GeneFinder™ COVID-19 Ag Rapid Test

CE

For in vitro diagnostics use only.
For professional use only.

Read this product insert completely before using the product. Follow the instructions carefully when performing the test as not doing so may result in inaccurate test results.

INTENDED USE

The GeneFinder™ COVID-19 Ag Rapid Test is a colorimetry lateral flow immunoassay intended for healthcare professionals at the clinical setup and point of care sites to aid in the early diagnosis SARS-CoV-2 antigens in nasopharyngeal swabs from individuals who are suspected of COVID-19 within the first several days of the onset of symptoms. Results are for the identification of SARS-CoV-2 antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.

PRINCIPLE

The GeneFinder™ COVID-19 Ag Rapid Test is based on a lateral flow immunoassay. The cassette contains membranes which are pre-coated with mouse anti-SARS-CoV-2 monoclonal antibodies on test line. Another mouse anti-SARS-CoV-2 monoclonal antibodies are bound to colloidal gold. When the sample is loaded to the sample inlet, SARS-CoV-2 antibodies, that were conjugated with colloidal gold nano-particles, and SARS-CoV-2 antigen complexes are formed and travel up the strip. The complexes will be captured by coated antibodies on membrane, and then the line will form a visible red line. The presence of SARS-CoV-2 antigen will be indicated by a visible red test line in T-marked position on side of result window. The control (C) line appears in each result window when sample has flowed through the strip. The control line is used as a procedural control. The control line should always appear if the test procedure is performed properly and the reagents are working as intended.

MATERIALS PROVIDED IN THE KIT

- 1 Instructions for use
- 25 GeneFinder™ COVID-19 Ag Rapid Test cassettes
- 25 Extraction buffer tubes
- 25 Tube filter cap
- 25 Specimen sampling swabs
- 1 Positive control swab
- 1 Negative control swab

MATERIALS REQUIRED, BUT NOT PROVIDED

- Timer
- Biohazard waste container

STORAGE

- Store the cassettes, extraction buffer tube, control swab at 2-30˚C in its sealed pouch.
- The shelf life is up to 18 months at 2-30˚C.
- If stored at 2-8˚C, keep it at 18-30 °C for 30 minutes before opening the product before use.
- Do not freeze the product or store it above 30˚C.

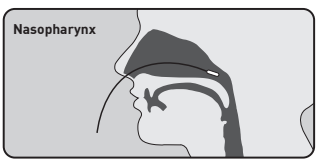
WARNING AND PRECAUTIONS

- For professional use only.
- All testing MUST be conducted under appropriate biosafety condition.
- This test should be performed at 18 to 30˚C (64 to 86˚F). If stored at 2-8˚C, keep it at 18-30 °C for 30 minutes before opening the product before use.
- Follow the instructions for use carefully. Reliability of assay results cannot be guaranteed if there is any deviation from the instructions in this package insert.
- Professionals must handle the potentially contaminated materials safely according to local requirements.
- Do not smoke, drink, eat, or use cosmetics in the working area.
- Wear personal protective equipment and disposable gloves when working with samples and reagents in order to prevent any infection or contamination.
- Wipe and wash any splashed sample with highly effective disinfectant. Avoid splashing and the formation of aerosols.
- Decontaminate and dispose of all samples, product, and potentially contaminated materials as if they were infectious waste, in a biohazard waste container.
- Do not use the cassette beyond the labeled expiry date indicated on the outer container.
- Use within 15 minutes of opening the pouch to prevent the strips in the cassette from being humidified. The cassette is sensitive to humidity as well as to heat.
- Do not use the cassette if the pouch is damaged or the seal is broken.
- The cassette cannot be reused.
- Testing must be performed within 15 minutes after opening the pouch.
- Avoid any foreign substances contaminating the sample inlet and measuring window.
- If there is evidence of microbial contamination or excessive turbidity in the extraction buffer tube, discard it and contact customer service part.
- Do not mix cassettes from other products into this product box.
- Perform the test in a clean environment free of contaminants.
- Do not arbitrarily disassemble or alter the product.

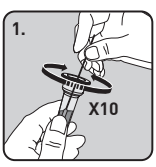
SPECIMEN COLLECTION AND PREPARATION

- Acceptable specimens for testing with this kit include nasopharyngeal swab specimens.
- Specimens obtained early during symptom onset will contain the highest viral titers.
- Nasopharyngeal swab specimens should be tested as soon as possible after collection.
- Inadequate specimen collection, improper specimen handling and/or transport may yield a false negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

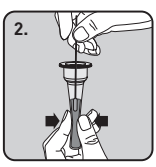
TEST PROCEDURE



Insert a sterile swab into nasopharynx, and collect the specimens.

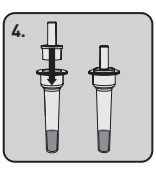


Stir the sample swab in the extraction buffer tube more than 10 times.

