GenBody COVID-19 Ag

Detection kit for SARS-CoV-2 antigen in nasopharyngeal and oropharyngeal swab from human

IVD CE

2020.06.22 (Rev.1)

INTENDED USE

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.

EXPLANATION OF THE TEST

GenBody COVID-19 Ag is an immunoassay kit for rapid and qualitative determination of SARS-CoV-2 infection from swab specimens. Antigens of SARS-CoV-2 in the specimens are allowed to react with the anti-SARS-CoV-2 monoclonal antibody-coupled gold conjugate followed by reaction with anti-SARS-CoV-2 monoclonal antibodies immobilized in the test line. When the sample contains SARS-CoV-2 antigens, a visible line appears in the test region on 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. GenBody COVID-19 Ag is also very useful to directly detect SARS-CoV-2 antigens from human swab samples.

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. Sterilized oropharyngeal swabs for sample collection (optional)
7. Instructions for use

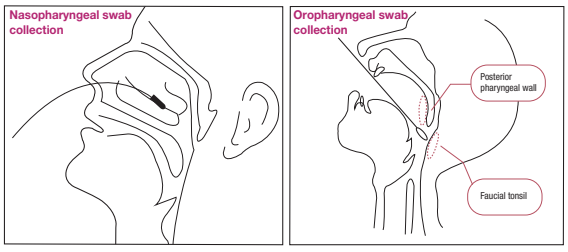
MATERIALS REQUIRED BUT NOT PROVIDED

1. Medical mask and medical latex gloves
2. Specimen collection container
3. Micropipette and disposable pipette tips
4. 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 (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 and 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 specimen.
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.

TEST PROCEDURE

[Nasopharyngeal swab/Oropharyngeal swab* test procedure]

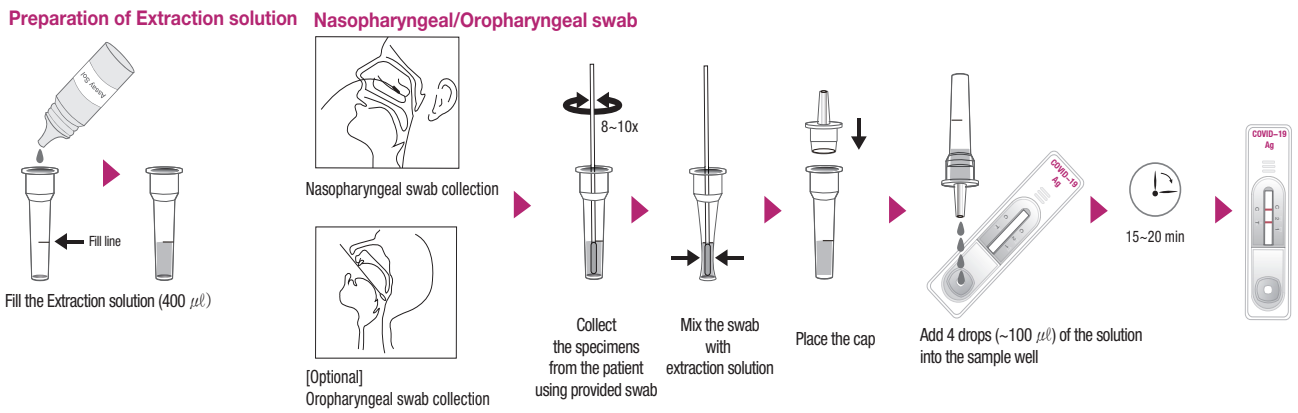
1. Place all specimens, test devices, and assay solution at room temperature prior to testing (15~30min).
2. Place the device on a flat surface.
3. Fill the Extraction tube with Extraction solution up to the buffer line (400 $\mu\ell$).
4. Insert the nasopharyngeal (and oropharyngeal) swab sample(s)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

* The use of oropharyngeal swab is optional.

INTERPRETATION OF THE 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 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.

<Assay Procedure>



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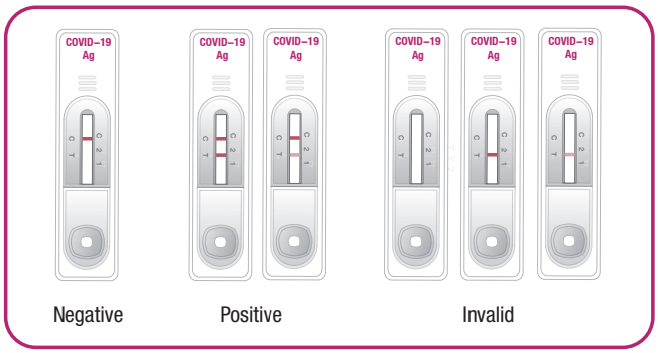


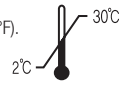
[Use analyzer]

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

Confiscope G20

STORAGE & EXPIRATION

1. GenBody COVID-19 Ag 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

- Detection limit (LoD): 2.87 x 10^3 $TCID_{50}$/ml (heat-inactivated culture fluid).
- Cross-reactivity: There 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.

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 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%)

LIMITATIONS OF THE TEST

GenBody COVID-19 Ag is designed for the primary 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.

REF COVAG025

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CHANGE AND INNOVATION

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