

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-80100
 Date Collected: 1/15/2020
 Date Received by Lab: 1/16/2020
 Date Accessioned: 1/16/2020
 Date Reported: 1/16/2020
 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
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SUMMARY Respiratory Pathogens Panel Lite			Collection Type: Swab
Influenza A	DETECTED - HIGH	1.00E+06	[1/16/2020 3:49 PM] If no bacterial pathogen is identified by PCR, reflexive culturing and antibiotic sensitivity testing not performed unless requested by submitting provider or lab.

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Lab Director: Ty Thomas, MD

Page: 1

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.

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Respiratory Pathogens Panel Lite			
Influenza A	DETECTED - HIGH	1.00E+06	
Influenza B	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	
Adenovirus	Not Detected	Not Detected	[1/16/2020 3:49 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	
Rhinovirus (types A & B)	Not Detected	Not Detected	[1/16/2020 3:49 PM] Assay is developed to detect all strains of this pathogen
Mycoplasma pneumoniae	Not Detected	Not Detected	
Streptococcus pyogenes (Group A)	Not Detected	Not Detected	

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Page: 2

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