Laboratory Director: Henry Tsai, MD PhD
11160 Warner Avenue, Suite 415 • Fountain Valley, CA 92708
Phone: 714-438-1009 • Fax: 714-438-2484 • www.labgenomic.com
Laboratory Certification: CLIA # 05D2026572

Patient: JANE DOE Date of Birth: JAN. 1, 1980 Sex: Female	Date Collected: Date Received: Accession #: 200201242	Ordering Physician: DOCTOR NAME

Respiratory Pathogen With Guidance

1. Molecular Diagnostic Results

Respiratory			
-	-	*A. baumannii*	Negative
-	-	*Adenovirus 1/2*	Negative
-	-	*Adenovirus 2/2*	Negative
-	-	*Bordetella*	Negative
-	-	*C. albicans*	Negative
-	-	*C. burnetii*	Negative
-	-	*C. immitis, C. posadasii*	Negative
-	-	*C. pneumoniae*	Negative
-	-	*CoV_229E_HKU1_NL63_OC43*	Negative
-	-	*Cytomegalovirus*	Negative
-	-	*Enterovirus*	Negative
-	-	*Epstein-Barr Virus*	Negative
-	-	*H. capsulatum*	Negative
-	-	*H. influenzae*	Negative
-	-	*HBoV*	Negative
-	-	*HHV6*	Negative
-	-	*hMPV*	Negative
-	-	*hPIV1_2_3*	Negative
-	-	*hPIV4*	Negative
-	-	*Human Respiratory Syncytial Virus*	Negative
+	L	*Human Rhinovirus 1/2*	Positive
-	-	*Human Rhinovirus 2/2*	Negative
+	H	*Influenza A*	Positive
-	-	*Influenza B*	Negative
+	L	*K. pneumoniae*	Positive
-	-	*L. pneumophila*	Negative
-	-	*M. catarrhalis*	Negative
-	-	*M. pneumoniae*	Negative
-	-	*Nocardia spp.*	Negative
-	-	*P. aeruginosa*	Negative
-	-	*P. jirovecii*	Negative
-	-	*RSVA*	Negative
+	L	*S. aureus*	Positive
+	L	*S. maltophilia*	Positive
-	-	*S. pneumoniae*	Negative
-	-	*S. pyogenes*	Negative
-	-	*SARS_CoV*	Negative
-	-	*Varicella-Zoster virus (VZV)*	Negative

Resistance Markers			
-	-	*ACT/MIR*	Negative
-	-	*blaNDM-1*	Negative
-	-	*CTX-M group 9*	Negative
-	-	*ErmA*	Negative
+	L	*ErmB*	Positive
-	-	*femA SA*	Negative
-	-	*KPC*	Negative
-	-	*mecA*	Negative
-	-	*QnrA*	Negative
-	-	*QnrB Combo*	Negative
-	-	*SHV*	Negative
-	-	*sul 1*	Negative
-	-	*sul 2*	Negative
+	L	*tetM*	Positive
-	-	*vanA2*	Negative
-	-	*vanB*	Negative
-	-	*VIM*	Negative

2. Antibiotic Treatment Options

The following table shows common treatment options for organisms assayed as present in this sample, combined with any positive or negative assayed resistance markers. "T" indicates a treatment option; "T:R" indicates a treatment option that may be affected by the detected resistance marker(s).

CFU equivalents

Low (L): ≤ 10^4 | Medium (M): 10^4 to 10^6 | High (H): ≥ 10^6 CFU

	K. pneumoniae	*S. aureus*	Resistances
Abundance	**L**	**L**	
ampicillin *(Extended-Spectrum-Beta lactam)*	-	T	Negative
streptomycin *(Glycoside)*	-	T	Not assayed
penicillin g *(Narrow-Spectrum-Beta lactam)*	-	T	Negative
nitrofurantoin *(Nitrofurans)*	T	T	Not assayed
ciprofloxacin *(Quinolone and fluoroquinolone)*	T	-	Negative
levofloxacin *(Quinolone and fluoroquinolone)*	T	-	Negative
trimethoprim/sulfamethoxazole *(Sulfonamides)*	T	-	Negative
† tigecycline *(Tetracyclines)*	-	T:R	tetM
vancomycin *(Vancomycin)*	-	T	Negative

† Consider alternate treatment due to detected resistance marker(s).

