERENCE LABORATORY

Patient: JOHN DOE **Specimen ID:** RT138117 **DOB:** 9/10/1992 **Gender:** Male **Race:** Unknown

Nancy Morgan WOUND CARE

Wound Care Report

View Overview

Wound Type	Wound Pathogen	Considerations	Other Dx Testing
Arterial Leg Ulcer	**Acinetobacter baumaunnii – Swab**	Replace intravenous line and catheters. Isolation precautions.	Send removed lines for culture.

Topical Management	Primary Dressing:	Secondary Dressing:
Cleansing with an antimicrobial cleanser followed by wound debridement as indicated. Avoid CHG, hydrogen peroxide, and providone iodine as wound cleansers.	Primary dressing of an antimicrobial wound dressing with evidence to support effectiveness against the bacteria. Consider bacteriocidal dressings such as silver or cadexomer of iodine. Contact the manufacturer and/or read the package insert of the dressing.	Use a secondary (Cover) dressing with a bacterial/viral barrier for a backing to help redue the risk of environmental contamination. Select a dressing to manage exudate, such as a super-absorbent dressing for moderate to high exudate or a moisture-retentive dressing, such as a hydrocolloid for low exudate wounds.

Dressing Considerations
Dressing changes may be daily in initial phases of infection where exudate levels are high. Dressing changes may vary from 3 times per week to weekly depending on compression therapy for venous leg ulcers and off-loading choices for diabetic foot ulcers.

Manual Reference Pages
Debridement of Biofilm Wound Cleansing Biofilm Wound Infection Antiseptic Agents - Table 18
Principles of Wound Healing Topical Wound Management Wound Infection/Biofilm

Molecular Antibiotic Resistance Report

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Detected Pathogen - Acinetobacter baumannii

\+ KPC

Our test result identified the presence of bacteria whose genomes include specific genes that, when expressed during patient infections, can reduce antimicrobial efficacy. Interpret genotypic resistance with caution. The sensitivity and specificity of detection of resistant genes varies with the specific method employed. Not all detected genes are active; some can be induced to an active state only after initiation of antibiotic therapy. Further, a given organism may harbor multiple mechanisms of resistance some of which not be detected by the methods in use. For these reasons, there is the possibility of a discordance between the results of genotypic resistance versus phenotypic in vitro antibiotic resistance testing. The patient's clinical response to empiric or specific antibiotic therapy remains the final arbitrator as to the success of a treatment regimen.

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Clinical Setting

- *Acinetobacter baumannii* complex causes a variety of local and systemic infections in both immunocompetent and immunocompromised patients
  - Hospital-acquired opportunistic pathogen, frequent cause of ventilator-associated pneumonia
  - Can cause a variety of other infections: e.g., soft tissue, wounds and bone; UTIs; meningitis; eye infections
  - Any of the above can be associated with bacteremia.

- Resistance is a problem
  - Acinetobacter sp. have among the largest number and variety of resistance mechanisms of all gram-negative bacilli
    - **Roughly 50% of *Acinetobacter baumanii* isolates demonstrate multi-drug resistance (MDR).** In certain locations, substantive % of isolates demonstrate extensive drug resistance and even pan-drug resistance
    - **Resistance mechanisms, alone or in combination, include:**
      - Production of extended spectrum beta-lactamases (ESBLs)
      - Production of AmpC cephalosporinases (rare)
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      - Change in drug target binding sites, e.g., penicillin binding protein sites and DNA gyrase mutations
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  - For further discussion of drug resistance classes and mechanisms see Gram-negative Resistance, Overview. See Comments for other recent references on evolving treatment considerations and options.

Primary Regimens

- **Treatment options below are for therapy of moderately-severe, or severe infections in patients requiring systemic therapy**
  - Complicated UTI
  - Ventilator associated Bacterial Pneumonia/ Hospital acquired bacterial pneumonia
  - Bacteremia
  - Meningitis: see Comments

Patient: JOHN DOE **Specimen ID:** RT138117 **DOB:** 9/10/1992 **Gender:** Male **Race:** Unknown

