



ISO
ISO 13485



GENEDIA *W* Series

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

GENEDIA *W* COVID-19 Ag SALIVA

643G-S

The GENEDIA W COVID-19 Ag (SALIVA) is an in vitro diagnostic single-use test and qualitative immunoassay to detect SARS-CoV-2 antigen in human saliva specimen.



15 Min.



Saliva



Omicron

Immediate on-site Antigen testing

- Allow wider testing with fast test time (15 minutes)
- Non-invasive specimen (Saliva)
- Reactivity against the omicron variant successfully validated in silico and In-vitro test (recombinant protein)



Performance compared with other methods

| For COVID-19 Ag | | Comparator (RT-PCR) | | Total |
|---------------------------------------|--------------|---------------------|--------------|-------|
| | | Positive (+) | Negative (-) | |
| GENEDIA W COVID-19 Ag (SALIVA) | Positive (+) | 56 | 0 | 56 |
| | Negative (-) | 4 | 60 | 64 |
| Total | | 60 | 60 | 120 |

* Clinical sensitivity : 93.33% (95% CI : 83.80% - 98.15%)

* Clinical specificity : 100% (95% CI : 94.04% - 100%)

* Total Agreement Ratio : 96.67%

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 | 98.96% (95% CI : 89.15%- 99.95%) |
| 8 to 14 | 11 | 8 | 72.73% (95% CI : 39.03%- 93.98%) |



Made in Korea

GENEDIA COVID-19 Ag SALIVA

TEST PROCEDURE

1 STEP
Open the extraction solution tube.

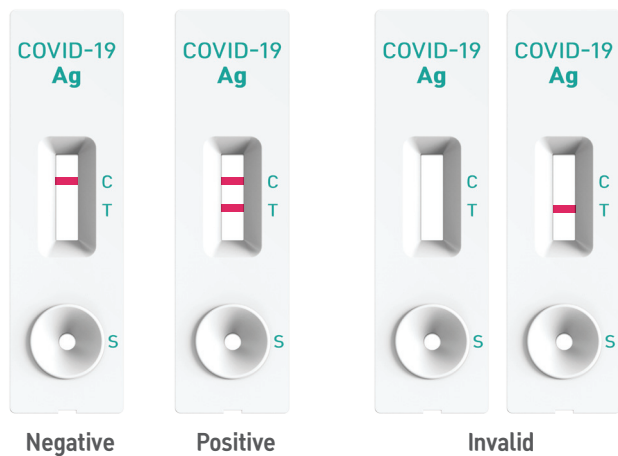
2 STEP
Insert the patient swab sample into the extraction solution tube. Then, swirl swab at least 6 times.

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 15 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
- ⑥ Cup for saliva collection : 20EA

Specification

| | |
|---------------|----------------------|
| Method | Immunochromatography |
| Packing unit | 20 Tests / kit |
| Certification | CE-IVD |
| Specimen | Saliva |

| | |
|-------------------|---|
| LOD | 7.50×10^2 TCID ₅₀ /mL |
| Running time | 15 minutes |
| Expiry date | 24 months from the date of manufacture |
| Storage condition | 2 ~ 30°C |



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