osom® COVID-19 Antigen Home Test

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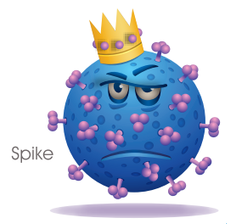
COVID-19 Antigen Home Test

KIT CONTENTS:
2 x Individually pouched Test Devices
2 x Tubes containing 300 µl of buffer liquid
2 x Sterile Swabs
4 x Tube holders (backside of carton)
1 x Quick Reference Instructions

Rapid Results in 15 Minutes

MADE IN THE USA



2 TESTS

CONTENTS

Single-use test device in a foil pouch

Collection tube with buffer liquid

Nasal swab package

Quick Reference Instructions

REF 1067-2 IVD

Distributed by:
SEKISUI Diagnostics, LLC
6659 Top Gun Street
San Diego, CA 92121 USA

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osom® COVID-19 Antigen Home Test

2 TESTS

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For an Emergency Use Authorization (EUA) only

The OSOM COVID-19 Antigen Home Test is intended for the qualitive detection of SARS-CoV-2 nucleocapsid protein antigen in anterior nasal (nares) swab samples.

This test does NOT determine if you had COVID-19 in the past or if you have immunity.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

If you test positive for COVID-19 please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation.

For home testing (ages 2 and up).

Scan QR Code to view video instructions.

TUBE HOLDERS

A B C D

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under Emergency Use Authorization (EUA). This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The OSOM COVID-19 Antigen Home Test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swabs. The test is authorized for individuals with symptoms of COVID-19 within the first five (5) days of symptom onset, when tested twice over three days with at least 48 hours between tests or individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three (3) times over five (5) days and at least 48 hours between tests.

For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests

Manufactured by:
ANP Technologies, Inc.
824 Interchange Blvd.
Newark, DE 19711, USA

Item necessary to use the test but not provided in the test kit is a timer.

Use within 30 minutes after opening the foil pouch.

Avoid contact of the extraction liquid in Tube with skin and eyes.

(01)00742860000003
(17)241113
(10)42823533

LOT 42823533

2024-11-13

SEKISUI DIAGNOSTICS
Because every result matters™

sekisuidiagnostics.com