Alcala LABS

Medical Director: David J. Smith, MD - CLIA# 05D2027247
3703 Camino Del Rio South #100-A, San Diego, CA, 92108
Tel: (619) 450-5870, Fax: (619) 450-6023

ACCESSION STICKER HERE

RESPIRATORY SARS-COVID-19 TEST REQUISITION FORM

PATIENT INFORMATION

Last Name _____ First Name _____ MI _____

Gender: ☐ M ☐ F ☐ M/F ☐ F/M Date of Birth ____/____/_____

Patient Address _____

City, State, ZIP code _____ **Contact Information (E-mail & Phone)**

Occupation/Exposure setting: _____

Pregnancy Status: ☐ Yes ☐ No ☐ N/A

Race: ☐ Amer Ind/Alaskan ☐ White ☐ Black/Afr Amer
☐ Asian ☐ Native Hawaiian/Pacific Islander ☐ Other

PROVIDER INFORMATION

Facility/Group _____ Referring Physician _____

NPI Provider Nr: _____

Physician Address _____

City, State, ZIP code _____

Diagnostic Codes (ICD-10 codes*** see Page 3) _____

*Clinical Information** (date of onset/exposure, travel history, previous lab results – attach additional info.)* _____

Ethnicity: ☐ Hispanic/Latino ☐ Non-Hispanic/Non-Latino ☐ Other

Billing information: ☐ Self-Pay (see Page 2) ☐ Commercial Insurance (attach copy) ☐ Medicare (attach copy)

RESPIRATORY PANEL SARS-COVID-19 (check all that apply):

☐ **Current Coronavirus "SARS-CoV-2":** ORF1ab (RdRp/nsp10), E gene and N gene

SAMPLE HANDLING

Time Collected: _____ AM/PM Date Collected: _____

Collected by: _____

The following ***MUST*** be completed (check all that apply):
☐ Clinical Information provided.
☐ Nasal, Oro-/Nasopharyngeal swab placed in transport medium and in biohazard bag (labeled with patient information – First/Last Name, DOB). If submitting to lab within 24 hours place swab back into sleeve and then in biohazard bag.

INFORMED CONSENT

I consent to the collection of specimens for the purpose of DNA testing, and certify that the tests ordered have been explained to me by an authorized health care provider. I understand that only tests ordered by a qualified provider will be performed. This sample may be stored indefinitely and used for internal test validation after personal identifiers have been removed. I also authorize lab to bill my insurance provider and to receive payment of benefits for the tests ordered by my physician. I further authorize lab and the ordering physician to release to my insurance provider any medical information necessary to process this claim. I acknowledge that lab may be an out-of-network facility with my insurance provider.

Signature of Patient or Legal Guardian:
If Guardian, Print Name:
Date:

PROVIDER INFORMATION

I attest that the requested testing is medically necessary and appropriate based on the patient's diagnosis and treatment plan. I have personally completed the diagnosis codes above to indicate the accurate diagnosis for this patient.

Authorized Provider Signature:

Date:

BILLING INFORMATION

☐ Insurance Bill ☐ Account Bill ☐ Patient Bill ☐ Pre-Pay (Payment Information must be completed)

Ordering Physicians should refer to applicable National and Local Coverage Determinations for further information concerning reimbursement policy. Tests submitted for Medicare and Medicaid reimbursement must meet program requirements (ICD10-codes required) or the claim may be denied.

Bill Ordering Institution: Bill Insurance:

(Provide legible photocopy of front & back of insurance card)

Name of Insured: Relation to Patient: Insurance Company: Member

Social Security #: Member Group #: Insurance Address: Member Policy #:

Insurance Phone:

PAYMENT INFORMATION (PRE-PAY)

Check Card Used for Payment: ☐ VISA ☐ MasterCard ☐ American Express ☐ Discover

Card Number: Card Security Code:

Signature: Exp. Date:

(*) Designates Bacterial targets

(**) Priority COVID-19 Testing Groups if mild/moderate symptoms observed (Fever, Cough, etc.):

- Evidence of lower respiratory disease without alternative diagnosis, especially if hospitalized
- Any resident of a senior living facility, including skilled nursing facilities or assisted living facilities
- Persons who care for the elderly
- Persons living in congregate setting (homeless shelters, etc.)
- Health care workers, first responders, and other emergency workers

Test information:

CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel - the oligonucleotide primers and probes for detection of 2019-nCoV were selected from regions of the virus nucleocapsid (N) gene. The panel is designed for specific detection of the 2019-nCoV(two primer/probe sets). An additional primer/probe set to detect the human RNase P gene (RP) in control samples and clinical specimens is also included in the panel. RNA isolated and purified from upper and lower respiratory specimens is reverse transcribed to cDNA and subsequently amplified in the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS version 1.4 software. The CDC protocol EUA-approved IFU confirms 100% Sensitivity at an LOD of 1000 to 3162 RNA copies/mL (or 1000 to 3162 NDU/mL = NAAT Detectable Units/mL). The viral load concentration in undiluted SeraCare positive specimens was confirmed to be 100% at 5.00E+03 GCE/mL and 100% Sensitivity at an LOD of at least 5.00E+03 GCE/mL (or 5000 NDU/mL = NAAT Detectable Units/mL).

