

CLINIC INFORMATION

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

PATIENT INFORMATION

Name: Test, Copia
 DOB: 10/28/2000 Sex: M
 Phone: (999)999-9999
 Address: 123 Test St BIRMINGHAM, AL 35243

SPECIMEN INFORMATION

Lab Accession Number: ASL-12102110190
 Date Collected: 12/09/21 1:42:00 PM
 Date Accessioned: 12/10/2021
 Date Reported: 12/10/2021
 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
Collection Type: Nasopharyngeal Swab		
COVID-19	Not Detected	[12/10/21 2:43:01 PM] COVID-19 assay reviewed and approved under FDA Emergency Use Authorization #200522.
nCoV_N1 (CT Value)	0	[12/10/21 2:43:01 PM] 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
Collection Type: Nasopharyngeal Swab			
Influenza A	DETECTED - MEDIUM	1.00E+03	
Proteus mirabilis	DETECTED - HIGH	1.00E+05	[12/10/21 2:43:01 PM] Limitation: Test does not differentiate between patient with acute infection or an asymptomatic carrier.

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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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Test Performed	Lab Result (4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
COVID Respiratory Plus			Collection Type: Nasopharyngeal Swab
Acinetobacter baumannii	Not Detected	Not Detected	
Adenovirus	Not Detected	Not Detected	[12/10/21 2:43:01 PM] Assay is developed to detect all strains of this pathogen
Bocavirus	Not Detected	Not Detected	[12/10/21 2:43:01 PM] Assay is developed to detect all strains of this pathogen
Bordetella pertussis	Not Detected	Not Detected	[12/10/21 2:43:01 PM] 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	[12/10/21 2:43:01 PM] Enterovirus includes Coxsackie virus types A9, A10, A16, B5, and Echovirus serotypes 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	DETECTED - MEDIUM	1.00E+03	
Influenza B	Not Detected	Not Detected	
Klebsiella aerogenes	Not Detected	Not Detected	
Klebsiella pneumoniae	Not Detected	Not Detected	
Legionella pneumophila	Not Detected	Not Detected	
mecA (Methicillin/Oxacillin resistance)	Not Detected	Not 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	DETECTED - HIGH	1.00E+05	[12/10/21 2:43:01 PM] Limitation: Test does not differentiate between patient with acute infection or an asymptomatic carrier.

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Pseudomonas aeruginosa	Not Detected	Not Detected	
Rhinovirus (types A & B)	Not Detected	Not Detected	[12/10/21 2:43:01 PM] Assay is developed to detect all strains of this pathogen May cross-react to Enterovirus
RSV A/B (Respiratory Syncytial Virus)	Not Detected	Not Detected	
Staphylococcus aureus	Not Detected	Not Detected	
Staphylococcus epidermidis	Not Detected	Not Detected	
Streptococcus pneumoniae	Not Detected	Not Detected	
Streptococcus pyogenes (Group A)	Not Detected	Not Detected	

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