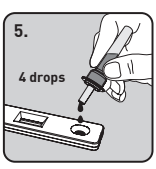


Squeeze out the swab by squeezing the extraction buffer tube with your fingers to extract all sample collected.

Remove and discard swab.



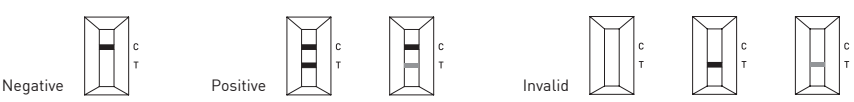
Place the nozzle cap with tube.



Apply 4 drops (~100 ul) of the solution into the sample well.

Read after 15 mins.

INTERPRETATION OF RESULTS



- A colored band will appear in the top section, control line (C), of the result window to show that the test is working property.
- A colored bandear in the lower section, test line (T), of the result window.
- Even if the control line is faint, or the test line is not uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.
- The presence of any line, no matter how faint the result is considered positive.
- Positive results should be considered in conjunction with the clinical history and other data available.

PERFORMANCE CHARACTERISTIC

CLINICAL PERFORMANCE

The performance of the GeneFinder™ COVID-19 Ag Rapid Test was established with 100 nasopharyngeal swabs prospectively collected and enrolled from individual patients who tested with a RT-PCR method for SARS-CoV-2 infection. All specimens within a pre-specified date range were selected and then sequentially tested in a blinded fashion. The performance of the GeneFinder™ COVID-19 Ag Rapid Test compared to RT-PCR for nasopharyngeal swabs.

		RT-PCR		
		Positive	Negative	Total
GeneFinder™ COVID-19 Ag Rapid Test	Positive	29	1	30
	Negative	1	99	100
	Total	30	100	130

- Sensitivity: 96.7% (95% CI: 83.3% - 99.4%)
- Specificity: 99.0% (95% CI: 94.6% - 99.8%)

Limit of detection (LoD)

The LoD is 5.00 x 10^2 $TCID_{50}$/mL. The study used "2019-nCoV/USA-WA1/2020" strain. The titer of cultured virus was confirmed by PCR. The cell is inactivated and spiked into nasopharyngeal swab specimen.

RT-PCR	2019-nCoV/USA-WA1/2020						
Stock titer	3.16 x 10^4 $TCID_{50}$/mL						
Conc. ($TCID_{50}$/mL)	8.00 x 10^3	4.00 x 10^3	2.00 x 10^3	1.00 x 10^3	5.00 x 10^2	2.50 x 10^2	1.25 x 10^2
Accuracy	100%	100%	100%	100%	100%	47.2%	0%
LOD	5.00 x 10^2 $TCID_{50}$/mL						

Cross-reactivity

Cross-reactivity of the GeneFinder™ COVID-19 Ag Rapid Test was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with the GeneFinder™ COVID-19 Ag Rapid Test. Each organism and virus was tested in triplicate. The final concentration of each organism is documented in the following table.

Potential cross-reactant	Concentration	Cross-reactivity
Human coronavirus 229E	1.00 X 10^5 $TCID_{50}$/mL	NEG
Human coronavirus OC43	1.26 X 10^5 $TCID_{50}$/mL	NEG
Human coronavirus NL63	1.00 X 10^5 $TCID_{50}$/mL	NEG
Adenovirus type1	2.57 X 10^5 $TCID_{50}$/mL	NEG
Adenovirus type2	1.15 X 10^5 $TCID_{50}$/mL	NEG
Adenovirus type3	3.80 X 10^5 $TCID_{50}$/mL	NEG
Adenovirus type5	3.39 X 10^5 $TCID_{50}$/mL	NEG
Adenovirus type7A	1.00 X 10^5 $TCID_{50}$/mL	NEG
Adenovirus type21	1.70 X 10^5 $TCID_{50}$/mL	NEG
hMPV 27 Type A2	3.80 X 10^5 $TCID_{50}$/mL	NEG
Parainfluenza virus 1	9.12 X 10^5 $TCID_{50}$/mL	NEG
Parainfluenza virus 2	1.00 X 10^5 $TCID_{50}$/mL	NEG
Parainfluenza virus 3	2.57 X 10^5 $TCID_{50}$/mL	NEG
Parainfluenza virus 4a	3.80 X 10^5 $TCID_{50}$/mL	NEG
Parainfluenza virus 4b	1.00 X 10^5 $TCID_{50}$/mL	NEG
Influenza A	4800 ngHA/mL	NEG
Influenza B	4096 HAunits/mL	NEG
Enterovirus type68	3.80 X 10^5 $TCID_{50}$/mL	NEG
Enterovirus type71	1.00 X 10^5 $TCID_{50}$/mL	NEG
Respiratory syncytial virus A	1.00 X 10^5 $TCID_{50}$/mL	NEG
Respiratory syncytial virus B	1.00 X 10^5 $TCID_{50}$/mL	NEG
Rhinovirus	1.00 X 10^5 $TCID_{50}$/mL	NEG
MERS-coronavirus	1.00 X 10^5 $TCID_{50}$/mL	NEG
Streptococcus pneumoniae	5 X 10^4 cells/mL	NEG
Streptococcus pyogenes	5 X 10^4 cells/mL	NEG
Mycoplasma pneumoniae	5 X 10^4 cells/mL	NEG
Legionella pneumophila	5 X 10^4 cells/mL	NEG