Lab reports	Modifying Circumstances	Recommended Regimens	Comments
***Acinetobacter* in sputum or sterile body site, antibiotic susceptibility results pending**	**Local rate of MDR <10-15%**, not critically ill, monotherapy is reasonable	**Empiric therapy** Cefepime 2 gm IV q8h OR Meropenem 2 gm IV infused over 3 hrs and repeat q8h (continuous infusion regimens in clinical trial) OR Ampicillin-sulbactam 9 gm (6 gm amp/3 gm sulb) IV over 4 hrs and repeat q8h	No commercial source for sulbactam alone. High dose: (Eur J Pharm Sci 136:104940, 2019)
	Local rate of MDR >10-15% and/or patient is critically ill, consider combination therapy to increase odds of administering at least one active drug:	**Empiric therapy** Ampicillin-sulbactam 9 gm (6gm amp/3 gm sulb) IV infused over 4 hrs and repeat q8h + Meropenem 2 gm IV infused over 3 hrs and repeat q8h + Polymyxin B 2.5 mg/kg loading dose IV infused over 2 hrs then, starting 12 hrs later, 1.5 mg/kg IV infused over 1 hr q12h	
Susceptibility to multiple antibiotics		Monotherapy with Cefepime, Meropenem, or Ampicillin-sulbactam as above (see Comments)	
Resistance to all cephalosporins, aztreonam, and carbapenems; susceptibility to polymyxins		**Recommend infectious diseases consultation** Cefiderocol 2 gm q8h IV over 3 hrs (see Comments: FDA approved for treatment of complicated UTIs and VABP/HABP)	Another option: combination therapy with one or more of the following if susceptible in vitro (see Comments): Minocycline 200 mg IV x one dose then 100 mg IV q12 h ± Amikacin (more active than gentamicin; check renal function and monitor serum levels) ± Ampicillin-sulbactam 9 gm of sulbactam (6 gm Amp/ 3 gm sulbactam) IV over 4 hr and repeat q8h
Resistance to all antibiotics tested, including polymyxins		No known effective therapy: Recommend infectious diseases consultation Consider Cefiderocol 2 gm q8h IV over 3 hrs (FDA approved for treatment of complicated UTIs & VABP)	See Comments

Alternative Regimens

- **Lab reports susceptibility to multiple antibiotics**
  - Some isolates may be susceptible to:
    - Ciprofloxacin 400 mg IV q8h or Levofloxacin 750 mg IV q24h
    - TMP-SMX 10 mg/kg/day (TMP component) IV divided q8h or q12h
- **Lab reports MDR or extensive drug resistance**
  - Test for in vitro susceptibility to:
    - Aminoglycosides:
      - Amikacin more frequently active in vitro than gentamicin (Antimicrob Agents Chemother 2019; 63: e01154-19)
      - Plazomicin: Aminoglycoside that is stable in presence of enzymes that inactivate gentamicin, tobramycin, and amikacin. Limited observational reports of success vs MDR pathogens.
    - Eravacycline and Omadacycline: Next generation tetracyclines. Better pharmacokinetics than Tigecycline. Active in vitro vs Acinetobacter. No clinical data.

- Combination therapy:
  - **Combination of Meropenem + polymyxin (either Polymyxin B or Colistin) not recommended:**
    - Based on a failed randomized controlled trial (Lancet Infect Dis 2018;18:391-400) of 406 patients with serious infections due to carbapenem-nonsusceptible Gram-negative bacteria, 77% of whom were infected with *Acinetobacter baumannii.*
      - Rate of clinical failure (83% for Colistin and 81% for the combination) and the rate for mortality (46% for Colistin and 52% for the combination) were no better with the combination than with Colistin monotherapy.
        - In subset analysis, patients infected with strains resistant to both carbapenems and colistin, mortality was less with colistin monotherapy despite the in vitro resistance (Clin Infect.Dis 2019;69:769)
      - The results were no better in patients given early empiric therapy with colistin, with or without, meropenem (Clin Infect Dis 2018; 67:1815)
      - The trial was under powered to compare efficacy vs carbapenem-resistant *Klebsiella* and *Pseudomonas aeruginosa* infections

