



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



Immediate on-site Antigen testing

- Allow wider testing with fast test time (10 minutes)
- Various type of specimen are available (Nasopharyngeal swab and sputum)
- All necessary materials provided / no equipment needed

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 |

- Clinical sensitivity : 90.1% (95% CI : 85.2% - 93.5%)
- Clinical specificity : 100% (95% CI : 98.4% - 100%)
- Total Agreement Ratio : 95.3%

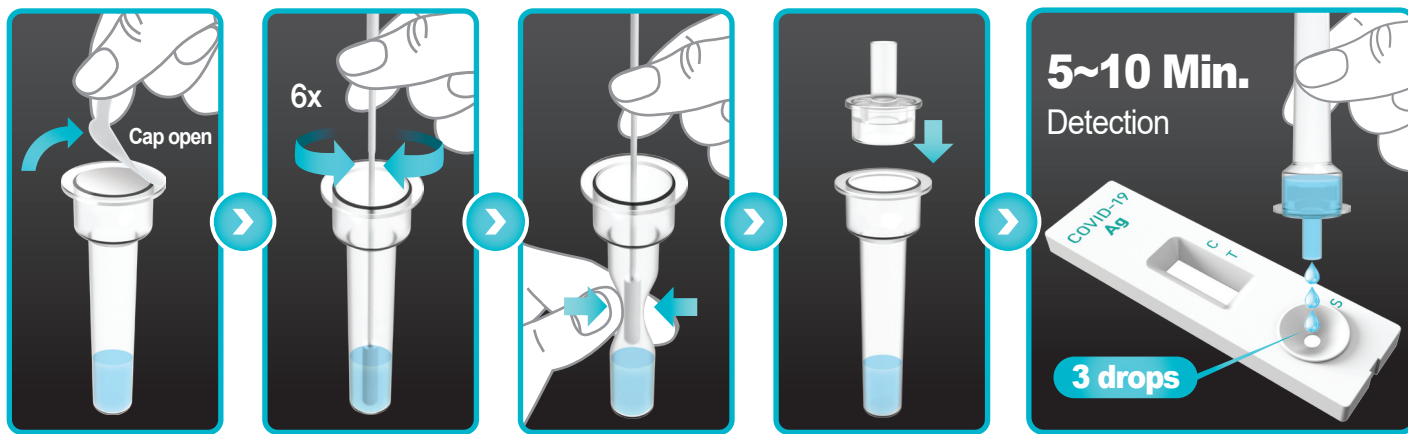
Positive results broken down by days since symptom onset

| Days Since Symptom Onset | RT-PCR Positive (+) | GENEDIA W COVID-19 Ag Positive (+) | PPA (Positive predictive agreement) |
|--------------------------|---------------------|------------------------------------|-------------------------------------|
| ≤7 | 68 | 64 | 94% (95% CI : 85.8% - 97.7%) |
| Asymptomatic | 54 | 46 | 85% (95% CI : 73.4% - 92.3%) |



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

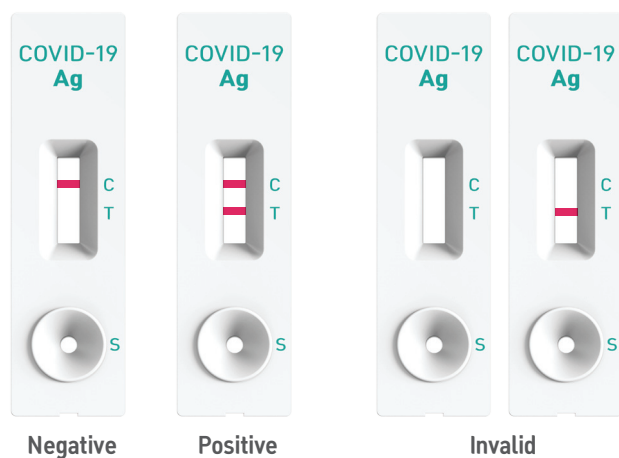
Bind the sample developing filter cap with the extraction tube.

5 STEP

5~10 Min. Detection

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°C |

