GenBody Inc.
(주)젠바디

Technical File

Product description

Product:	**GenBody COVID-19 Ag**
Date:	**2020-06-02**

Prepared by / date	Reviewed by / date	Approved by / date
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2020-06-02	**2020-06-02**	**2020-06-02**

0. Revision history

Revision History		
Rev.O	2020. 06. 02	Release of the product description for the GenBody COVID-19 Ag

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1. COMPANY PROFILE

Founded in 2012 with the pursuit for human and global health, GenBody Inc. creates innovative technologies for the development of raw materials for diagnostic use. We offer diagnostic total solution such as rapid diagnostic tests (RDTs), fluorescent immuno-diagnostic tests, ELISA, molecular diagnostic tests (MDx) and clinical chemistry. With over 20 years combined experience in the diagnostic industry and through vast bio-networks between several key institutes, universities, and hospitals, our core strength is in R&D. we specialize in developing monoclonal antibodies and recombinant antigens in-house at our facility in South Korea. We also have patented technologies including fluorescent immuno-diagnostics, which will be one of the major IVD technologies of the future. Our Mission statement is to bring Technology to Your life. We continuously develop innovative diagnostics and pharmaceutical technologies for improving your quality of life.

We have aggressively developed many special devices and produced those IVD kits under Good Manufacturing Practices of Korea (KGMP) and ISO 13485 system. Thus, GenBody Inc. is very confident on that its quality and user-oriented service**.**

2. General description of the device

2.1. The name of the device

GenBody COVID-19 Ag

2.2. The variants

Product Name	Contents	Number
GenBody COVID-19 Ag - Cat.No.COVIAG025	GenBody COVID-19 Ag test device	25 ea
	Extraction solution	2 ea
	Extraction tube	25 ea
	Disposable dropper cap	25 ea
	Sterilized nasopharyngeal swabs for sample collection	25 ea
	Sterilized oropharyngeal swabs for sample collection (optional)	25 ea
	Instructions for use	1 sheet

2.3. Components

Cat.No. COVAG025

Name	Composition	Quantity	CAS number
Test device	Anti COVID-19 monoclonal antibody	QS	N/A
	Anti-Nus monoclonal antibody	QS	N/A
	Nus-gold conjugate	QS	N/A
	Anti COVID-19 monoclonal antibody conjugate	QS	N/A
	Absorbance pad	QS	N/A
	Conjugation pad	QS	N/A
	Nitrocellulose membrane	QS	N/A
Outer plastic ware	Poly Ethylene	N/A	N/A
Silica gel	Silica gel	N/A	N/A

2.4. Classification of the product

EDMA code: 15 04 80 90 00 Other Viral Antigen/Antibody Detection
IVDD Classification: Others
(Neither Listed in Annex II of IVDD, nor self-testing device)

2.5. Additional special equipment

N/A

2.6. The microbiological state if appropriate

N/A

3. A Short description of the intended use and operation of the device, containing;

3.1. Intended use

GenBody COVID-19 Ag kit is an immunochromatographic assay for the qualitative detection of SARS-CoV-2 antigen in nasopharyngeal and oropharyngeal swab from human.

3.2. History of the product

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), previously known by the provisional name 2019 novel coronavirus (2019-nCoV), is a positive-sense single-stranded RNA virus. It is contagious in humans and is the cause of the ongoing 2019–20

coronavirus outbreak, an epidemic of coronavirus disease 2019 (COVID-19) that has been designated a Public Health Emergency of International Concern by the World Health Organization (WHO).

SARS-CoV-2 has close genetic similarity to bat coronaviruses, from which it likely originated. An intermediate reservoir such as a pangolin is also thought to be involved in its introduction to humans. From a taxonomic perspective SARS-CoV-2 is classified as a strain of the species severe acute respiratory syndrome-related coronavirus (SARSr-CoV). To avoid confusion with the disease SARS, the WHO sometimes refers to the virus as "the virus responsible for COVID-19" in public health communications.

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS coronavirus 2 or SARS-CoV-2), a virus closely related to the SARS virus. The disease was discovered and named during the 2019–20 coronavirus outbreak. Those affected may develop a fever, dry cough, fatigue, and shortness of breath. A sore throat, runny nose or sneezing is less common. Cases can progress to pneumonia and multi-organ failure.

The infection is spread from one person to others via respiratory droplets produced from the airways, often during coughing or sneezing. Time from exposure to onset of symptoms is generally between 2 and 14 days, with an average of 5 days. The standard method of diagnosis is by reverse transcription polymerase chain reaction (rRT-PCR) from a nasopharyngeal swab or sputum sample, with results within a few hours to 2 days. Antibody assays can also be used, using a blood serum sample, with results within a few days. The infection can also be diagnosed from a combination of symptoms, risk factors, and a chest CT scan showing features of pneumonia.

