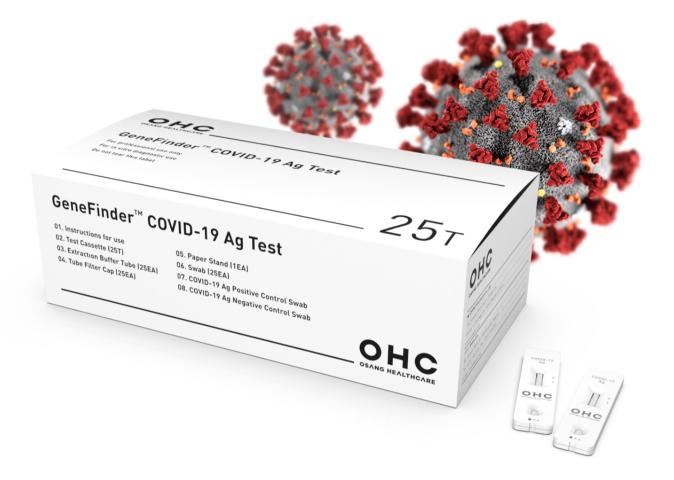
CE

OHC GeneFinder™ COVID-19 Ag Rapid Test





STRONG POINTS

- Suitable and simple detection of SARS-CoV-2 antigen
- User friendly Cassette Type & Color
- Easy to use
- Room temperature storage
- Fast result within 15 min
- Point-Of-Care Diagnostic Test

PROFILE

Intended use	Detection of SARS-CoV2 antigen		
Time to Result	Within 15 minutes		
Specimen	Nasopharyngeal Swab		
Storage	2-30°C/36-86°F		
Shelf Life	18 Months		
Pack Size	25 Tests / Box		



COMPONENTS

- Instructions for use
- 25 GeneFinder[™] COVID-19 Ag Rapid Test cassettes
- 25 Extraction buffer tubes
- 25 Tube filter cap
- Sterilized nasopharyngeal swabs for sample collection
- 1 Positive control swab
- 1 Negative control swab

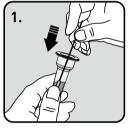
PROCEDURE



HOW TO USE



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



4

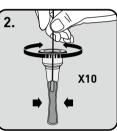
Negative

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

Place the nozzle cap

with tube.

Positive



5.

4 drops

C

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

Apply 4drops (~100 ul)

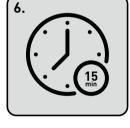
of the solution into

Invalid

the sample well.



Remove and discard swab.



С

Read after 15 mins.

С



CLINICAL PERFORMANCE

INTERPRETING TEST RESULTS

C

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% C1- 94.6% - 99.8%)				

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