



GENEDIA  **Series**

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

GENEDIA COVID-19 Ag

GENEDIA W COVID-19 Ag device is a chromatographic immunoassay for the qualitative detection of specific antigens to COVID-19 present in human nasopharyngeal swab and sputum.



10 Min.



Sputum



Asymptomatic



Immediate on-site Antigen testing

- Allow wider testing with fast test time (10 minutes)
- Various type of specimen are available (Nasopharyngeal swab and sputum)
- Clinically proven data of asymptomatic patients available (Sensitivity in asymptomatic patients: 85%)

Performance compared with other methods

For COVID-19 Ag		Comparator (RT-PCR)		Total
		Positive (+)	Negative (-)	
GENEDIA W COVID-19 Ag	Positive (+)	182	0	182
	Negative (-)	20	229	249
Total		202	229	431

Positive results broken down by days since symptom onset

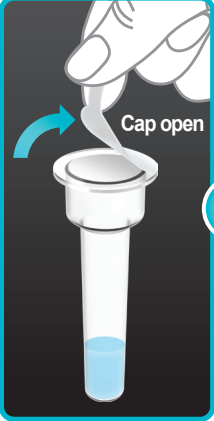
Days Since Symptom Onset	RT-PCR Positive (+)	GENEDIA W COVID-19 Ag Positive (+)	PPA (Positive predictive agreement)
≤7	68	64	94% (95% CI : 85.6%- 98.4%)
Asymptomatic	54	46	85% (95% CI : 73.0% - 93.4%)

- Clinical sensitivity : 90.1% (95% CI : 85.1% - 93.9%)
- Clinical specificity : 100% (95% CI : 98.4% - 100%)
- Total Agreement Ratio : 95.3%




Made in Korea

TEST PROCEDURE




1 STEP

Open the extraction solution tube.



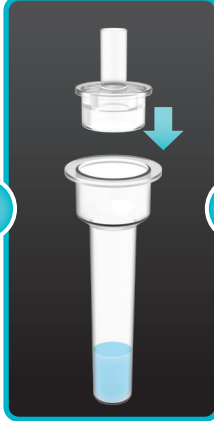
2 STEP

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.



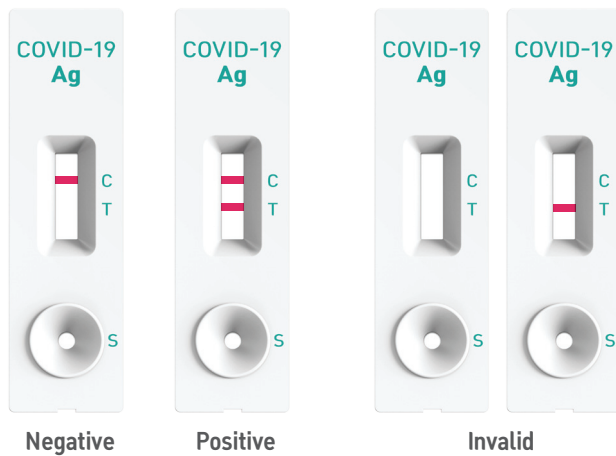
5 STEP

5~10 Min. Detection

3 drops

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 : 1 EA

Specification

Method	Immunochromatography
Packing unit	20 Tests / kit
Certification	CE-IVD
Specimen	Nasopharyngeal swab and sputum
LOD	7.50X10 ² TCID ₅₀ /mL
Running time	10 minutes

Materials provided	Test device individually foil-pouched with a desiccant
	Extraction solution in dropping bottle
	Sample developing filter cap
	Sterilized swabs for sample collection
	Instructions for Use
Expiry date	24 months from the date of manufacture
Storage condition	2 ~ 30°C

