

**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-08232210305  
 Date Collected: 08/22/22 3:13:00 PM  
 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>COVID-19</b> <span style="float: right;"><b>Collection Type: Nasopharyngeal Swab</b></span>		
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 Lite</b> <span style="float: right;"><b>Collection Type: Nasopharyngeal Swab</b></span>			
Influenza A	DETECTED - HIGH	1.00E+04	
RSV A/B (Respiratory Syncytial Virus)	DETECTED - LOW	1.00E+01	

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Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
<b>COVID Respiratory Lite</b>		<b>Collection Type: Nasopharyngeal Swab</b>	
Influenza A	DETECTED - HIGH	1.00E+04	
Influenza B	Not Detected	Not Detected	
Haemophilus influenzae	Not Detected	Not Detected	
Moraxella catarrhalis	Not Detected	Not Detected	
Mycoplasma pneumoniae	Not Detected	Not Detected	
RSV A/B (Respiratory Syncytial Virus)	DETECTED - LOW	1.00E+01	
Streptococcus pyogenes (Group A)	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.