

## CLINIC INFORMATION

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

## PATIENT INFORMATION

Name: Test, Test  
 DOB: 10/10/2000 Sex: F  
 Phone: (999) 999-9999  
 Address: 123 Main St  
 Test, AL 11111 U.S.A.

## SPECIMEN INFORMATION

Lab Accession Number: ASL-392941  
 Date Collected: 4/22/2021  
 Date Accessioned: 4/22/2021  
 Date Reported: 4/22/2021  
 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.

## Test Performed

## Test Result

## Comments

COVID-19		Collection Type: Not Specified
COVID-19	DETECTED	[4/22/2021 8:39 AM] Reflexive testing for B.1.1.7 (UK) Variant will be performed as requested by provider. [4/22/2021 8:39 AM] 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.
nCoV_N1 (CT Value)	20.00	
UK Variant B.1.1.7 (COVID-19)		Collection Type: Not Specified
UK Variant B.1.1.7 (COVID-19)	Not Detected	

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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.