- Use of other agents
  - **Doripenem** is not approved to treat any type of pneumonia and it is not approved for doses > 500 mg q8h.
  - **Tigecycline** is not recommended due to sub-therapeutic serum concentrations in bacteremia plus increased risk of all cause mortality compared with other agents (Clin Infect Dis 2012 Jun;54(12):1699)
  - **Minocycline IV**:
    - Limited clinical experience (Infect Dis Ther 2017; 6:199)
    - In vitro data (Antimicrob Agents Chemother 2019;63:e01154-19) indicates susceptibility of 67-86 % of clinical isolates
    - In retrospective study of 76 patients, clinical cure and microbiologic eradication in 79% and 82% of those with monomicrobial infection (Antimicrob Agents Chemother 2019;63:e01154-19)
  - **Cefiderocol**
    - Broad range of antibacterial activity against Gram-negatives that produce ESBLs, AmpC cephalosporinases, oxacillinases, serine carbapenemases (KPCs), metallo-beta-lactamases (NDM, VIM)
    - **Inconclusive clinical trial results**
      - **Cefiderocol vs. Best Available Therapy (BAT)**
        - Underpowered, randomized open label study of patients with nosocomial pneumonia, sepsis, complicated UTI, and bacteremia due to carbapenemase producing gram-negative bacilli: 28 day all cause mortality was 9/49 (18.4%) with BAT and 25/101 (24.8%) with cefiderocol therapy (not statistically significant): Lancet Infect Dis 2021; 21: 226
      - **Cefiderocol vs high dose meropenem for treatment of HABP/VABP** due to resistant GNB in randomized double blind trial
        - Cefiderocol 2 gm IV over 3 hr q8h was non-inferior to meropenem 2 gm IV over 3 hr q8h. In 16 patients with meropenem resistant Acinetobacter, day 14 all cause mortality was 0% in 5 patients treated with cefiderocol and 46% in 11 patients treated with meropenem (Lancet Infect Dis 2021; 21: 213)

- References: Evolving treatment considerations and options
  - IDSA treatment guidance (Clin Infect Dis 2022, 74:2089)
  - Semin Respir Crit Care Med 2022, 43:97

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Phone Number: (407) 476-1646
Lab Director: Vidhya Narayanan, Ph.D.
CLIA: 10D2276452

Patient:	JOHN DOE	Specimen:	**Nail**	Specimen ID:	**RT138111**
Patient DOB:	**9/10/1992**	Collected:	**10/19/23 11:55 AM EDT**	Provider:	**Joe Smith**
Patient Age:	**31**	Received:		Account:	**6588**
Patient Sex:	**Male**	Reported:	**10/19/23 11:57 AM EDT**	Facility:	**Rising Tide Demo**

Nail Fungal Comprehensive Molecular Antibiotic Resistance Report

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POSITIVES

High Grade Infection, > 10^6 CFU | Moderate Grade Infection, 5 x 10^4 - 10^6 CFU | Low Grade Infection, 10^4 - 5 x 10^4 CFU

Other

Candida albicans - High Grade Infection, > 10^6 CFU

LOW | MED | HIGH

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The data provided are intended to serve as a general guide to antibacterial usefulness based on package insert, treatment guidelines, published reports, in vitro activity, predominant patterns of susceptibility or resistance and/or demonstrated clinical effectiveness. Variability in resistance patterns due to local or regional differences or as a consequence of clinical setting, e.g., community onset vs. ICU-acquired infection, should be taken into account when using this information because the activity of antimicrobial agents can differ significantly and hence is beyond the scope of this general summary. Susceptibility testing results and your local antibiogram should be consulted in every case.

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- **[X] Allergy:** Patient has indicated they are allergic to a medication.

Medication Allergies: No medication allergies specified.

Pathogens	Fluconazole	Itraconazole	Voriconazole	Posaconazole	Isavuconazole
Candida albicans	1	2	2	2	2

Patient: JOHN DOE **Specimen ID:** RT138111 **DOB:** 9/10/1992 **Gender:** Male **Race:** Unknown

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Negative Tests

Nail Fungal Comprehensive

Other

Acremonium strictum Alternaria alternata Aspergillus niger Aspergillus terreus Candida auris Candida glabrata Candida krusei Candida lusitaniae Candida parapsilosis Candida tropicalis Epidermophyton flocossum Fusarium solani Microsporom gypseum Microsporum audouinii/Microsporum canis Microsporum nanum Neofusicoccum mangiferae Trichophyton interdigitale Trichophyton spp Trichophyton tonsurans Trichosporon beigelli Trichosporon mucoides

Intended Use

The detection and identification of specific pathogens and drug resistance markers from individuals exhibiting signs and symptoms of the infectious disease. This test aids in the diagnosis if used in conjunction with other clinical and epidemiological information. This test is a Laboratory Derived (LDT) qualitative nucleic acid multiplex diagnostic test intended for use on an Applied Biosystems™ QuantStudio™ 7 Flex Real-Time PCR System for the simultaneous detection and identification of multiple pathogen nucleic acids in clinical samples obtained from individuals exhibiting signs and symptoms of the infectious disease.

