

**CLINIC INFORMATION**

 Name: Streamline Pathology Laboratory  
 Address: 2868 Acton Road Suite 207 BIRMINGHAM, AL 35243  
 Provider: Test, Doctor MD

**PATIENT INFORMATION**

 Name: PATIENT, TEST  
 DOB: 6/30/1980 Sex: M  
 Phone: (205)332-3160  
 Address: 2868 ACTON ROAD VESTAVIA, AL35243

**SPECIMEN INFORMATION**

 Lab Accession Number: S-08232210321  
 Date Collected: 08/22/22 12:00:00 AM  
 Date Accessioned: 08/23/2022  
 Date Reported: 08/23/2022  
 Faxed to: 18777966185

**Controls**

Patient Extraction Control <sup>1</sup>	PASS
Endogenous Positive Control <sup>1</sup>	PASS
Pathogen Positive Control <sup>2</sup>	PASS
Pathogen Negative Control <sup>3</sup>	PASS

(1) Endogenous control confirms sample collection, DNA/RNA extraction, and assay enzyme activity  
 (2) Positive control is synthetic inactive pathogen  
 (3) Negative Control contains primers, probe, and enzymes with no DNA/RNA template  
 (4) A "Detected" result indicates the presence of a pathogen (99.99% confidence) above the assay cutoff.

Test Performed	Test Results	Comments
<b>Collection Type: Nasopharyngeal Swab</b>		
COVID-19	Not Detected	[08/23/22] COVID-19 assay reviewed and approved under FDA Emergency Use Authorization #200522.
nCoV_N1 (CT Value)	0	[08/23/22] CT value indicates the number of amplification cycles of real-time PCR needed to detect COVID-19, a specific SARS-CoV-2 gene sequence. CT values are inversely proportional to the amount of target nucleic acid in the sample (i.e. the lower the CT level, the greater the amount of target nucleic acid in the sample). The reference range for Assurance Scientific Laboratories RT-PCR assays is <40 cycles of amplification.

Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
<b>SUMMARY COVID Respiratory Plus</b>			
<b>Collection Type: Nasopharyngeal Swab</b>			
<i>Acinetobacter baumannii</i>	DETECTED - HIGH	1.00E+06	[08/23/22] Limitation: Test does not differentiate between patient with acute infection or an asymptomatic carrier.
<i>mecA</i> (Methicillin/Oxacillin resistance)	DETECTED	DETECTED	
Rhinovirus (types A & B)	DETECTED - MEDIUM	1.00E+03	[08/23/22] Assay is developed to detect all strains of this pathogen [08/23/22] May cross-react with Enterovirus
<i>Streptococcus pneumoniae</i>	DETECTED - LOW	1.00E+01	[08/23/22] Limitation: Test does not differentiate between patient with acute infection or an asymptomatic carrier.

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<b>COVID Respiratory Plus</b>			<b>Collection Type: Nasopharyngeal Swab</b>
<i>Acinetobacter baumannii</i>	DETECTED - HIGH	1.00E+06	[08/23/22] Limitation: Test does not differentiate between patient with acute infection or an asymptomatic carrier.
Adenovirus	Not Detected	Not Detected	[08/23/22] Assay is developed to detect all strains of this pathogen
Bocavirus	Not Detected	Not Detected	[08/23/22] Assay is developed to detect all strains of this pathogen
Bordetella pertussis	Not Detected	Not Detected	[08/23/22] Shares homology with B.holmesii.
Chlamydia pneumoniae	Not Detected	Not Detected	
Coronavirus 229E	Not Detected	Not Detected	
Coronavirus HKU1	Not Detected	Not Detected	
Coronavirus NL63	Not Detected	Not Detected	
Coronavirus OC43	Not Detected	Not Detected	
EBV (Mononucleosis)	Not Detected	Not Detected	
Enterobacter cloacae	Not Detected	Not Detected	
Enterovirus	Not Detected	Not Detected	[08/23/22] Enterovirus includes Coxsackievirus types A9, A10, A16, B5, and Echovirus serotypes [08/23/22] May cross-react with Rhinovirus (types A and B)
Haemophilus influenzae	Not Detected	Not Detected	
HMPV A (Human Metapneumovirus)	Not Detected	Not Detected	
HMPV B (Human Metapneumovirus)	Not Detected	Not Detected	
Influenza A	Not Detected	Not Detected	
Influenza B	Not Detected	Not Detected	
Klebsiella aerogenes	Not Detected	Not Detected	
Klebsiella pneumoniae	Not Detected	Not Detected	
Legionella pneumophila	Not Detected	Not Detected	
<i>mecA</i> (Methicillin/Oxacillin resistance)	DETECTED	DETECTED	
Moraxella catarrhalis	Not Detected	Not Detected	
Mycoplasma pneumoniae	Not Detected	Not Detected	
Parainfluenza 1	Not Detected	Not Detected	
Parainfluenza 2	Not Detected	Not Detected	
Parainfluenza 3	Not Detected	Not Detected	
Parainfluenza 4	Not Detected	Not Detected	
Proteus mirabilis	Not Detected	Not Detected	
Pseudomonas aeruginosa	Not Detected	Not Detected	

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Test results must be evaluated with clinical symptoms to diagnose disease. All tests established and validated by Laboratory and not FDA approved unless otherwise indicated.  
 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, resulting 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.

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RSV A/B (Respiratory Syncytial Virus)	Not Detected	Not Detected	
Staphylococcus aureus	Not Detected	Not Detected	
Staphylococcus epidermidis	Not Detected	Not Detected	
Streptococcus pneumoniae	DETECTED - LOW	1.00E+01	[08/23/22] Limitation: Test does not differentiate between patient with acute infection or an asymptomatic carrier.
Streptococcus pyogenes (Group A)	Not Detected	Not Detected	

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