Endogenous/Exogenous interference substances

There was no interference for potential interfering substances listed below. However, abnormally high concentration in sample may cause inaccurately low or high results.

Category	Interference substances	Concentration	Result
Endogenous	Mucin	1 mg/mL	NEG
	Whole blood	5%	NEG
Nasal Spray or drops	Phenylephrine	1 mg/mL	NEG
	Sodium chloride	5%	NEG
	Oxymetazoline	10 ug/mL	NEG
Homeopathic Nasal Spray	Budesonide	0.63 g/dL	NEG
	Dexamethasone	5 mg/mL	NEG
Antibiotic, Nasal ointment	Mupirocin	5 mg/mL	NEG
Antibiotic, systemic	Tobramycin	1 mg/mL	NEG
Anti-inflammatory medication	Acetylsalicylic acid	0.5 mg/mL	NEG
Anti-viral drugs	Zanamivir	5 mg/mL	NEG
	Oseltamivir Phosphate	5 mg/mL	NEG

LIMITATIONS

- Use of GeneFinder™ COVID-19 Ag Rapid Test is limited to laboratory personnel who have been trained. Not for home use.
- This product is only used for testing of nasopharyngeal swab specimens. Other specimen types have not been evaluated and should not be used with this assay.
- Clinical performance was evaluated with frozen samples, and test performance may be different with fresh samples.
- Reading test results earlier than 15 minutes after the addition of sample may yield erroneous results. Do not interpret the result over 20 minutes.
- User should test the specimen as quickly as possible after specimen collection.
- Positive test results do not rule out co-infections with other pathogens.
- Results from the GeneFinder™ COVID-19 Ag Rapid Test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
- A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.
- Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
- The GeneFinder™ COVID-19 Ag Rapid Test can detect both viable and non-viable SARS-CoV-2 material. The GeneFinder™ COVID-19 Ag Rapid Test performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
- Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.
- Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False negative test results are more likely when prevalence of disease caused by SARS-CoV-2 is high.
- This device has been evaluated for use with human specimen material only.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.
- Negative results should be treated as presumptive.

EXTERNAL QUALITY CONTROL

External positive and negative control swabs are supplied in the kit and should be tested using the same procedure as used for patient specimens. The positive control swab contains recombinant protein as SARS-CoV-2 antigen.

REFERENCE

- Centers for Disease Control and Prevention(2020) https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Peng Zhou, Xing-Lou Yang, Xian-Guang Wang, et al., A pneumonia outbreak associated with a new coronavirus of probable bat origin. Nature. 2020 Mar;579(7798): 270-273
- bioRxiv.(2020)https://www.biorxiv.org/content/10.1101/2020.02.07.937862v1
- Roujian Lu, Xiang Zhao, Juan Li et al., Genomic characterization and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding. Lancet. 2020 Feb 22; 395(10224): 565-574

MODEL NAME

OI-01SA-SN

SYMBOL

Symbol	Description	Symbol	Description
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro Diagnostic medical device.	EC REP	Authorisd representative in the European community.
	Consult Instructions for use.		Do not re-use.
	Use By date.		Date of manufacture.
	Caution, consult accompanying documents.		Manufacturer.
IVD	In vitro diagnostic medical device.		Temperature limitation.
LOT	Batch Code.		Biohazard.
REF	Catalogue number.		Contains sufficient for 1 test.

OSANG Healthcare Co., Ltd 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, Korea (14040) www.osanghc.com

EC REP **Obelis S.A.** Bd. General Wahis 53 1030 Brussels, Belgium **Tel:** +(32) 2.732.59.54 **Fax:** +(32) 2.732.60.03 **E-Mail:** mail@obelis.net

Manufacturer and Authorized representative information for sterile swabs is as below.

Noble Biosciences, Inc. 13-50, Sinbaek-gil, Jeongnam-myeon, Hwaseongsi, Gyeonggi-do, 18521 Korea Tel: +82-31-291-0044

EC REP **S.B PHARMA GMBH** Max-Planck Str.39a D-50858, Koin, Germany **Tel:** 49 (0) 2234 988 1521

CE 2292

REF INFI01ACA ISC02675 Rev. 2020-12-02