



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

PATIENT INFORMATION			PROVIDER INFORMATION	
Last Name _____	First Name _____	MI _____	Facility/Group _____	Referring Physician _____
Gender: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> M/F <input type="checkbox"/> F/M			NPI Provider Nr: _____	
Date of Birth ____/____/____			Physician Address _____	
Patient Address _____			City, State, ZIP code _____	
Occupation/Exposure setting: _____			Diagnostic Codes (ICD-10 codes*** see Page 3) _____	
Pregnancy Status: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A			<i>Clinical Information** (date of onset/exposure, travel history, previous lab results – attach additional info.)</i> _____	
Race: <input type="checkbox"/> Amer Ind/Alaskan <input type="checkbox"/> White <input type="checkbox"/> Black/Afr Amer				
<input type="checkbox"/> Asian <input type="checkbox"/> Native Hawaiian/Pacific Islander <input type="checkbox"/> Other				
Ethnicity: <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Non-Hispanic/Non-Latino <input type="checkbox"/> Other				
Billing information: <input type="checkbox"/> Self-Pay (see Page 2) <input type="checkbox"/> Commercial Insurance (attach copy) <input type="checkbox"/> 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: _____	<p>The following MUST be completed (check all that apply):</p> <input type="checkbox"/> Clinical Information provided. <input type="checkbox"/> 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.
Collected by: _____	
INFORMED CONSENT	PROVIDER INFORMATION
<p>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.</p>	<p>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.</p>
Signature of Patient or Legal Guardian: If Guardian, Print Name: _____ Date: _____	Authorized Provider Signature: 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 Lab 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.