

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-197264
 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	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.

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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.