ISO 13485

GENEDIA W Series

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

GENEDIA W 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.

Immediate on-site Antigen testing

- Allow wider testing with fast test time (10 minutes)
- All necessary materials provided / no equipment needed
- High capacity to meet the most urgent medical and public health needs

Performance compared with other methods

For COVID-19 Ag		Comparator (RT-PCR)		Total
		Positive (+)	Negative (-)	
GENEDIA W COVID-19 Ag	Positive (+)	89	0	89
	Negative (-)	13	129	142
Total		102	129	231

- Clinical Sensitivity = 87.25% (95% CI : 79.41% - 92.4%)
- Clinical Specificity = 100.0% (95% CI : 97.11% - 100%)
- Agreement : 94.4%

Positive results broken down by days since symptom onset

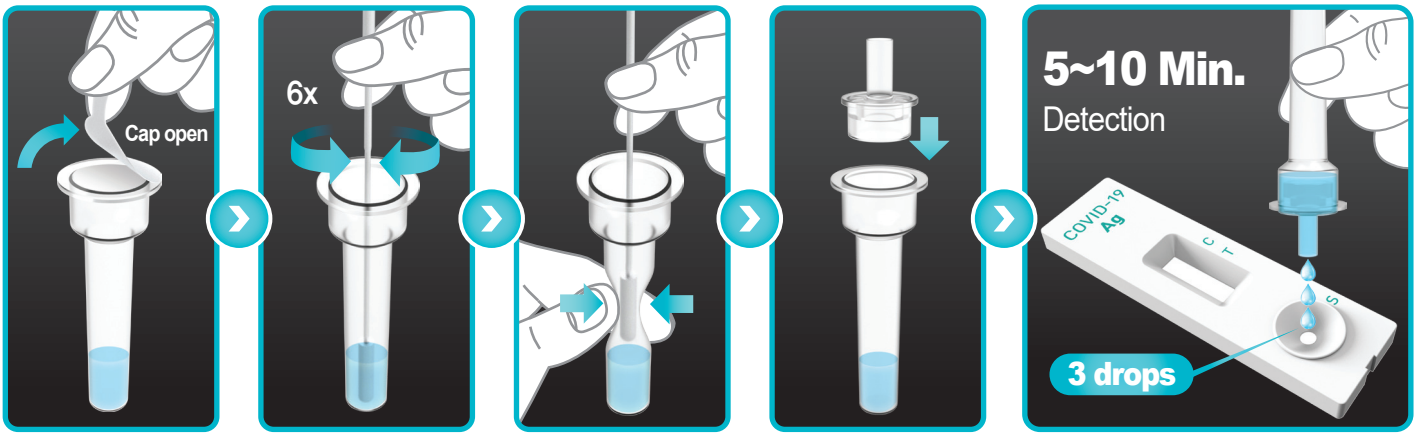
Days Since Symptom Onset	RT-PCR Positive (+)	GENEDIA W COVID-19 Ag Positive (+)	PPA (Positive Predictive Agreement)
≤7	49	48	98%
Asymptomatic	24	18	75%

GC MS

Made in Korea

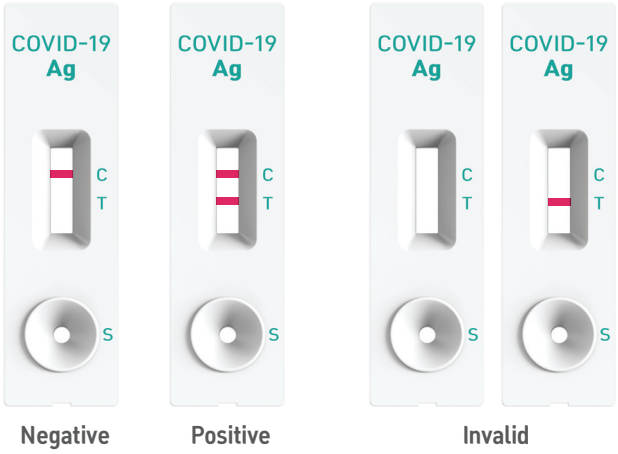
GENEDIA COVID-19 Ag

TEST PROCEDURE



1 STEP	2 STEP	3 STEP	4 STEP	5 STEP
Open the extraction solution tube.	Insert the patient swab sample into the extraction solution tube. Then, swirl swab at least 6 times.	Roll the swab head against the inside of the tube as you remove it.	Place the sample developing screw cap into the extraction tube and close it.	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	12 months from the date of manufacture
Storage condition	2 ~ 30℃

Manufacturer
GCMS
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