

CLINIC INFORMATION

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

PATIENT INFORMATION

Name: Test, Copia
 DOB: 10/28/2000 Sex: M
 Phone: (999)999-9999
 Address: 123 Test St BIRMINGHAM, AL 35243

SPECIMEN INFORMATION

Lab Accession Number: ASL-12102110174
 Date Collected: 12/09/21 11:48:00 AM
 Date Accessioned: 12/10/2021
 Date Reported: 12/10/2021
 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.

| Test Performed | Test Results | Comments |
|---|--------------|--|
| Collection Type: Nasopharyngeal Swab | | |
| COVID-19 | DETECTED | [12/10/21 2:40:55 PM] COVID-19 assay reviewed and approved under FDA Emergency Use Authorization #200522. Laboratory will immediately notify appropriate Federal, State, or local public health agencies of all positive results. |
| nCoV_N1 (CT Value) | 31.25 | [12/10/21 2:40:55 PM] CT value indicates the number of amplification cycles of real-time PCR needed to detect COVID-19, a specific SARS-CoV-2 gene sequence. CT values are inversely proportional to the amount of target nucleic acid in the sample (i.e. the lower the CT level, the greater the amount of target nucleic acid in the sample). The reference range for Assurance Scientific Laboratories RT-PCR assays is <40 cycles of amplification. |

| Test Performed | Lab Result (4) (Qualitative Low/Medium/High) | DNA Copy Number | Comments |
|---|---|--------------------|----------|
| Collection Type: Nasopharyngeal Swab | | | |
| Chlamydomphila pneumoniae | DETECTED - MEDIUM | 1.00E+03 | |

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Lab Director: Ty Thomas, MD

Page: 1

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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| Test Performed | Lab Result (4) (Qualitative Low/Medium/High) | DNA Copy Number | Comments |
|---------------------------------------|---|---|--|
| COVID Respiratory Panel | | Collection Type: Nasopharyngeal Swab | |
| Adenovirus | Not Detected | Not Detected | [12/10/21 2:40:55 PM] Assay is developed to detect all strains of this pathogen |
| Bocavirus | Not Detected | Not Detected | [12/10/21 2:40:55 PM] Assay is developed to detect all strains of this pathogen |
| Bordetella pertussis | Not Detected | Not Detected | [12/10/21 2:40:55 PM] Shares homology with B.holmesii. |
| Chlamydia pneumoniae | DETECTED - MEDIUM | 1.00E+03 | |
| Coronavirus HKU1 | Not Detected | Not Detected | |
| Coronavirus 229E | 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 | [12/10/21 2:40:55 PM] Enterovirus includes Coxsackie virus types A9, A10, A16, B5, and Echovirus serotypes May cross-react with Rhinovirus (types A and B) |
| Haemophilus influenzae | Not Detected | Not Detected | |
| HMPV A (Human Metapneumovirus) | Not Detected | Not Detected | |
| HMPV B (Human Metapneumovirus) | Not Detected | Not Detected | |
| Influenza A | Not Detected | Not Detected | |
| 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 | [12/10/21 2:40:55 PM] Assay is developed to detect all strains of this pathogen May cross-react to Enterovirus |
| RSV A/B (Respiratory Syncytial Virus) | Not Detected | Not Detected | |
| Staphylococcus aureus | Not Detected | Not Detected | |
| Streptococcus pneumoniae | Not Detected | Not Detected | |
| Streptococcus pyogenes (Group A) | Not Detected | Not Detected | |

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Page: 2

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