Curative Labs Inc.
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Final Results Report

Patient Name:	Takane, Kotaro	**Facility:**	Curative Los Angeles
Patient MRN:	CLA134308456	**Requisition:**	42993120
Date of Birth:	2011-03-12 (10 years old)	**Kit ID:**	241017648441
Sex:	male	**Collected:**	06/14/21 04:53:20 PM PDT
Address:	2300 Maple Ave. APT 140 Torrance, CA 90503	**Received:**	06/15/21 12:07:57 AM PDT
Phone Number:	18478677102	**Released:**	06/15/21 10:33:02 AM PDT
Email:	kenji.takane@gmail.com	**Specimen Type:**	Oral swab
Physician:	Zalzala, Sajad (1639311509)	**Reviewed By:**	Thanhthao Tran

Test	Result
Curative SARS-CoV-2 Assay (RNA Detection Test by RT-qPCR)	**Negative**

Interpretation:

- Positive: SARS-CoV-2 RNA detected by RT-qPCR
- Negative: SARS-CoV-2 RNA not detected by RT-qPCR
- Indeterminate: Indeterminate for SARS-CoV-2 RNA by RT-qPCR.

The Curative SARS-CoV-2 Assay is a real-time reverse transcription polymerase chain reaction (RT-qPCR) test. Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Collection of oral fluid specimens is limited to patients with symptoms of COVID-19 and should be performed under the supervision of a trained healthcare worker at the specimen collection site.

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. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities. 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. Negative results for SARS-CoV-2 RNA from oral fluid specimens should be confirmed by testing of an alternative specimen type if clinically indicated.

Indeterminate results may occur in the case of an inadequate specimen such as quantity not sufficient. Specimen must be recollected if test is still required.

Testing is only authorized at Curative Labs high-complexity CLIA certified laboratories.

The assay is intended for use under the Food and Drug Administration's Emergency Use Authorization.

Disclaimer:

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

This test was developed and its performance characteristics determined by Curative Labs, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing.

Lab director: Arthur Baca, MD PhD; CLIA # 05D2141174; Report generated at: 06/15/21 10:44:49 AM PDT