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Lab Director: Daniel Leighton, CLB
CLIA# 05D2203452
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PATIENT REPORT

Patient Information		Specimen Details	
Name:	Doe, John	Collected:	12/27/2021 15:51 PT
DOB:	01/01/2001	Received:	
Contact #:	714-883-4182	Accessioned:	
Specimen ID:	TEST123456789	Reported:	12/27/2021 15:51 PT

Physician Details

Steve Kim, M.D.
NPI: 1043313992
268 E. Hamilton Ave
Campbell, CA 95008
949-868-4740

TEST	RESULT
Source: Nasal	
COVID-19 Antigen	**NEGATIVE**

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. Optimum specimen types and timing for peak viral levels during infections caused by SARS-CoV-2 have not been determined. Collection of multiple specimens or types of specimens may be necessary to detect virus. Improper specimen collection and handling, sequence variability under primers/probes, or viruses present below the limit of detection may lead to false negative results. Positive and negative predictive values of testing are highly dependent on prevalence.

This SARS-CoV-2 test is intended for the qualitative detection of antigens from SARS-CoV-2 in nasal samples from patients who meet COVID-19 clinical and/or epidemiological criteria. Testing methodology is lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein antigens specific to SARS-CoV-2.

Test results must be correlated with clinical presentation and other laboratory data. Test performance can be affected by specimen type, collection time during the course of infection, and concentration of nucleocapsid protein antigens.

This test has not been Food and Drug Administration (FDA) cleared or approved and has been authorized by FDA under an Emergency Use Authorization (EUA). The test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of SARS-CoV-2 under Section 564(b)(1) of the Act, 21 U.S.C. section 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. Inspire Diagnostics Labs is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. section 263a, to perform high complexity tests. CLIA# 05D2203452; CLF# 90002274

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CareStart COVID-19 Antigen test - Fact Sheet for Patients (inspirediagnostics.com)