Resource Summary Report

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LooK SPOT Antigen Rapid Test System

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Protocol Information

URL: https://dx.doi.org/10.17504/protocols.io.bp32mqqe

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Group: Coronavirus Method Development Community, XPRIZE Rapid Covid Testing

Summary: LooK SPOT COVID-19 antigen rapid test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasal swabs from patients suspected of COVID-19 within the first seven (7) days of symptom onset. 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 complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in a patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.].Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in nasal samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of thedisease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.Negative results should be treated as presumptive, and do not rule out SARS-CoV-2 infection, 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, and confirmed with a molecular assay, if necessary, for patient management. LooK SPOT COVID-19 Antigen Rapid Test can deliver a diagnosis of the SARS-CoV-2 virus detection between 5 to 8 minutes by using machine learning AI. LooK SPOT's AI algorithm has high accuracy and can identify the fluorescence response when human eyes cannot identify the low positive cases. Healthcare responders in the COVID-19 test sites often need to make time-sensitive decisions to determine the test results

during the time many patients are within their vicinity. But the tempo, volume, stress, fatigue, lighting, fear, and various other factors can overwhelm healthcare responders when making the visual interpretation of antigen test results. It is of paramount importance to reduce healthcare responders' cognitive load by providing accurate test results in an easy-to-read format. LooK SPOT COVID-19 Antigen Rapid Test is a COVID-19 rapid test solution designed with a tactical edge to fight COVID-19. The LooK SPOT COVID-19 Antigen Rapid Test is intended for use at the Point of Care (POC) settings by trained personnel specifically instructed and trained in vitro diagnostic procedures. It is only for use under the Food and Drug Administration's Emergency Use Authorization.

Affiliations: Laipac Technology Inc.

External URL: https://laipac.com/look-spot-point-of-care-covid-19-test-kit/

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