Hand washing, maintaining distance from people who are coughing and not touching one's face with unwashed hands are measures recommended to prevent the disease.[26] It is recommended to cover one's nose and mouth with a tissue or a bent elbow when coughing. Those who suspect they carry the virus are recommended to wear a surgical face mask and seek medical advice by calling a doctor rather than visiting a clinic in person. Masks are also recommended for those who are taking care of someone with a suspected infection but not for the general public. There is no vaccine or specific antiviral treatment, with management involving treatment of symptoms, supportive care, and experimental measures. The case fatality rate is estimated at between 1% and 3%.

The WHO has declared the 2019–20 coronavirus outbreak to be a Public Health Emergency of International Concern (PHEIC). As of 29 February 2020, China, Hong Kong, Iran, Italy, Japan, Singapore, South Korea and the United States are areas having evidence of community transmission of the disease.

4. Measures to protect personnel

- Wear disposable powder-free gloves, face mask and lab coats
- No drinks or foods in working place
- Trained personnel use only
- Other general precautions are listed in the user's manual.

5. Protocol

5.1. Materials provided

GenBody COVID-19 Ag contains the following items:

Contents	COVIAG025
GenBody COVID-19 Ag test device	25 ea
Extraction solution	2 ea
Extraction tube	25 ea
Disposable dropper cap	25 ea
Sterilized nasopharyngeal swabs for sample collection	25 ea
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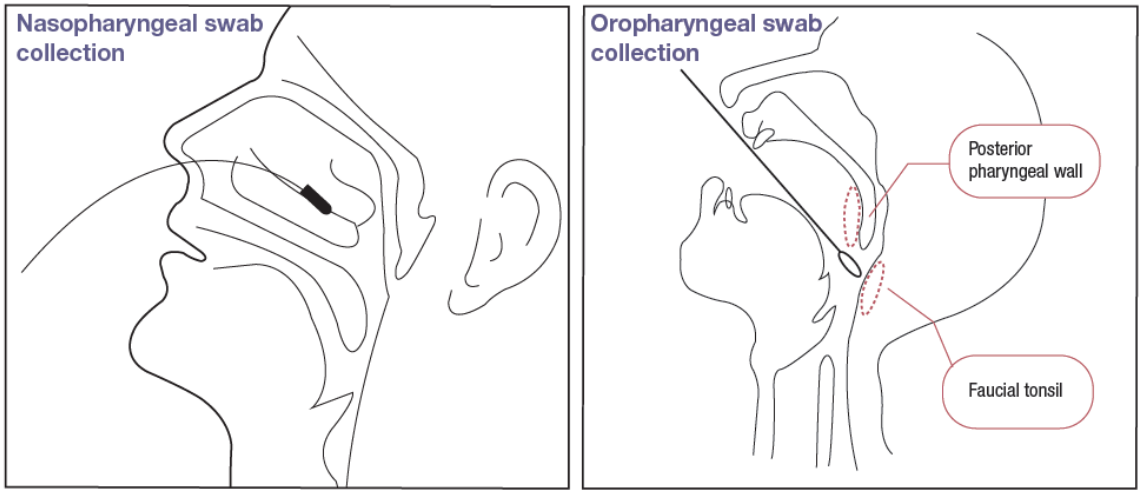
5.2. Specimen collection



(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 a few 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 because an insufficient collection of specimen is thought about.

(4) All specimens should be tested as soon as early 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.

5.3. Storage and precaution

(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 (4 drops) to the center of sample well area.
(5) Bring test plate and extraction solution to 15 - 30 °C prior to testing.
(6) Keep interpretation time because it causes false negative and false positive.
(7) When using samples from viral/universal transport media, It may cause inaccurate results due to decrease in test sensitivity.
(8) When using swab for specimen collection, DO NOT use Nucleic Acid Preservation & Transport (NAPT) Medium.

5.4. Test procedure

(1) Place all specimens, test devices, and assay solution at room temperature prior to testing (15~30min).
(2) Place the device on a flat surface.
(3) Fill the Extraction tube with Extraction solution up to the buffer line (400 $\mu\ell$).

