

CLINIC INFORMATION

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

PATIENT INFORMATION

Name: TEST, PATIENT
 DOB: 3/31/1995 Sex: M
 Phone: (777) 777-7777
 Address: 456 MAPLE ST BIRMINGHAM, AL 35243

SPECIMEN INFORMATION

Lab Accession Number: ASL-197268
 Date Collected: 7/7/2020
 Date Received by Lab: 7/8/2020
 Date Accessioned: 7/8/2020
 Date Reported: 7/8/2020
 Faxed to: 18777966185

Controls

Patient Extraction Control	1	PASS
Endogenous Positive Control	2	PASS
Pathogen Positive Control	3	PASS
Pathogen Negative Control		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.
 Assay cutoff is represented by CFU (bacteria), PFU (viruses) or Copy Number (DNA)

Test Performed	Lab Result(4) (Qualitative Low/Medium/High)	DNA Copy Number	Comments
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COVID-19			Collection Type: Oropharyngeal Swab
COVID-19	Not Detected	Not Detected	[7/8/2020 5:37 PM] COVID-19 assay reviewed and approved under FDA Emergency Use Authorization. Laboratory will immediately notify appropriate Federal, State, or local public health agencies of all positive results.

SUMMARY COVID Respiratory Plus			Collection Type: Oropharyngeal Swab
Coronavirus 229E	DETECTED - HIGH	1.00E+05	

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Lab Director: Ty Thomas, MD

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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) (Low/Medium/High)	DNA Copy Number	Comments
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COVID Respiratory Plus			
Adenovirus	Not Detected	Not Detected	[7/8/2020 5:25 PM] Assay is developed to detect all strains of this pathogen
Bocavirus	Not Detected	Not Detected	[7/8/2020 5:25 PM] Assay is developed to detect all strains of this pathogen
Bordetella pertussis	Not Detected	Not Detected	
Chlamydomphila pneumoniae	Not Detected	Not Detected	
Coronavirus 229E	DETECTED - HIGH	1.00E+05	
Coronavirus HKU1	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	[7/8/2020 5:25 PM] Enterovirus includes Coxsackie virus types A9, A10, A16, B5, and Echovirus serotypes
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	
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	[7/8/2020 5:25 PM] Assay is developed to detect all strains of this pathogen
RSV A (Respiratory Syncytial Virus)	Not Detected	Not Detected	
RSV B (Respiratory Syncytial Virus)	Not Detected	Not Detected	
Staphylococcus aureus	Not Detected	Not Detected	
Streptococcus pneumoniae	Not Detected	Not Detected	
Streptococcus pyogenes (Group A)	Not Detected	Not Detected	
Acinetobacter baumannii	Not Detected	Not Detected	
Enterobacter cloacae	Not Detected	Not Detected	
Klebsiella aerogenes	Not Detected	Not Detected	
Klebsiella pneumoniae	Not Detected	Not Detected	
Legionella pneumophila	Not Detected	Not Detected	
Proteus mirabilis	Not Detected	Not Detected	
Pseudomonas aeruginosa	Not Detected	Not Detected	
Staphylococcus epidermidis	Not Detected	Not Detected	
mecA (Methicillin/Oxacillin resistance)	Not Detected	Not Detected	

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