



POINT-OF-CARE



OSOM® COVID-19 Antigen Rapid Test

RELIABLY DETECT SARS-CoV-2 IN ONLY 15 MINUTES AT THE POINT-OF-CARE

Features and Benefits

- **Trust your results** – High positive percent agreement & negative percent agreement to help you reduce the risk of misdiagnosis & inappropriate treatment
- **Easy-to-use** – Can be performed in a CLIA-waived setting & comes with everything you need to run a test, without the need for specialized equipment
- **Save valuable time** – Get results to your patient in 15-minutes, with the ability to run multiple tests simultaneously
- **Simple sample collection** – Direct Mid-Turbinate nasal swab to help you improve patient comfort & satisfaction
- **Get it when you need it** – Proudly made in the USA & backed by a trustworthy supply chain so you can avoid delays from international shipments
- **Exceptional support** – Experienced support teams & online training modules to help streamline your testing implementation & staff training

Performance Characteristics

	Positive Percent Agreement*	Negative Percent Agreement*	Sample Type	Limit of Detection**	Storage Temperature	Time to Result
SARS-CoV-2	95.1%	97.0%	Nasal swabs	311 TCID ₅₀ /mL	15-30°C/59-86°F	15 minutes

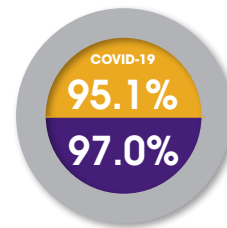
*Compared to RT-PCR. See IFU.

**Refer to IFU for additional LOD information.



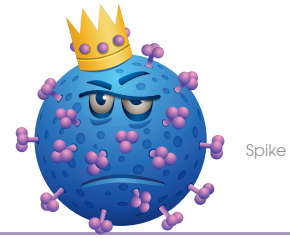
POSITIVE PERCENT AGREEMENT

NEGATIVE PERCENT AGREEMENT



This test has not been FDA cleared or approved. It is authorized by FDA under an EUA for use by authorized laboratories. It has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens and 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 3360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

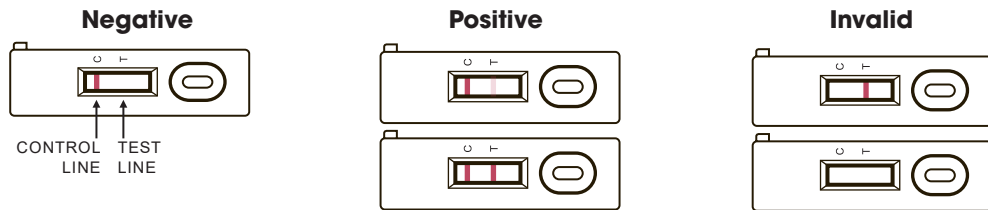
OSOM® COVID-19 Antigen Rapid Test



Quick and Easy Test Procedure

- 1 REMOVE THE WHITE CAP FROM THE COLLECTION TUBE.**
- 2 INSERT SWAB INTO BUFFER, PLUNGING IT UP AND DOWN FOR 15 SECONDS.**
- 3 REMOVE SWAB AND CAP THE BUFFER WITH THE AFFIXED DROPPER TIP.**
- 4 DISPENSE FIVE DROPS OF THE SAMPLE INTO THE SAMPLE WELL OF THE CASSETTE.**
- 5 READ TEST AT 15 MINUTES.**

INTERPRETATION OF RESULTS



Ordering Information

	Configuration	Catalog Number	CPT Code
OSOM® COVID-19 ANTIGEN RAPID TEST	40 tests per kit	1066-40	87811QW
OSOM® COVID-19 ANTIGEN CONTROL KIT	5 x SARS-CoV-2 Positive Control Swabs 5 x SARS-CoV-2 Negative Control Swabs	1068	

To learn more about all of our OSOM Tests scan the code or go to osomtests.com



THE AMERICAS

SEKISUI Diagnostics, LLC
One Wall Street
Burlington, MA 01803
Phone: 800 332 1042
Fax: 800 762 6311
Email: questions@sekisui-dx.com



Because every result matters™

sekisuidiagnostics.com

