

3703 Camino del Rio South #100-A,
 San Diego, CA 92108-4031, US
 619-450-5870 - Phone
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 CLIA# 05D2027247 - Director: David J. Smith, MD

Patient :	Patient, Test		Acc #:	AL-SAL-240504
Patient #:		Birth:	03/01/1950	
Doctor:	COVID Direct Specimen	Age:	71 years	Collection Date: 04/20/2021 00:00
		Gender:	Male	Received in Lab: 04/21/2021 00:00

SALIVA RESPIRATORY PATHOGEN TEST (COVID-19): see COMMENTS

Test Name	Result
RESPIRATORY	
SARS-CoV-2	Negative

Comments:

This test was performed at Alcala Testing and Analysis Services (CLIA# 05D2027247).

Test information - RT-PCR SALIVA DIRECT TEST:

SalivaDirectTM is an RNA-extraction free, dualplex RT-qPCR method for SARS-CoV-2 detection performed on the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS version 1.4 software. It can be broadly implemented as it (1) does not require saliva collection tubes containing preservatives, (2) does not require specialized equipment for nucleic acid extraction, and (3) is validated for use with products from multiple vendors. Thus, the simplicity and flexibility of SalivaDirectTM means that it is not as affected by supply chain bottlenecks as some other assays. The method is nucleic acid extraction-free, which enables testing of low volume and minimally processed saliva in dualplex RT-qPCR for SARS-CoV-2 detection. Saliva is first treated with proteinase K followed by a heat inactivation step, and is then directly used as input in the dualplex RT-qPCR test using validated primer and probe sets (2019-nCoV_N1 and RP) developed by the US CDC. The human Ribonuclease P (RP) probe was modified with a different fluorophore so that the primer/probe set could be combined in a dualplex assay, reducing the number of tests to 1 assay with 2 sets of primers.

SalivaDirectTM is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-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 Lab under the Yale EUA. 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; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities. Please contact your Primary Care Provider (PCP) and implement steps to help prevent the spread of COVID-19 as recommended by the CDC (Center for Disease Control):

Stay home. Most people with COVID-19 have mild illness and can recover at home without medical care. Do not leave your home, except to get medical care. Do not visit public areas.

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Take care of yourself. Get rest and stay hydrated. Take over-the-counter medicines, such as acetaminophen, to help you feel better.

Stay in touch with your doctor. Call before you get medical care. Be sure to get care if you have trouble breathing, or have any other emergency warning signs, or if you think it is an emergency.

Avoid public transportation, ride-sharing, or taxis.

When to Seek Emergency Medical Attention

Look for **emergency warning signs*** for COVID-19. If someone is showing any of these signs, **seek emergency medical care immediately:**

- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion
- Inability to wake or stay awake
- Bluish lips or face

*This list is not all possible symptoms. Please call your medical provider for any other symptoms that are severe or concerning to you. **Call 911 or call ahead to your local emergency facility:** Notify the operator that you are seeking care for someone who has or may have COVID-19.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Reviewed By: _____

Date: **04/21/2021 16:24** _____