MEDICAL RECORD

PATIENT INFORMATION	FACILITY INFORMATION
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TEST DETAILS

[redacted] [redacted]

TEST NAME:	Rapid Antigen Testing - SARS-CoV-2
TEST DEVICE:	Sofia 2 SARS Antigen FIA
COLLECTION DATE:	12/30/2020
TEST DATE:	12/30/2020 10:57:03
TEST RESULT:	**NEGATIVE**

TEST INFORMATION

The Sofia SARS Antigen FIA is a lateral flow immunofluorescent sandwich assay that is used with the Sofia and Sofia 2 instrument intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and nasal (NS) swab specimens directly from individuals who are suspected of COVID19 by their healthcare provider within the first five days of the onset of symptoms. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. The Sofia SARS Antigen FIA does not differentiate between SARS-CoV and SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine 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, from patients with symptom onset beyond five days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. The Sofia SARS Antigen FIA is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings, and proficient in performing tests using the Sofia and Sofia 2 instruments. The Sofia SARS Antigen FIA is only for use under the Food and Drug Administration's Emergency Use Authorization. The Sofia SARS Antigen FIA should be used with Sofia or Sofia 2.

Information sourced from: https://www.fda.gov/media/137885/download