Methodology

Real-Time PCR was performed on genomic DNA extractions using the UTI and Wound Advanced RT-PCR Detection Kit, analyzed on a QuantStudio™ 7 Flex. The CFU (Colony Forming Units) equivalent ranges were calculated from the Linearity studies performed using titered control DNA for each organism on the panel. Upon data analysis, absence or presence (in low, medium or high prevalence) of the pathogens is determined, based upon whether the amplification is above or below the threshold of detection.

Limitations

Negative results do not preclude an infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out infection, or co-infection with other pathogens not on our panel. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence and radiography) and clinical presentation must be taken into consideration in the final diagnosis.

This test detects the presence of pathogens and must be evaluated with clinical symptoms to diagnose a disease. All tests established and validated by the laboratory are not FDA approved. The detection of viral, fungal and bacterial nucleic acid is dependent upon proper specimen collection, handling, transporting, storage and preparation.

Comments:

No comments.

Rising Tide REFERENCE LABORATORY

Patient: JOHN DOE **Specimen ID:** RT138111 **DOB:** 9/10/1992 **Gender:** Male **Race:** Unknown

Molecular Antibiotic Resistance Report

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Detected Pathogen - Candida albicans

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Clinical Setting

- Candidemia, disseminated candidiasis: non-neutropenic, neutropenic patients
- Most common cause of mucosal and cutaneous candidaisis
- Normal human flora
- Risk factors: Antibiotic use, GI surgery, immunocompromised state
- Positive blood culture for yeast, suspected catheter-related bloodstream infection

Primary Regimens

- Empiric Therapy (see Comments):
  - Caspofungin 70 mg IV loading dose, then 50 mg IV qd
  - Micafungin 100 mg IV qd
  - Anidulafungin 200 mg IV loading dose, then 100 mg IV qd
  - Rezafungin 400 mg x 1 loading dose, then 200 mg IV once weekly
- Directed Therapy (species identified)
  - Fluconazole 800 mg (12 mg/kg) loading dose, then 400 mg IV/po qd once blood cultures have cleared and clinically stable

Alternative Regimens

- Empiric Therapy Non-Neutropenic Patients:
  - Fluconazole 800 mg (12 mg/kg) loading dose, then 400 mg IV/po qd (in cases of mild-to-moderate illness and no prior azole therapy)
  - Lipid-based Amphotericin B 3-5 mg/kg IV qd
  - Amphotericin B 0.7 mg/kg IV qd
  - Voriconazole 6 mg/kg bid x 2 doses, then 4 mg/kg bid

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Patient:	TEST A7 LAKE	Specimen:	**Swab**	Specimen ID:	**LV1029018753**
Patient DOB:	**1/1/1996**	Collected:	**3/16/23 9:24 AM EDT**	Provider:	**Joe Smith**
Patient Age:	**27**	Received:		Account:	**6588**
Patient Sex:	**Male**	Reported:	**3/16/23 9:55 AM EDT**	Facility:	**Rising Tide Demo**

Mini Respiratory Panel Molecular Antibiotic Resistance Report

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POSITIVES

Virus

Influenza A/B

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- **[X] Allergy:** Patient has indicated they are allergic to a medication.

Medication Allergies: No medication allergies specified.

Pathogens	Peramivir	Zanamavir	Baloxavir
Influenza	1	1	2

Patient: TEST A7 LAKE **Specimen ID:** LV1029018753 **DOB:** 1/1/1996 **Gender:** Male **Race:** Unknown

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Negative Tests

Mini Respiratory Panel

Virus
RSV A/B SARS-CoV-2

Intended Use

The VIASURE SARS-CoV-2, Flu & RSV Real Time PCR Detection Kit is a real-time RT-PCR test designed for the qualitative detection of RNA from the SARS-CoV-2, Influenza A/B (Flu A/B) and/or Human Respiratory Syncytial Virus A/B (RSV A/B) in respiratory specimens from individuals suspected of respiratory infections by their healthcare provider.

Methodology

Real-Time PCR was performed on genomic DNA extractions using the VIASURE SARS-CoV-2, Flu & RSV Real Time PCR Detection Kit, analyzed on a QuantStudio™ 7 Flex. Upon data analysis, absence or presence of the pathogens is determined, based upon whether the amplification is above or below the threshold of detection.

Limitations

Negative results do not preclude an infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out infection, or co-infection with other pathogens not on our panel. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence and radiography) and clinical presentation must be taken into consideration in the final diagnosis.