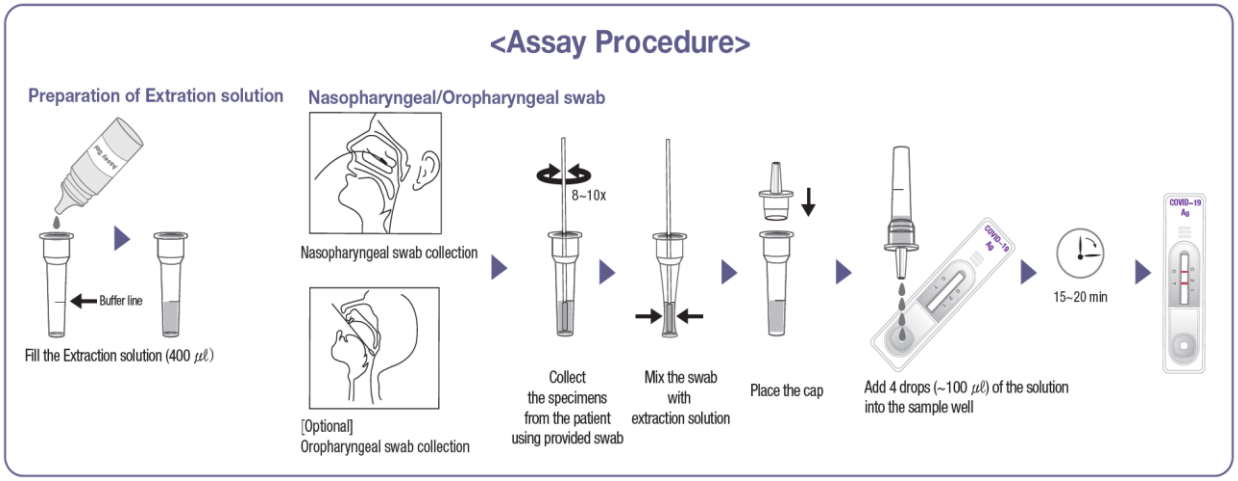
(4) Insert the both nasopharyngeal and oropharyngeal swab samples into the extraction solution, then, mix the swab 8~10 times.

(5) Remove the swabs while pressing against the solution tube in order to extract most of the specimen.

(6) Place the dropper cap and drop 4 drops (~100 ㎕) into the sample well [S]

(7) After 15~20 minutes, interpret the test results. Please do not read the results after 30 minutes of this testing.

* Using of oropharyngeal swab is optional.



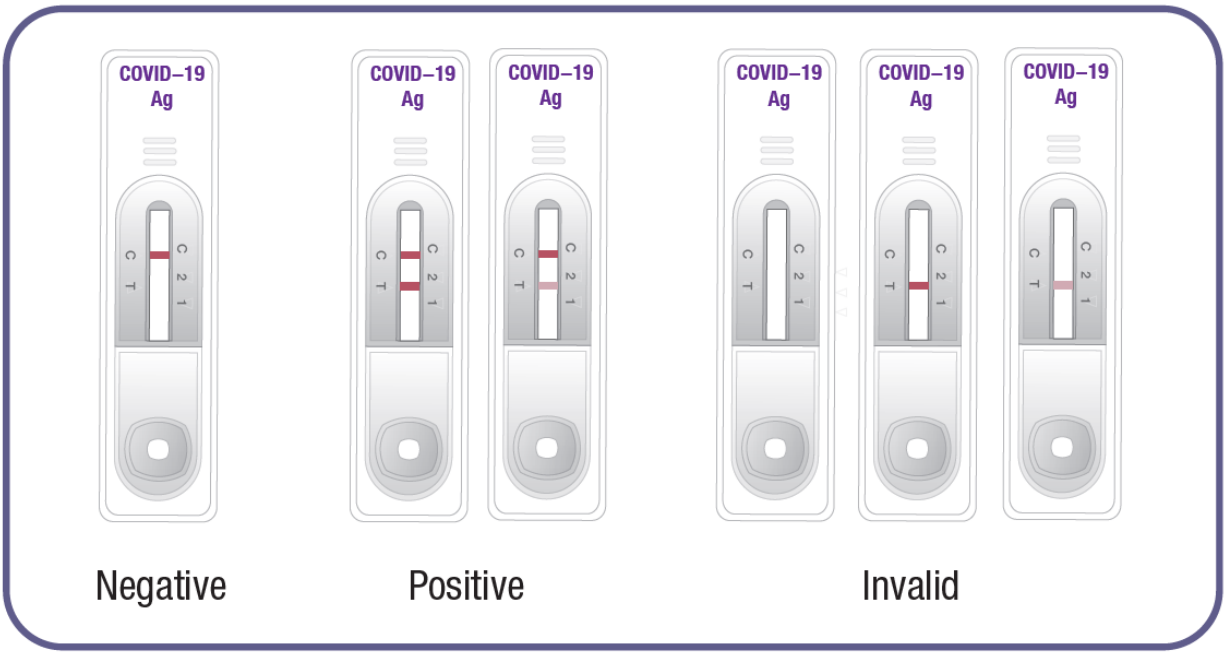
5.5. Reading and interpretation of results

(1) Negative result: ONLY one band in the control line (C).

(2) Positive result: Two bands are appeared in the test line (T) and control line (C).

(3) Invalid result:

If a red color band dose 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]

(1) Using Confiscope G20 is optional.

(2) Please refer to the instructions for use in analyzer package.


Confiscope G20

5.6. Storage and expiration

(1) GenBody COVID-19 Ag 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.

5.7. Limitations of the method

GenBody COVID-19 Ag is designed for the primary screening test of SARS-CoV-2 antigen and only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.

5.8. Precautions

1. For *in vitro* diagnostic use only. Do not use after expiry date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged.

4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
5. The used test should be discarded according to local regulations.
6. Keep out of the reach of children.