# GenBody Influenza/COVID–19 Ag Multi

IVD CE

Detection kit for the antigens of influenza virus (type A and B) and SARS-CoV-2 in nasopharyngeal swab from human

2020.07.07 (Rev.0)

## INTENDED USE

GenBody Influenza/COVID-19 Ag Multi is an immunochromatographic assay kit for qualitatively and simultaneously detecting the antigens of influenza virus (type A and B) and SARS-CoV-2 in nasopharyngeal swab from human.

## EXPLANATION OF THE TEST

GenBody Influenza/COVID-19 Ag Multi is combined of COVID-19 antigen test and influenza A and B antigen test, which use the immunoassay method. In the case of COVID-19 antigen test, the kit detects the nucleoprotein (NP) of SARS-CoV-2 in the swab specimen. Monoclonal antibody (mAb) specific for NP of SARS-CoV-2 is immobilized on the test line region and another mAb is conjugated with gold nanoparticle and placed in the pad. When the sample contains the SARS-CoV-2 antigens, the antigens are allowed to react with anti-SARS-CoV-2 mAb-coupled gold conjugate followed by the reaction with another mAb in the test line (T), which make a visible line in the membrane. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing another band in the control region (C).
In the case of influenza antigen test of the kit, mAbs specific for NP of influenza A and B are coated on the A and B region in the membrane, respectively. And, another anti-influenza A and anti-influenza B mAbs are conjugated with colloidal gold, respectively, and placed in the pad. When the sample contains the influenza antigens, the antigens are allowed to react with anti-influenza A/B mAb-coupled gold conjugate followed by the reaction with another mAb in the test line (A/B), which make a visible line in the membrane. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing another band in the control region (C).
GenBody Influenza/COVID-19 Ag Multi is very useful to directly and simultaneously detect the SARS-CoV-2 antigens and influenza A and B antigens in the human swab specimen.

## MATERIALS PROVIDED

1. Test device individually foil-pouched with a desiccant
2. Extraction solution
3. Extraction tube
4. Disposable dropper cap
5. Sterilized nasopharyngeal swabs for sample collection
6. Instructions for use

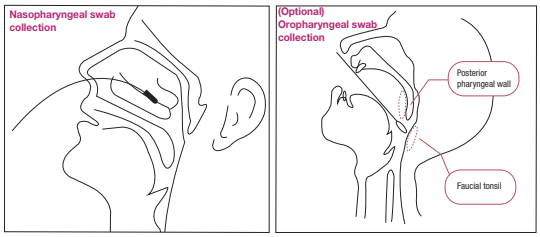
## MATERIALS REQUIRED BUT NOT PROVIDED

1. (Optional) Sterilized oropharyngeal swabs for sample collection
2. Medical mask and medical latex gloves
3. Specimen collection container
4. Micropipette and disposable pipette tips
5. Watch or timer

## PRECAUTIONS

1. The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
2. For in vitro diagnostic use only. DO NOT re-use the test device.
3. Collected specimen should be prepared as sample in accordance with after-mentioned "Specimen Collection and Storage" and tested as soon as possible.
4. Add the fixed volume (3~4 drops) to the center of sample well area.
5. Bring the test kit and extraction solution to 15 - 30 °C prior to testing.
6. Keep interpretation time because it causes false negative or false positive.
7. When using samples from viral/universal transport media, it may cause inaccurate results due to decreasing the sensitivity of the test.
8. When using swab for collecting specimen, DO NOT use Nucleic Acid Preservation & Transport (NAPT) Medium.

## SPECIMEN COLLECTION AND STORAGE




1. Specimen to be tested should be obtained and handled by standard methods for their collections.
2. Nasopharyngeal swab specimen:
   To collect nasopharyngeal specimen, carefully insert the sterile swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab til resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall.
3. [Optional] Oropharyngeal swab specimen:
   Insert swab from oral cavity into pharynx slowly and collect mucous membrane epidermis by rubbing posterior pharyngeal wall or faucial tonsil several times. Antigen of enough quantity cannot be collected with upper respiratory tract. Collection specimen by letting the spherical trip touch the part near posterior pharyngeal wall surely so as to rub a part near lower respiratory tract. In addition, do not use nasopharyngeal swab when collecting samples as it may cause insufficient collection of specimens.
4. All specimens should be tested as soon as they are prepared. If necessary, they may be stored at 2-8°C for up to 24 hours or at -20°C for longer periods.