Guidance
H = High growth of bacteria
M = Moderate growth of bacteria
L = Low growth of bacteria
- = No growth of bacteria

Abundance Relative to Colony Forming Units (CFU)
L < 10,000 CFU
M 10,000 to 100,000 CFU
H > 100,000 CFU

Antibiotic Resistance

	Assay	Presence
ACT/MIR	AmpC resistance	
blaNDM-1	Extended-Spectrum-Betalactamase	
CTX-M group 9	Extended-Spectrum-Betalactamase	
ErmA	Macrolide resistance	
ErmB	Macrolide resistance	Detected
femA SA	Species specific, S. aureus	
KPC	Carbapenem resistance	
mecA	Methicillin resistance	
QnrA	Quinolone and fluoroquinolone resistance	
QnrB Combo	Quinolone and fluoroquinolone resistance (QnrB pool)	
SHV	Extended-Spectrum-Betalactamase	
sul 1	Sulfonamide 1 resistance	
sul 2	Sulfonamide 2 resistance	
tetM	tetracycline-resistant ribosomal protection protein	Detected
vanA2	Vancomycin resistance	
vanB	Vancomycin resistance	
VIM	Carbapenem resistance	

3. Microorganisms Tested by Lab Genomics, LLC

Organism/Assay	Ct Mean	Presence
A. baumannii		Not Detected
ACT/MIR		Not Detected
Adenovirus 1/2		Not Detected
Adenovirus 2/2		Not Detected
blaNDM-1		Not Detected
Bordetella		Not Detected
C. albicans		Not Detected
C. burnetii		Not Detected
C. immitis, C. posadasii	29.128	Not Detected
C. pneumoniae		Not Detected
CoV_229E_HKU1_NL63_OC43		Not Detected
CTX-M group 9		Not Detected
Cytomegalovirus		Not Detected
Enterovirus		Not Detected
Epstein-Barr Virus	28.053	Not Detected
ErmA		Not Detected
ErmB (Macrolide resistance)	28.506	Detected
femA SA		Not Detected
H. capsulatum		Not Detected
H. influenzae		Not Detected
HBoV		Not Detected
HHV6		Not Detected
hMPV		Not Detected
hPIV1_2_3		Not Detected
hPIV4		Not Detected
Human Respiratory Syncytial Virus		Not Detected
Human Rhinovirus 1/2	30.058	Detected
Human Rhinovirus 2/2		Not Detected
Influenza A	14.780	Detected
Influenza B		Not Detected
K. pneumoniae	27.645	Detected
KPC		Not Detected
L. pneumophila		Not Detected
M. catarrhalis		Not Detected
M. pneumoniae		Not Detected
mecA		Not Detected
Nocardia spp.		Not Detected
P. aeruginosa		Not Detected
P. jirovecii		Not Detected
QnrA		Not Detected
QnrB Combo		Not Detected
RSVA		Not Detected
S. aureus	24.542	Detected
S. maltophilia	29.285	Detected
S. pneumoniae		Not Detected
S. pyogenes		Not Detected
SARS_CoV		Not Detected
SHV		Not Detected
sul 1		Not Detected
sul 2		Not Detected
tetM (tetracycline-resistant ribosomal protection protein)	28.562	Detected
vanA2		Not Detected
vanB		Not Detected
Varicella-Zoster virus (VZV)		Not Detected
VIM		Not Detected

Limitation: An absence of detection does not imply the absence of microorganisms other than those listed or does not exclude the possibility that the target sequence is present below the limit of detection. The Respiratory Pathogen With Guidance does not take into consideration patient history, drug-drug interactions, drug sensitivity, and/or allergies. It is the responsibility of the ordering physician to determine appropriate drug and dosing choices based on all available data.

Methodology: Array based assays simultaneously detect a wide array of bacteria, viruses, and parasites at analytical sensitivity and specificity >99%.

Disclaimer: These tests were developed and characterized by Lab Genomics, LLC and interpreted by Coriell Life Sciences, 4747 South Broad Street, Building 101, Suite 222, Philadelphia, PA 19112. The tests in this UTI panel have not been approved by the Food and Drug Administration. The FDA has determined that such approval is not necessary, provided that the laboratory both (1) maintains its good standing as a clinical testing laboratory with all mandatory accrediting bodies, and (2) continually demonstrates that its testing protocols and procedures achieve a high degree of analytical accuracy.

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