

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-197271
 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: Nasopharyngeal Swab
COVID-19	DETECTED	DETECTED	[7/8/2020 5:25 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 Lite			Collection Type: Nasopharyngeal Swab
NO PCR TARGETS DETECTED	N/A	N/A	

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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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COVID Respiratory Lite

Influenza A	Not Detected	Not Detected	
Influenza B	Not Detected	Not Detected	
Streptococcus pyogenes (Group A)	Not Detected	Not Detected	
Mycoplasma pneumoniae	Not Detected	Not Detected	
Moraxella catarrhalis	Not Detected	Not Detected	
Haemophilus influenzae	Not Detected	Not Detected	

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