

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-08232210317
 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 ¹	PASS
Endogenous Positive Control ¹	PASS
Pathogen Positive Control ²	PASS
Pathogen Negative Control ³	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
COVID-19 Collection Type: Nasopharyngeal Swab		
COVID-19	DETECTED	[08/23/22] COVID-19 assay reviewed and approved under FDA Emergency Use Authorization #200522. [08/23/22] COVID-19 assay reviewed and approved under FDA Emergency Use Authorization #200522. Laboratory will immediately notify appropriate Federal, State, or local public health agencies of all positive results.
nCoV_N1 (CT Value)	25.00	[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
SUMMARY COVID Respiratory Panel Collection Type: Nasopharyngeal Swab			
Bocavirus	DETECTED - MEDIUM	1.00E+03	[08/23/22] Assay is developed to detect all strains of this pathogen
Influenza B	DETECTED - HIGH	1.00E+05	
Streptococcus pneumoniae	DETECTED - LOW	1.00E+02	[08/23/22] Limitation: Test does not differentiate between patient with acute infection or an asymptomatic carrier.

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Page: 1

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Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
COVID Respiratory Panel			Collection Type: Nasopharyngeal Swab
Adenovirus	Not Detected	Not Detected	[08/23/22] Assay is developed to detect all strains of this pathogen
Bocavirus	DETECTED - MEDIUM	1.00E+03	[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.
Chlamydomphila pneumoniae	Not Detected	Not Detected	
Coronavirus HKU1	Not Detected	Not Detected	
Coronavirus 229E	Not Detected	Not Detected	
Coronavirus NL63	Not Detected	Not Detected	
Coronavirus OC43	Not Detected	Not Detected	
EBV (Mononucleosis)	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	DETECTED - HIGH	1.00E+05	
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	
Rhinovirus (types A & B)	Not Detected	Not Detected	[08/23/22] Assay is developed to detect all strains of this pathogen [08/23/22] May cross-react with Enterovirus
RSV A/B (Respiratory Syncytial Virus)	Not Detected	Not Detected	
Staphylococcus aureus	Not Detected	Not Detected	
Streptococcus pneumoniae	DETECTED - LOW	1.00E+02	[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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Page: 2

 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.