Alcala LABS

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ACCESSION STICKER HERE

# SARS-COVID-19 TEST - Saliva-Direct™ FORM

| PATIENT INFORMATION | PROVIDER INFORMATION |
|---|---|
| Last Name / First Name / MI | Facility/Group / Referring Physician |
| **Gender:** ☐ M ☐ F ☐ M/F ☐ F/M Date of Birth ____/____/_____ | NPI Provider Nr: _____ |
| Patient Address | Physician Address |
| City, State, ZIP code **Contact Information (E-mail & Phone)** | City, State, ZIP code |
| **Occupation/Exposure setting**: _____ | Diagnostic Codes (ICD-10 codes*** see Page 3) |
| **Pregnancy Status:** ☐ Yes ☐ No ☐ N/A | *Clinical Information** (date of onset/exposure, travel* |
| **Race:** ☐ Amer Ind/Alaskan ☐ White ☐ Black/Afr Amer ☐ Asian ☐ Native Hawaiian/Pacific Islander ☐ Other | *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)

**SARS-COVID-19 (check all that apply):**

☐ **Current Coronavirus "SARS-CoV-2 SALIVA-DIRECT":** N gene

| SAMPLE HANDLING | |
|---|---|
| Time Collected: _____ AM/PM Date Collected: _____<br>Collected by: _____ | The following ***MUST*** be completed (check all that apply):<br>☐ Clinical Information provided.<br>☐ At least 0.5 mL of Saliva collected by gently expelling from the mouth into a wide-mouth, sterile collection tube, sealed with screw cap and placed in biohazard bag (labeled with patient information – First/Last Name, DOB). Please mail to testing Lab within 24 hours. |

| INFORMED CONSENT | PROVIDER INFORMATION |
|---|---|
| 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. | 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. |
| **Signature of Patient or Legal Guardian:**<br>*If Guardian, Print Name:*<br>Date: | **Authorized Provider Signature:**<br><br>Date: |

☐ 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: _____

**Considerations for saliva collection:**

- This protocol is intended for the collection of the normal saliva that naturally pools into the mouth. Coughing or sniffing prior to sample collection must be avoided.
- Saliva should be gently expelled from the mouth into the collection tube, no forceful spitting is required.
- Ideally, the study participant should avoid drinking water 10 minutes prior to collection. Other drinks, food, chewing gum, nasal sprays and oral hygiene should be avoided for 30 minutes before sample collection.
- If the time between sample collection and the initial processing steps (aliquoting) is likely to exceed 24 hours, samples can be stored at 2-8°C for up to 72 hours, -20°C for 2-4 weeks, or -80°C for long-term storage, then later thawed on ice for testing. The virus RNA in saliva however, remains stable at room temperature for up to 7 days.

**Test information:**

SalivaDirect™ is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from SARSCoV-2 in saliva collected without preservatives in a sterile container from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories designated by the Yale School of Public Health, Department of Epidemiology of Microbial Diseases, that includes the Clinical Molecular Diagnostics Laboratory, Department of Pathology, Yale School of Medicine, located at 310 Cedar St., New Haven, CT 06510, that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet the requirements to perform high complexity tests. Alcala Labs is a designated laboratory by Yale School of Public Health for Saliva-Direct™ testing.

Results are for the detection and identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in saliva specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA.

*Analytical Sensitivity*: The LoD (Limit of Detection) when utilizing the standard SalivaDirect protocol with the Proteinase K and heat inactivation confirms to be 6 copies/µl.
*Analytical Specificity*: The sequences for the N1 primers and probe used in this assay are identical to the primer/probe sequences used in the FDA authorized CDC SARS-CoV-2 assay, specificity = 100%.

**** ICD10 Codes: SARS-CoV-2:*
*U07.1 COVID-19*
*Z20.828 Contact with and (suspected) exposure to other viral communicable diseases.*