



GENEDIA  **Series**

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

GENEDIA

COVID-19 Ag 643K

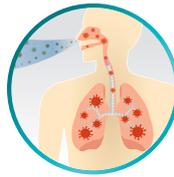
The GENEDIA W COVID-19 Ag is an in vitro diagnostic single-use test for the qualitative immunoassay to detect SARS-CoV-2 antigen in anterior nasal swab from human. This assay is designed for professional personnel in laboratory and at point-of-care as an aid in screening patients suspected of COVID-19 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 (-)		
GENEDIA W COVID-19 Ag	Positive (+)	105	0	105
	Negative (-)	2	124	126
Total		107	124	231

Positive results broken down by days since symptom onset

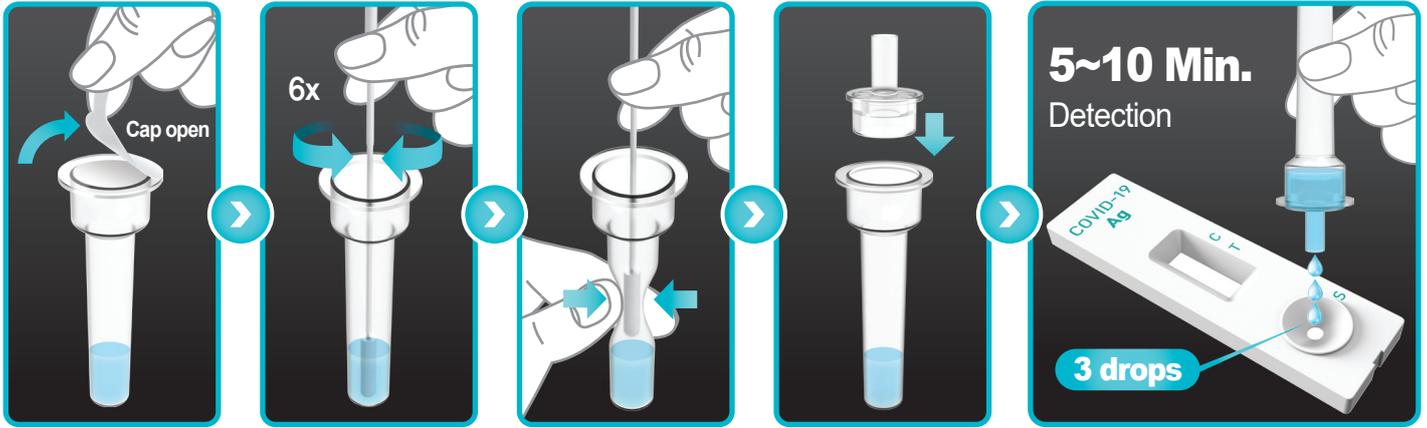
Days Since Symptom Onset	RT-PCR Positive (+)	GENEDIA W COVID-19 Ag Positive (+)	PPA	95% Confidence Interval
Symptomatic	58	57	98.3%	91.0%-99.7%
Asymptomatic	49	48	98.0%	89.5%-99.7%

* 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

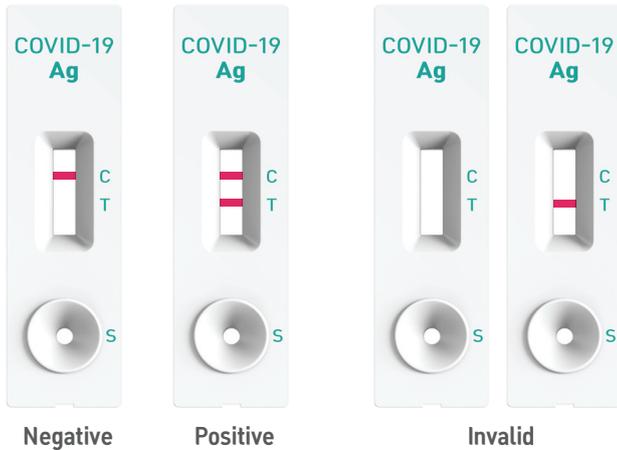
Bind the sample developing filter cap with the extraction tube.

5 STEP

5~10 Min. Detection

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

INTERPRETATION OF THE RESULTS



MATERIALS PROVIDED



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

Please read the results within 15 minutes.

Specification

Method	Immunochromatography
Packing unit	5 Tests / kit
Certification	CE-IVD
Specimen	Anterior nasal swab
LOD	7.50X10 ² TCID ₅₀ /mL
Running time	10 minutes

Materials provided	<ul style="list-style-type: none"> ① Test device : 5 EA ② Extraction solution : 5 EA ③ Sample developing filter cap : 5 EA ④ Sterilized swabs for sample collection : 5 EA ⑤ Instructions for use: 1EA
Expiry date	24 months from the date of manufacture
Storage condition	2 ~ 30°C