## TEST PROCEDURE

[Nasopharyngeal swab/ (Optional) Oropharyngeal swab test procedure]

1. Place all specimens, test devices, and assay solution at room temperature prior to testing (15~30 min).
2. Place the device on a flat surface.
3. Fill the Extraction tube with Extraction solution up to the buffer line (400 $\mu\ell$).
4. Insert the nasopharyngeal (and oropharyngeal) swab sample(s) into the extraction solution, then, mix the swab 8~10 times.
5. In order to extract most of the specimen, keep pressing the extraction tube while removing the swabs.
6. Place the dropper cap and add 3~4 drops (~100 $\mu\ell$) into each sample well [S].
7. After 10~15 minutes, interpret the test results.
   Please do not read the results after 30 minutes from testing.

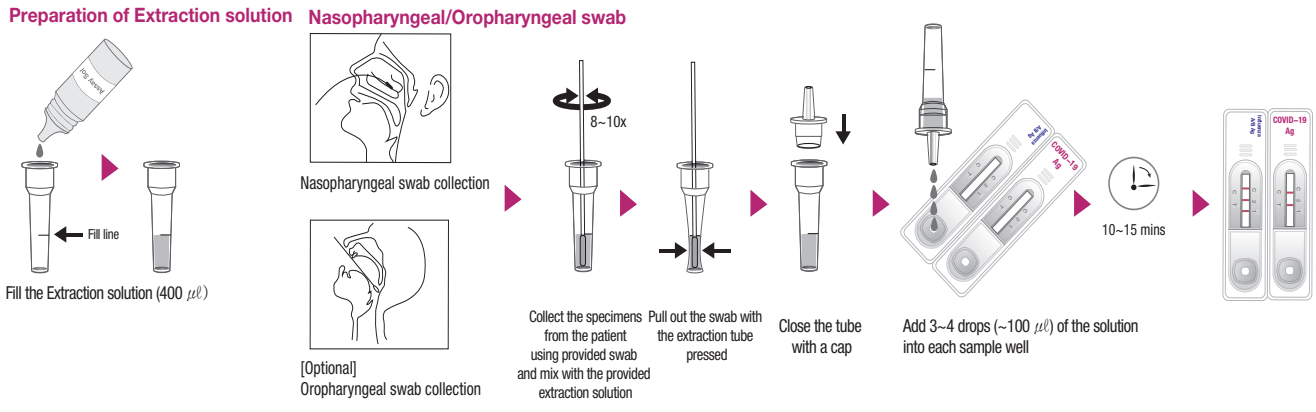
## INTERPRETATION OF THE RESULTS

1. Negative result: ONLY one band in each control line (C).
2. Influenza virus Positive result:

1) Positive for influenza virus type A: two bands appeared in the test line 1 (T1) and control line (C) in the right side of device.
2) Positive for influenza virus type B: two bands appeared in the test line 2 (T2) and control line (C) in the right side of device.
3) Positive for influenza virus type A and B: three bands appeared in the test line 1 (T1), test line 2 (T2) and control line (C) in the right side of device.

3. COVID-19 Positive result:
   Two bands are appeared in the test line (T) and control line (C) in the left side of device.

## <Assay Procedure>



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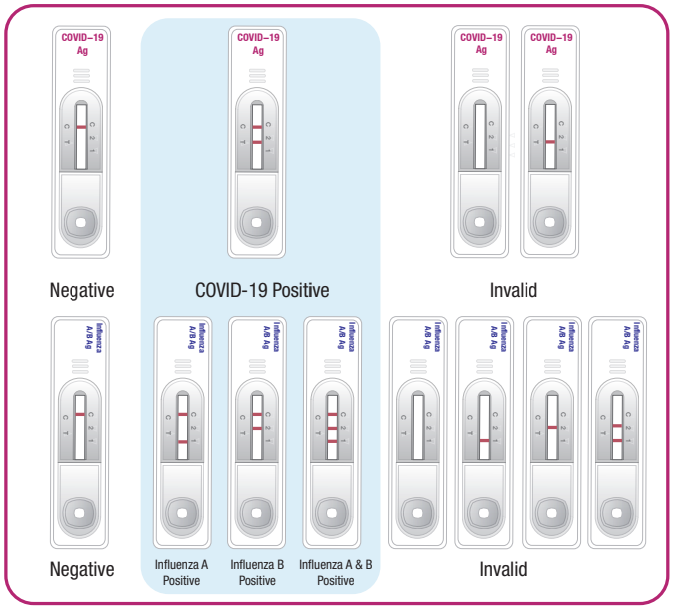
4. Invalid result:
   If a red color band does not appear in the control line (C) after 30 minutes, the result is considered invalid regardless of any shade of a pink-to-red test line (T) appears. If the test is invalid, a new test should be performed with a new patient sample and a new test device.

