Assurance Scientific Laboratories

2868 Acton Road, Suite 207
Birmingham, AL, 35243
Phone: (855) 319-4459
CLIA ID: 01-D2074949

Molecular PCR Summary Lab Report

CLINIC INFORMATION

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

PATIENT INFORMATION

Name: TEST, TEST

DOB: 5/12/1965
Gender: M

SPECIMEN INFORMATION

Lab Accession Number: ASL-80102
Date Collected: 1/19/2020
Date Received by Lab: 1/20/2020
Date Accessioned: 1/20/2020
Date Reported: 1/20/2020
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. 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
SUMMARY Respiratory Pathogens Panel			**Collection Type: Swab**
Influenza A	DETECTED - MEDIUM	1.00E+03	
Streptococcus pneumoniae	DETECTED - MEDIUM	1.00E+03	[1/20/2020 9:19 AM] Limitation: Test does not differentiate between patient with acute infection or an asymptomatic carrier.

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Molecular PCR Detailed Lab Report

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Test Performed	Lab Result(4) (Low/Medium/High)	DNA Copy Number	Comments
Respiratory Pathogens Panel			
Adenovirus	Not Detected	Not Detected	[1/20/2020 9:19 AM] Assay is developed to detect all strains of this pathogen
Bocavirus	Not Detected	Not Detected	[1/20/2020 9:19 AM] Assay is developed to detect all strains of this pathogen
Bordetella pertussis	Not Detected	Not Detected	
Chlamydophila 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	
Enterovirus	Not Detected	Not Detected	[1/20/2020 9:19 AM] 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	DETECTED - MEDIUM	1.00E+03	
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	[1/20/2020 9:19 AM] 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	DETECTED - MEDIUM	1.00E+03	[1/20/2020 9:19 AM] Limitation: Test does not differentiate between patient with acute infection or an asymptomatic carrier.
Streptococcus pyogenes (Group A)	Not Detected	Not Detected	

This test detects the presence of pathogen and must be evaluated with clinical symptoms to diagnose disease. All tests established and validated by Laboratory and not FDA approved.
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.