Comments:

No comments.

Rising Tide REFERENCE LABORATORY

Patient: TEST A7 LAKE **Specimen ID:** LV1029018753 **DOB:** 1/1/1996 **Gender:** Male **Race:** Unknown

Molecular Antibiotic Resistance Report

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Detected Pathogen - Influenza

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Clinical Setting

- Seasonal influenza. Generally December-April in temperate northern hemisphere. For immunization and prevention see Influenza, Vaccines.
- 2022-2023 season
  - Concurrently circulating respiratory viruses of particular concern: RSV and COVID-19.
  - Symptoms overlap and etiology cannot be easily determined without testing
  - Influenza and COVID-19 co-infection in may be associated with increased morbidity and mortality in those <18 years (MMWR December 16, 2022 / 71(50);1589)
- Symptoms of fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills, fatigue and sometimes, diarrhea and vomiting.
- Complications can include:
  - Pulmonary: influenza pneumonia with/without bacterial superinfection
  - Other respiratory tract: Bronchiolitis, bronchitis, otitis media, parotitis
  - Extrapulmonary: myositis/rhabdomyolysis, myocarditis/encephalitis, encephalitis, and rarely toxic shock syndrome, Reyes syndrome, post-influenza Guillian-Barre syndrome
  - Other: Exacerbation of COPD, coronary artery disease, asthma
- Risk factors for complications include: age < 2 yrs, age >65 yrs, chronic pulmonary, cardiac, renal, hematologic or metabolic disorders, neurologic and neuro-developmental disorders, immunosuppression, extreme obesity, residing in nursing home, American Indian and native Alaskan, and pregnancy (https://www.cdc.gov/flu/about/disease/high_risk.htm; N Engl J Med 370: 2211, 2014).
- Resistance to Amantadine, Rimantadine > 95%. Do not use.
- For influenza updates including influenza activity by region, see http://www.cdc.gov/flu/weekly/.
- Treatment: IDSA guidelines: Clin Infect Dis 2019;68: 895
- Vaccine ACIP recommendations of the CDC Advisory Committee on Immunization practices (ACIP): https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm or Med Lett 62:145, 2020

Patient: TEST A7 LAKE **Specimen ID:** LV1029018753 **DOB:** 1/1/1996 **Gender:** Male **Race:** Unknown

Primary Regimens

- **Antiviral therapy is recommended** for all persons with high risk conditions, those with severe disease, and for all patients hospitalized with influenza. Multiple observational studies suggest mortality benefit in hospitalized patients.
- Antiviral therapy has modest benefits in otherwise healthy outpatients if started within 48 hours. **Treatment can be considered**. **CDC HAN (12/14/2022): Interim guidance in light of reduced availability of oseltamivir (Tamiflu and generic) during high seasonal influenza activity.**
  - Oseltamivir:
    - Adult: 75 mg po bid x 5 days
    - Pediatric (age 1-12 years): age / weight-based dosing:
      - Infant 2 wks-11 months: 3 mg/kg bid x 5 days
      - ≤15 kg: 30 mg bid x 5 days
      - >15 kg to 23 kg: 45 mg bid x 5 days
      - >23 kg to 40 kg: 60 mg bid x 5 days
      - >40 kg: 75 mg bid x 5 days
  - Zanamivir 2 inhalations (5 mg each) bid x 5 days (age > 7 yrs, without significant asthma or COPD)
  - Baloxavir (age ≥5 years): weight based dosing:
    - 40 mg po once if wt 20-<80 kg
    - 80 mg po once if wt >80 kg
- Hospitalized severe influenza
  - In hospitalized patients, antiviral therapy is beneficial even if started at least up to 5 days after symptom onset, although greater benefit with early therapy
  - Viral replication is longer in patients immunocompromised patients and those with severe illness
    - Hence, start oseltamavir therapy regardless of duration of influenza symptoms
    - Consider longer duration of oseltamivir (10 or more days) in the critically ill and severely immunocompromised patients
    - See CDC Guidance: https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm
  - Avoid use of corticosteroids unless indicated for other indications (e.g. COPD, adrenal insufficiency) due to reports of increased mortality (J Infect Dis 2015: 212: 183)
  - If oral therapy is not possible, Peramivir 600 mg IV one time if CrCl >60 ml/min is FDA approved for uncomplicated influenza
    - Renal excretion; Dose varies with degree of renal impairment
    - For patients unable to take, or non-compliant with, use an oral medication
    - Longer duration may be given once daily IV for severely ill hospitalized patients
  - Laninamivir is available in Japan. Trials showed non-inferiority to oseltamivir (Clin Infect Dis 10:1167, 2010)
    - Adult: 40 mg inhalation single dose
    - Child age < 10 yrs: 20 mg