FOSUN COVID-19 RT-PCR Detection kit - This EUA-approved method is a fluorescent probe-based Taqman RT-PCR assay system. The ORF1ab (Rdrp region included), N and E gene of SARS-CoV-2 will be detected qualitatively, including a separate internal reference. dUTP and UNG enzyme are used in the kit to prevent contamination of the amplified products. RNA isolated and purified from upper and lower respiratory specimens is reverse transcribed to cDNA and subsequently amplified in the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS version 1.4 software. The FOSUN COVID-19 RT-PCR detection panel was confirmed at 100% Sensitivity at 5.00E+03 GCE/mL and 100% Sensitivity at an LOD of at least 5.00E+03 GCE/mL (or 5000 NDU/mL = NAAT Detectable Units/mL).

NxTAG® Respiratory SARS-CoV-2 (COVID-19) - The NxTAG® CoV Extended Panel (NxTAG CoV) is an EUA-approved (In Vitro Diagnostic Use Under Emergency Use Authorization) test authorized by the FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. incorporates multiplex Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) with the Luminex® proprietary universal tag sorting system on the Luminex platform to easily detect SARS-CoV-2s. Extracted total nucleic acid is added to pre-plated, Lyophilized Bead Reagents (LBRs) and mixed to resuspend the reaction reagents. The reaction is amplified via RT-PCR and the reaction product undergoes near simultaneous bead hybridization within the sealed reaction well. The hybridized, tagged beads are then sorted and read on the MAGPIX® instrument. Sensitivity: The Limit of Detection (LoD) study established the lowest SARS-CoV-2 viral concentration (Genomic Copy Equivalents or GCE = 5.00E+03 GCE/mL) that can be detected by the NxTAG® CoV Extended Panel Assay at least 95% of the time using viral genomic RNA. 100% at 3X LoD and 5X LoD. Specificity: 100% PPV and NPV.

***** ICD10 Codes:**

SARS-CoV-2:

U07.1 COVID-19
Z20.828 Contact with and (suspected) exposure to other viral communicable diseases

General Respiratory Virus:

B30.2 Viral pharyngoconjunctivitis
B34.0 Adenovirus infection, unspecified
B34.2 Coronavirus infection, unspecified
B97.0 Adenovirus as the cause of diseases classified elsewhere
B97.21 SARS-associated coronavirus. cause of diseases classified elsewhere
B97.29 Other coronavirus as the cause of diseases classified elsewhere
B97.4 Respiratory syncytial virus as the cause of diseases classified elsewhere
B97.81 Human metapneumovirus as the cause of diseases classified elsewhere
B97.89 Other viral agents as the cause of diseases classified elsewhere
J00 Acute nasopharyngitis [common cold]
J05.0 Acute obstructive laryngitis [croup]
J06.9 Acute upper respiratory infection, unspecified
J09.X1 Influenza due to identified novel influenza A virus with pneumonia
J09.X2 Influenza due to identified novel influenza A virus with other respiratory manifestations
J09.X3 Influenza due to identified novel influenza A virus with gastrointestinal manifestations
J09.X9 Influenza due to identified novel influenza A virus with other manifestations
J10.00 Influenza due to other identified influenza virus with unspecified type of pneumonia
J10.01 Influenza due to other identified influenza virus with the same other identified influenza virus pneumonia
J10.08 Influenza due to other identified influenza virus with other specified pneumonia
J10.1 Influenza due to other identified influenza virus with other respiratory manifestations
J10.2 Influenza due to other identified influenza virus with gastrointestinal manifestations
J10.81 Influenza due to other identified influenza virus with encephalopathy
J10.82 Influenza due to other identified influenza virus with myocarditis
J10.83 Influenza due to other identified influenza virus with otitis media
J10.89 Influenza due to other identified influenza virus with other manifestations
J11.00 Influenza due to unidentified influenza virus with unspecified type of pneumonia
J11.08 Influenza due to unidentified influenza virus with specified pneumonia
J11.1 Influenza due to unidentified influenza virus with other respiratory manifestations
J11.2 Influenza due to unidentified influenza virus with gastrointestinal manifestations
J11.81 Influenza due to unidentified influenza virus with encephalopathy
J11.82 Influenza due to unidentified influenza virus with myocarditis
J11.83 Influenza due to unidentified influenza virus with otitis media
J11.89 Influenza due to unidentified influenza virus with other manifestations
J12.0 Adenoviral pneumonia
J12.1 Respiratory syncytial virus pneumonia
J12.2 Parainfluenza virus pneumonia
J12.3 Human metapneumovirus pneumonia
J12.81 Pneumonia due to SARS-associated coronavirus
J12.9 Viral pneumonia, unspecified
J20.4 Acute bronchitis due to parainfluenza virus
J20.5 Acute bronchitis due to respiratory syncytial virus
J20.6 Acute bronchitis due to rhinovirus
J21.0 Acute bronchiolitis due to respiratory syncytial virus
J21.9 Acute bronchiolitis, unspecified
J22 – Unspecified acute lower respiratory infection
Z11.59 Encounter for screening for other viral diseases

Pneumonia:
A49.3 Mycoplasma infection, unspecified site
B96.0 Mycoplasma pneumoniae [M. pneumoniae] as the cause of diseases classified elsewhere
J15.7 Pneumonia due to Mycoplasma pneumoniae
J20.0 Acute bronchitis due to Mycoplasma pneumoniae
Z11.2 Encounter for screening for other bacterial diseases