CLINIC INFORMATION PATIENT INFORMATION SPECIMEN INFORMATION

Provider:	Name:	John Jones	Date Collected:	9/7/2019
Dr. Smith	DOB:	11/2/1965	Date Received by Lab:	9/7/2019
	Gender:	Male	Run Date:	9/7/2019
			Date Reported:	9/7/2019
			Source:	SWAB
<u>Controls</u>				
Patient Extraction Control 1	PASS	(1) Endogenous control confirms sample collection, DNA/RNA extraction, and assay enzyme activity		
Endogenous Positive Control 1	PASS	(2) Positive control is synthetic inactive pathogen.		

Respiratory Pathoger	is - Bacterial		
S. pneumoniae	Not detected	N/A	
S. pyogenes	Not detected	N/A	
H. influenzae	Not detected	N/A	
M. catarrhalis	Not detected	N/A	
B. pertussis	Not detected	N/A	
C. pneumoniae	Detected - HIGH	Doxycycline 100 mg po bid x 14 days OR Azithromycin 500 mg po day 1 then 250 mg po daily x 4 days OR Levofloxacin 750 mg po x 5-7 days or Clarithromycin 500 mg bid x 10 days	
M. pneumoniae	Not detected	N/A	
L. pneumoniae	Not detected	N/A	
S. epidermidis	Not detected	N/A	
S. aureus	Not detected	N/A	
A. baumannii	Detected - HIGH	Meropenem, Colistin, Polymyxin, Amikacin, Rifampin, Minocyclin, Tigecycline	
E. aerogenes	Not detected	N/A	
E. cloacae	Not detected	N/A	
K. pneumoniae	Not detected	N/A	
P. mirabilis	Not detected	N/A	
P. aeruginosa	Not detected	N/A	
mecA	Not detected	N/A	

**Technician: David Ray** 

Lab Director: Dr. Lab Page 1



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			Source:	SWAB	
<u>Controls</u>					
Patient Extraction Control <sub>1</sub>	PASS	(1) Endogenous control confirms sample collection, DNA/RNA extraction, and assay enzyme activity			
Endogenous Positive Control <sub>1</sub>	PASS	(2) Positive control is synthetic inactive pathogen.			
Pathogen Positive Control 2	PASS	(3) Negative Control contains primers, probe, and enzymes with no DNA/RNA template			
Pathogen Negative Control <sub>3</sub>	PASS	(4) A "Detected" result indicates the presence of a pathogen (99.99% confidence) above the assay cutoff.  Assay cutoff is represneted by CFU (bacteria), PFU (viruses) or Copy Number (DNA).			

d Treatment

## **Technician: David Ray**

Lab Director: Dr. Lab Page 2

<sup>\*</sup>This test detects the presence of pathogen and must be evaluated with clinical symptoms to/ diagnose disease. All test established and validated by Laboratory and not FDA approved.

Methodology statement: Real-time PCR assays are designed to detect pathogens with clinical significance and analytical sensitivity and specificity greater than 99%.

Limitations: While these assays are very sensitive and specific, theoretically these assays could detect pathogens not listed,r esulting in a false positive.

In addition, while these assays are very specific, there may be target pathogen sequences with unknown sequence variability which may not be detected, resulting in a false negative result.