- **Severe illness:**
  - Investigate and consider treating bacterial co-infection (in addition to antivirals) in patients with overwhelming disease, high procalcitonin, or who deteriorate after initial improvement.
  - High dose oseltamivir shown no more effective than standard dosage for influenza A. Do not routinely administer steroids for severe influenza (unless clearly indicated for another reason e.g. asthma, COPD).Data suggest increased mortality (J Infect Dis 212:183, 2015)
  - IV Zanamivir no longer available (since 2018)

- **References**
  - 2018 IDSA Guidelines for treatment
  - CDC guidance: http://www.cdc.gov/flu/weekly; http://www.cdc.gov/flu/professionals/antivirals/index.htm
  - Respiratory viruses & CAP: Infect Dis Clin N Am 27:157, 2013
  - Vaccination information http://www.cdc.gov/flu/professionals/vaccination/index.htm; Influenza vaccines for 2019-2020; Med Lett 62:145, 2020
  - Editorial: Use of neuraminidase inhibitors for treatment of severe influenza (Clin Infect Dis. 2017;64:368).

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Patient:	TEST A2 JOHNSON	Specimen:	**Urine**	Specimen ID:	**LV1029018758**
Patient DOB:	**1/1/1991**	Collected:	**3/16/23 9:04 AM EDT**	Provider:	**Joe Smith**
Patient Age:	**32**	Received:		Account:	**6588**
Patient Sex:	**Female**	Reported:	**3/16/23 10:54 AM EDT**	Facility:	**Rising Tide Demo**

STI Panel Molecular Antibiotic Resistance Report

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POSITIVES

Bacteria

Chlamydia trachomatis

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- **[X] Allergy:** Patient has indicated they are allergic to a medication.

Medication Allergies: No medication allergies specified.

Pathogens	Ofloxacin	Levofloxacin	Azithromycin	Doxycycline	Ampicillin	Amoxicillin	Moxifloxacin	Gemifloxacin	Gatifloxacin	Erythromycin	Clarithromycin	Minocycline	Tetracycline
C. trachomatis	1	1	1	1	2	2	2	2	2	2	2	2	2

Patient: TEST A2 JOHNSON **Specimen ID:** LV1029018758 **DOB:** 1/1/1991 **Gender:** Female **Race:** Unknown

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Negative Tests

STI Panel

Bacteria	
Mycoplasma genitalium	Neisseria gonorrhoeae

Parasite
Trichomonas vaginalis

Intended Use

The ThermoFisher TrueMark STI Select Panel Combo Kit is a multiplexed real time PCR assay designed to identify four common sexually transmitted infection bacteria: Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), Trichomonas vaginalis (TV), Mycoplasma genitalium (MG) with human RNase P as the internal control. The sample types will include clinician-collected or self-collected vaginal swab samples, female or male first-void samples. (Defined as the first 20-30 mL of the urine stream), clinician- collected endocervical swabs from females or clinician-collected urethral swabs from males.

Methodology

Real-Time PCR was performed on genomic DNA extractions using the TrueMark STI Select Panel Combo Kit, analyzed on a QuantStudio™ 7 Flex. Upon data analysis, absence or presence of the pathogens is determined, based upon whether the amplification is above or below the threshold of detection.

Limitations

Negative results do not preclude an infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out infection, or co-infection with other pathogens not on our panel. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence and radiography) and clinical presentation must be taken into consideration in the final diagnosis.

Comments:

No comments.

Rising Tide REFERENCE LABORATORY

Patient: TEST A2 JOHNSON **Specimen ID:** LV1029018758 **DOB:** 1/1/1991 **Gender:** Female **Race:** Unknown

Molecular Antibiotic Resistance Report

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Detected Pathogen - Chlamydia trachomatis