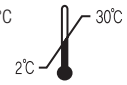



[Use analyzer]
- Using Confiscope G20 is optional.
- Please refer to instructions for use in the analyzer package.

Confiscope G20

## STORAGE & EXPIRATION

1. GenBody Influenza/COVID-19 Ag Multi kit should be stored between 2 to 30 °C (35.6 to 86 °F).
2. Expiration date of this kit is 12 months after its manufacture date.




## PERFORMANCE CHARACTERISTICS

**1. Analytical sensitivity/cross-reactivity**

1) Detection limit (LOD)
- COVID-19 Ag was 2.87 x $10^3$ $TCID_{50}$/ml (heat-inactivated culture fluid).
- Influenza virus type A (H1N1) was 19.53 HA units/ml, Influenza type A (H3N2) was 20.02 HA units/ml and Influenza type B was 5.78 HA units/ml.

2) Cross-reactivity:
- COVID-19 Ag was cross-reactivity of SARS-CoV-1. However, there were no cross-reactivities of MERS-coronavirus, Human coronavirus (NL63), Human coronavirus (229E), Human coronavirus (OC43), Human Adenovirus type 1, Human Adenovirus type 3, Human Adenovirus type 8, Human Adenovirus type 18, Human Adenovirus type 23, Human Adenovirus type 7, Human Adenovirus type 5, Human Adenovirus type 11, Human Parainfluenza virus type 1, Human Parainfluenza virus type 2, Human Parainfluenza virus type 3, Human Parainfluenza virus type 4, Human Rhinovirus type 1, Human Rhinovirus type 14, Human Rhinovirus type 42, Human Metapneumovirus, Respiratory syncytial virus-A, Respiratory syncytial virus-B.
- Influenza A/B Ag was no cross-reactivities of SARS-CoV-2, SARS-CoV-1, MERS-coronavirus, Human coronavirus (NL63), Human coronavirus (229E), Human coronavirus (OC43), Adenovirus type 1, Adenovirus type 2, Measles virus, Parainfluenza virus 1, Parainfluenza virus 2, Respiratory syncytial virus, Rhinovirus, *Escherichia coli, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus salivarius.*

**2. Interference**

Not interfered for Whole blood, Mouth wash, Phenylephrine, Acetylsalicylic acid, Beclomethasone, Benzocaine, Flunisolide, Guaiacol glyceryl ether, Menthol, Oxymetazoline, Tobramycin, Zanamivir, Oseltamivir phosphate, mucous.

**3. Clinical evaluation**

For the evaluation of SARS-CoV-2 diagnostic performance, COVID-19 positive samples form 30 individuals and COVID-19 negative samples from 100 individuals were introduced in this study.

| | | Real-Time PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| GenBody COVID-19 Ag | Positive | 27 | 2 | 29 |
| | Negative | 3 | 98 | 101 |
| Total | | 30 | 100 | 130 |

- Sensitivity = 90.0% (95% CI = 73.47% to 97.89%)
- Specificity = 98.0% (95% CI = 92.96% to 99.76%)

For the evaluation of influenza virus (type A and B) diagnostic performance, Influenza type A positive samples form 53 Influenza type A, 62 Influenza type B individuals and Influenza negative samples from 176 individuals were introduced in this study.

| | | Other RDT kit | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| GenBody Influenza type A | Positive | 53 | 9 | 62 |
| | Negative | 0 | 229 | 229 |
| Total | | 53 | 238 | 291 |

- Sensitivity = 100% (95% CI = 93.28% to 100%)
- Specificity = 96.22% (95% CI = 92.94% to 98.26%)

| | | Other RDT kit | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| GenBody Influenza type B | Positive | 61 | 12 | 73 |
| | Negative | 1 | 217 | 218 |
| Total | | 62 | 229 | 291 |

- Sensitivity = 98.39% (95% CI = 91.34% to 99.96%)
- Specificity = 94.76% (95% CI = 91.03% to 97.26%)

## LIMITATIONS OF THE TEST

GenBody Influenza/COVID-19 Ag Multi is designed for the primary test of SARS-CoV-2 and influenza virus (type A and type B) antigen and only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.

REF CVIFG010

GenBody Inc. CHANGE AND INNOVATION
3-18, Eopseong 2-gil, Seobuk-gu, Cheonan-si, Chungcheongnam-do, 31077, Republic of Korea
Tel.82-41-523-8990, (International) 82-41-523-8993, Fax.82-41-523-8991
http://www.genbody.co.kr

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EC REP

MT Promedt Consulting GmbH Altenhofstr. 80
D-66386 St.Ingbert, Germany, Tel +49 6894 5810 20