GenBody Inc.
CHANGE AND INNOVATION

# COVID-19 Ag

## Quick Immunoassay


# GenBody COVID-19 Ag

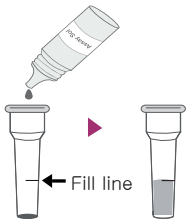
## Detection kit for SARS-CoV-2 antigen

The pandemic of COVID-19 has been already announced by WHO (World Health Organization). The symptoms of COVID-19 are diverse, but generally include fatigue, fever, cough, loss of smell and taste and breathing difficulties. The symptoms of COVID-19 start to show in the period of 1 to 14 days after exposure to the virus. Even though the molecular test (RT-PCR) has become the standard method for the diagnosis of this disease, a lot of clinic systems need more simple and convenient methods due to several limitations of molecular test.

GenBody COVID-19 Ag is an immunochromatographic assay kit for the qualitative detection of SARS-CoV-2 antigen in nasopharyngeal and oropharyngeal swab from human. This kit is simply used to detect the SARS-CoV-2 virus, providing results in 10 to 20 mins. One of the best advantages of this kit is inexpensive despite high sensitivity and specificity.

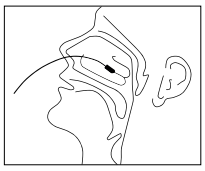
## Assay Procedure

### Preparation of Extraction solution



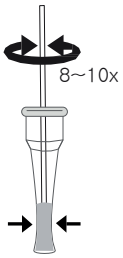

Bring swabs, specimens, and test kit to 15-30 min prior to use.
Add the Extraction Solution to the Fill Line indicated on the Extraction Tube (400 µL).

### Nasopharyngeal swab



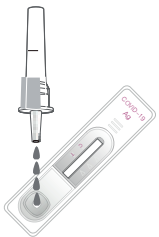
Nasopharyngeal swab collection: Collect the specimens from the patient using the provided swab.

Insert the nasopharyngeal swab samples into the extraction solution.




Mix by squeezing the tube and simultaneously rotating the swab 8-10 times.

Remove the swab from the extraction tube while pressing the swab against the side of the tube to extract the solution. Place the disposable dropper cap on the extraction tube.



Add 4 drops (~100 uL) of the solution to the center of the sample well of the test device.

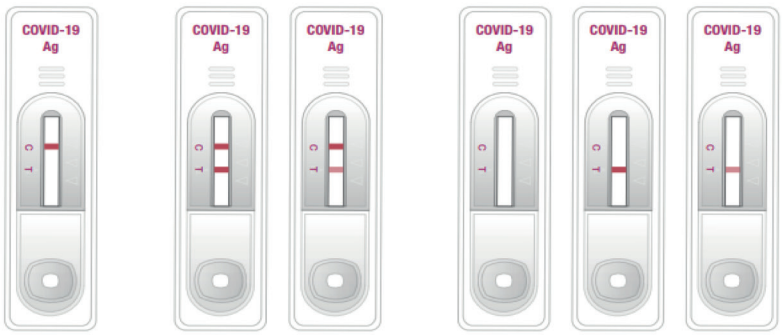
15~20 min

Read the test between 15-20 min after the addition of the sample. Treat samples, swab, tube and test device as biohazardous waste.

# Interpretation of the Results


C: Control line
T: Test line

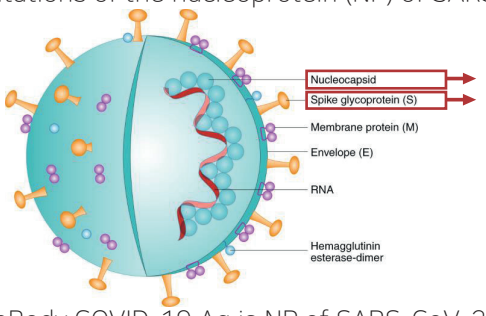
Sample well




Negative Positive Invalid

# Diagnosis of GenBody COVID-19 Ag kit for the SARS-CoV-2 variants

- Current variants of SARS-CoV-2: mainly mutated in spike protein (SP).
- Total 23 mutated positions by SNPs (single-nucleotide polymorphisms) or deletion.
- Very less or none mutations of the nucleoprotein (NP) of SARS-CoV-2.




No change → GenBody Ag Test
23 changes → Molecular Test
Other Immuno-tests
Vaccine Development

- Target protein of GenBody COVID-19 Ag is NP of SARS-CoV-2 in human respiratory specimens.
  → No effect to diagnose from these kinds of SARS-CoV-2 variants.
- In summary, GenBody COVID-19 Ag can surely detect the current variants of SARS-CoV-2.

*Reference
1. Leonid Y. et al. Structural and functional analysis of the D614G SARS-CoV-2 spike protein variant. Cell (2020) 183, p739-751.
2. Andrew R. et al. Preliminary genomic characterization of an emergent SARS-CoV-2 lineage in the UK defined by a novel set of spike mutations. nCoV-2019 Genomic Epidemiology (2020) https://virological.org/t/preliminary-genomic-characterisation-of-an-emergent-sars-cov-2-lineage-in-the-uk-defined-by-a-novel-set-of-spike-mutations/563

# Clinical evaluation

- Under the strict IRB regulation, we collected and performed the clinical studies using total 506 patient's samples (493 specimens : Ct ≤ 30, 13 specimens : Ct > 30) which were confirmed to be COVID-19 positive and its negative in Korea (2 sites) and in USA (1 site). The method of confirmation was RT-PCR kit (Korean/US FDA-EUA approved).

| n = 493 (Ct ≤ 30) | | Molecular test (RT-PCR) | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| GenBody COVID-19 Ag | Positive | 119 | 4 | 123 |
| | Negative | 4 | 366 | 370 |
| Total | | 123 | 370 | 493 |

Sensitivity = 96.83% (95% CI: 92.07% to 99.%), (Ct > 30: Less than 50%)
Specificity = 99.18% (95% CI: 97.25% to 99.59%)
PPV (Positive Predictive Value) =
96.83%NPV (Negative Predictive Value)

| n = 285 | | Real-Time PCR | | | | |
|---|---|---|---|---|---|---|
| | | Positive | | | Negative | Total |
| | | Asymptomatic | *Day 1~6 | *Day 7~ | | |
| GenBody COVID-19 Ag | Positive | 5 | 48 | 24 | 3 | 80 |
| | Negative | 1 | 4 | 3 | 197 | 205 |
| Total | | 6 | 52 | 27 | 200 | 285 |

*Day after the onset of symptoms.
- Sensitivity = 83.3% (Asymptomaticcases)
  92.3% (95% CI = 81.5% to 97.9%) at Day 1~6
  88.9% (95% CI = 70.8% to 97.7%) at after Day 7
- Specificity = 98.5% (95% CI = 95.7% to 99.7%)

# Ordering Information

| Cat no. | Product Name | Package | Box Size (mm) | Carton Size(mm) |
|---|---|---|---|---|
| COVAG025 | GenBody COVID-19 Ag | 25 Tests/Kit | 250 x 125 x 90 | 570 x 390 x 520 |