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Clinical Setting

- Different serovars of *C. trachomatis* are associated with different clinical syndromes:
  - Serovars A, B, Ba, & C cause trachoma
  - D-K cause urogenital syndromes (e.g., urethritis/cervicitis)
  - L1-L3 cause Lymphogranuloma venereum (LGV).
- Urogenital *C. trachomatis* syndromes are the most frequent reportable infectious diseases in the U.S.
- Associated with:
  - Sexually transmitted infections including nongonococcal cervicitis, urethritis, pelvic inflammatory disease, proctitis
  - Lymphogranuloma venereum (LGV)
  - Trachoma: a chronic bacterial keratoconjunctivitis that is the most common cause of infectious blindness world-wide. Trachoma is endemic in resource-poor regions of poverty.
- Urethral and cervical infections are commonly asymptomatic.
- Annual screening is recommended in sexually active women age <25 years and older women at risk (N Engl J Med 2017;376:765). Screening of MSM is also advisable.
  - If tests positive and treated with Azithromycin or Doxycycline, need to repeat screening in 3 months
  - If positive screen, suggest testing all sexual contacts that occurred within the the 60 days before the diagnosis or symptoms
- Neonates who contract infection from their mother can present with Ophthalmia Neonatorum or pneumonia.

Diagnosis

- Diagnosis of *C. trachomatis* serovars D-K by NAAT of first-catch urine or swab of involved anatomic site (cervix, urethra).
- NAAT is more sensitive than culture, which, in turn, is more sensitive than direct fluorescent antibody (DFA) testing.
- When NAATs are used, similar sensitivity and specificity with vaginal swab (collected by patient or physician) or swab of endocervical canal
- Can use first voided urine but sensitivity is slightly lower
- NAATs cannot distinguish different serotypes (e.g. D-K vs L1-L3) need further PCR genotyping.

Primary Regimens

- See specific clinical syndrome.
- 2021 CDC STI guidelines MMWR Recomm Rep 70 (RR-4):1 2021 Doxycycline 100 mg bid x 7 preferred regimen
- For most syndromes, Azithromycin and Doxycycline are effective, yet single dose Azithromycin found less effective in patients with rectal infection (Clin Infect Dis 2019;69:1946; Clin Infect Dis 73:824 2021)
  - Urethritis or cervicitis
  - Proctitis
  - Ophthalmia neonatorum
  - Neonatal pneumonia
  - Trachoma
  - LGV
  - Pharyngitis (frequency and importance unclear)

Alternative Regimens

- Pregnancy: Amoxicillin can be used in treatment of pregnant women with *Chlamydia trachomatis* infection but exposure to penicillin-class antibiotics is reported to induce a persistent state in the organism (J Infect Dis 201:S88, 2010) so amoxicillin is considered an alternative treatment.

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Lab Director: Vidhya Narayanan, Ph.D.
CLIA: 10D2276452

Patient:	TEST A9 WILLIAMS	Specimen:	**Urine**	Specimen ID:	**RT13842**
Patient DOB:	**9/10/1984**	Collected:	**5/22/23 5:01 PM EDT**	Provider:	**Joe Smith**
Patient Age:	**39**	Received:		Account:	**6588**
Patient Sex:	**Female**	Reported:	**5/22/23 5:19 PM EDT**	Facility:	**Rising Tide Demo**

Urinalysis Molecular Antibiotic Resistance Report

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Urinalysis

Positives: **Nitrite - Detected**
Negatives: Bilirubin Blood Clarity Color Glucose Ketone Leukocytes pH Protein Specific Gravity Urobilinogen

POSITIVES

High Grade Infection, > 10^6 CFU | Moderate Grade Infection, 5 x 10^4 - 10^6 CFU | Low Grade Infection, 10^4 - 5 x 10^4 CFU

Bacteria

Citrobacter freundii - High Grade Infection, > 10^6 CFU

LOW | MED | HIGH

Resistant Genes

Vancomycin resistance (vanB)

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- **[X] Allergy:** Patient has indicated they are allergic to a medication.

Medication Allergies: No medication allergies specified.

Pathogens	Ciprofloxacin	Delafloxacin	Ofloxacin	Levofloxacin	Moxifloxacin	Norfloxacin	Prulifloxacin	Gemifloxacin	Gatifloxacin	Omadacycline	Fosfomycin (po)	TMP-SMX	Nitrofurantoin
C. freundii	2	2	2	2	2	2	2	2	2	2	2	3	3

Patient: TEST A9 WILLIAMS **Specimen ID:** RT13842 **DOB:** 9/10/1984 **Gender:** Female **Race:** Unknown

