



**GENEDIA**  **Series**

Real Time PCR • LAMP PCR • RAPID Ab •  
**RAPID Ag** • RAPID Ag FIA

# GENEDIA

## COVID-19 Ag 643K

The GENEDIA W COVID-19 Ag is an in vitro diagnostic single-use test for the qualitative immunoassay to detect SARS-CoV-2 antigen in anterior nasal swab from human. This assay is designed for professional personnel in laboratory and at point-of-care as an aid in screening patients suspected of COVID-19 infection.



**10 Min.**



**Anterior  
Nasal Swab**



**Asymptomatic**

## Easy & Quick Antigen testing

- Allow wider testing with fast test time (10 minutes)
- Easier specimen collection from frontal part of the nose
- Clinically proven data of asymptomatic patients available



### Performance compared with other methods

For COVID-19 Ag		Comparator (RT-PCR)		Total
		Positive (+)	Negative (-)	
<b>GENEDIA W COVID-19 Ag</b>	Positive (+)	105	0	105
	Negative (-)	2	124	126
<b>Total</b>		107	124	231

### Positive results broken down by days since symptom onset

Days Since Symptom Onset	RT-PCR Positive (+)	GENEDIA W COVID-19 Ag Positive (+)	PPA	95% Confidence Interval
Symptomatic	58	57	98.3%	91.0%-99.7%
Asymptomatic	49	48	98.0%	89.5%-99.7%

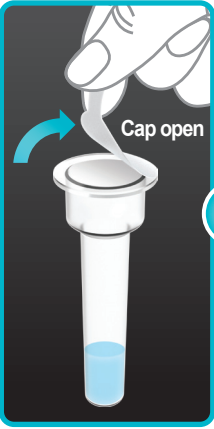
\* Clinical sensitivity : 98.1% (95% CI : 93.4% - 99.5%)

\* Clinical specificity : 100% (95% CI : 97.0% - 100%)




**Made in Korea**


## TEST PROCEDURE



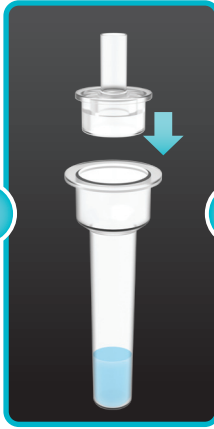
**1 STEP**  
Open the extraction solution tube.




**2 STEP**  
Insert the patient swab sample into the extraction solution tube. Then, swirl swab at least 6 times.



**3 STEP**  
Roll the swab head against the inside of the tube as you remove it.

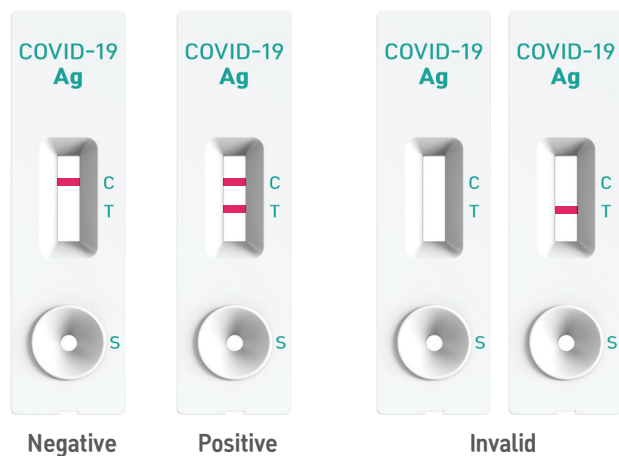


**4 STEP**  
Bind the sample developing filter cap with the extraction tube.



**5 STEP**  
Add 3 drops of the extraction solution with specimen into the sample well. After 10 minutes, interpret the test results.

## INTERPRETATION OF THE RESULTS



Please read the results within 15 minutes.

## MATERIALS PROVIDED



- ① Test device : 20 EA
- ② Extraction solution : 20 EA (10X2)
- ③ Sample developing filter cap : 20 EA
- ④ Sterilized swabs for sample collection : 20 EA
- ⑤ Instructions for use: 1EA

## Specification

Method	Immunochromatography
Packing unit	20 Tests / kit
Certification	CE-IVD
Specimen	Anterior nasal swab
LOD	7.50X10 <sup>2</sup> TCID <sub>50</sub> /mL
Running time	10 minutes

Materials provided	① Test device : 20 EA ② Extraction solution : 20 EA ③ Sample developing filter cap : 20 EA ④ Sterilized swabs for sample collection : 20 EA ⑤ Instructions for use: 1EA
Expiry date	24 months from the date of manufacture
Storage condition	2 ~ 30°C