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Tests

UTI Panel old

Bacteria

Acinetobacter baumannii Bacteroides fragilis Citrobacter braaki Citrobacter koseri Enterobacter cloacae Enterococcus faecalis Escherichia coli Klebsiella aerogenes Klebsiella michiganensis Klebsiella oxytoca Klebsiella pneumoniae Morganella morganii Mycoplasma genitalium Mycoplasma hominis Prevotella bivia Proteus mirabilis Pseudomonas aeruginosa Serratia marcescens Staphylococcus aureus Staphylococcus epidermidis Staphylococcus saprophyticus Streptococcus pyogenes (Group A Strep) Ureaplasma urealyticum

Fungi

Candida albicans Candida dubliniensis Candida glabrata Candida krusei Candida parapsilosis Candida tropicalis

Resistant Genes

Vancomycin resistance (vanB) - DETECTED Bactrim resistance (Sul1) Carbapenem resistance (KPC) Carbapenem resistance (NDM) ESBL resistance (CTX-M Group 1) Fluoroquinolone resistance (QnrA) Methicillin resistance (mecA) Trimethoprim resistance (DfrA) Vancomycin resistance (vanA1, vanA2)

Intended Use

The detection and identification of specific pathogens and drug resistance markers from individuals exhibiting signs and symptoms of the infectious disease. This test aids in the diagnosis if used in conjunction with other clinical and epidemiological information. This test is a Laboratory Derived (LDT) qualitative nucleic acid multiplex diagnostic test intended for use on an Applied Biosystems™ QuantStudio™ 7 Flex Real-Time PCR System for the simultaneous detection and identification of multiple pathogen nucleic acids in clinical samples obtained from individuals exhibiting signs and symptoms of the infectious disease.

Methodology

Real-Time PCR was performed on genomic DNA extractions using the UTI and Wound Advanced RT-PCR Detection Kit, analyzed on a QuantStudio™ 7 Flex. The CFU (Colony Forming Units) equivalent ranges were calculated from the Linearity studies performed using titered control DNA for each organism on the panel. Upon data analysis, absence or presence (in low, medium or high prevalence) of the pathogens is determined, based upon whether the amplification is above or below the threshold of detection.

Limitations

Negative results do not preclude an infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out infection, or co-infection with other pathogens not on our panel. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence and radiography) and clinical presentation must be taken into consideration in the final diagnosis.

This test detects the presence of pathogens and must be evaluated with clinical symptoms to diagnose a disease. All tests established and validated by the laboratory are not FDA approved. The detection of viral, fungal and bacterial nucleic acid is dependent upon proper specimen collection, handling, transporting, storage and preparation.

Comments:

No comments.

Rising Tide REFERENCE LABORATORY

Patient: TEST A9 WILLIAMS **Specimen ID:** RT13842 **DOB:** 9/10/1984 **Gender:** Female **Race:** Unknown

Molecular Antibiotic Resistance Report

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Detected Pathogen - Citrobacter freundii

SANFORD GUIDE 熱病

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Overview

- Citrobacter species cause a variety of infections ranging from uncomplicated urinary tract infections to life-threatening infections of the abdomen, skin and soft tissue, lung, CNS and other sites in both normal and immuno-compromised hosts.
- Suggested treatment regimens vary with the species, status of cultures and the results of in vitro susceptibility.
- Antibiotic resistance is an increasing problem:
  - Major mechanism of resistance is production of beta-lactamases
    - Citrobacter strains can produce **extended-spectrum beta-lactamases (ESBL)**. ESBLs destroy antibacterial activity of most extended spectrum cephalosporins, penicillins, and aztreonam, though Cefepime may be an exception.
    - *Citrobacter freundii* in particular can harbor a repressed chromosomal **ampC gene** that can be de-repressed by treatment with cephalosporins.
      - Can occur in up to 20% of Enterobacter infections andpatients with Citrobacter infections. (Clin Infect Dis 2019; 69:1446).
      - **Important: ampC gene is found in a high percentage of *C.freundii* isolates but virtually none of *C. koserii* isolates**
    - Often concomitant resistance to fluoroquinolones, aminoglycosides and TMP/SMX.
    - Other potential mechanisms of resistance: **porin closure with reduced cell wall permeability, change in cell wall binding protein, and efflux pumps**
- **Treatment**
  - Choice of **empiric regimen** depends on local resistance pattern, fragility of the patient and the severity of the infection. **Specific therapy** is directed results of in vitro susceptibility testing.
  - For further discussion see Gram Negative Bacilli, Beta-lactam Resistance, Overview.
- For uncomplicated cystitis, see Cystitis, adult female.

Topics Links

- *Citrobacter freundii*
- *Citrobacter koseri (formerly diversus)*