GenBody COVID-19 Ag

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

EN IVD

2021.07.12 (Rev.3.5)

TEST PROCEDURE

[Nasopharyngeal swab/Oropharyngeal swab* test procedure]

1. Place all specimens, test devices, and Extraction solution at room temperature prior to testing (15~30min).
2. Place the device on a flat surface.
3. Open the sealed cover of extraction tube.
4. Insert the nasopharyngeal swab sample 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 is required.
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 using of oropharyngeal swab is optional.

[Viral Transport Media (VTM) or Universal Transport Media (UTM) test procedure]

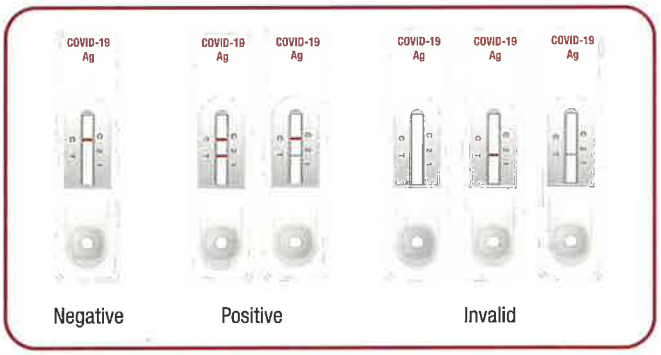
8. Place all specimens, test devices, and Extraction solution at room temperature prior to testing (15~30min).
9. Place the device on a flat surface.
10. Open the sealed cover of extraction tube and pull out the solution 200 $\mu\ell$ from the tube by using the pipette.
11. Add 200 $\mu\ell$ VTM (or UTM) sample into the extraction tube.
12. Place the dropper cap and mix strongly.
13. Drop 4 drops (~100 $\mu\ell$) into the sample well [S].
14. After 15~20 minutes, interpret the test results.

⚠ Please do not read the results after 30 minutes of this testing.

⚠ Please do not use the Nucleic Acid Preservation & Transport (NAPT) Medium.

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.



[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 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

1. **Analytical sensitivity/cross-reactivity**
   - Detection limit (LoD): 5.07 x 10^2 $TCID_{50}$/ml (SARS-CoV-2 heat-inactivated culture fluid).
   - Cross-reactivity: There was cross-reactivity of SARS-CoV. 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**
   The clinical performance of the GenBody COVID-19 Ag kit was determined by testing Five hundred six (n=506) residual wet NP swabs (In the United States and Republic of Korea). Upon receiving the swabs, they were placed in individual collection tubes containing 400 $\mu\ell$ of GenBody extraction solution and mixed thoroughly as instructed in the GenBody COVID-19 Ag kit IFU. Each sample was then subjected to Antigen testing (GenBody COVID-19 Ag), RNA extraction, and molecular assay (FDA-EUA or MFDS-EUA authorized RT-PCR) in parallel. If simultaneous testing was not possible, the collection tubeswere sealed and stored at -75 °C accordingly. The table below summarizes the clinical performance analysis results on GenBody COVID-19 Ag kit.

		Real-Time PCR		Total
		Positive	Negative	
GenBody COVID-19 Ag	Positive	122	3	125
	Negative	15	366	381
Total		137	369	506

- Sensitivity: 89.05% (95% CI: 82.58% to 93.74%)
- Specificity: 99.19% (95% CI: 97.64% to 99.83%)
- Positive Predictive Value: 97.60% (95% CI: 92.94% to 99.21%)
- Negative Predictive Value: 96.06% (95% CI: 93.80% to 97.52%)
- Accuracy: 96.44% (95% CI: 94.44% to 97.88%)

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.

⚠ Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

⚠ Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1 and SARS-CoV.

COMPOSITION

1-test device contains:

Test line: Anti-SARS-CoV-2 NP monoclonal antibody.....0.96±0.192 μg

Control line: Anti-Nus monoclonal antibody .....0.96±0.192 μg

Gold conjugate: Rec. Nus-colloidal gold conjugate .....0.2±0.04 μg

Gold conjugate: Anti-SARS-CoV-2 NP monoclonal antibody-colloidal gold conjugate ..0.5±0.1 μg

REF COVAG025-1

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CHANGE AND INNOVATION

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INTERNATIONAL SYMBOL USAGE

	Use-by date	LOT	Batch code	IVD	*In vitro* diagnostic medical device	CE	CE Mark
REF	Catalog number		Consult instructions for use		Manufacturer	Σ	Contains sufficient for <n> tests
	Temperature limit	EC REP	Authorized representative in the European Community		Do not reuse		Caution
TEST	Test Device	CAP DROP	Dropper Cap	EXT TUBE	Extraction Tube	EXT SOLN	Extraction Solution

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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. Disposable dropper cap
4. Sterilized nasopharyngeal swabs for sample collection
5. Sterilized oropharyngeal swabs for sample collection (optional)
6. Instructions for use

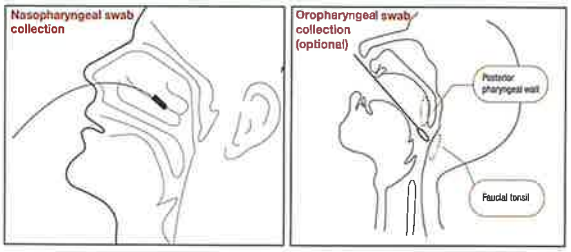
MATERIALS REQUIRED BUT NOT PROVIDED

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 at room temperature (15-30°C) prior to testing (15 -30 min).
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 transport media for collecting specimen, DO NOT use Nucleic Acid Preservation & Transport (NAPT) Medium.

SPECIMEN COLLECTION AND STORAGE

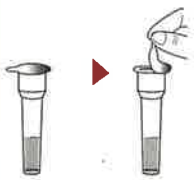


9. Specimen to be tested should be obtained and handled by standard methods for their collections.
10. Nasopharyngeal swab specimen:
    To collect nasopharyngeal specimen, carefully insert the sterile swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab till 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.
11. [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.
12. All specimens should be tested as soon as they are collected.
13. In case of direct sampling (using Nasopharyngeal/Oropharyngeal swab), extraction solution contain specimen may be stored at room temperature for up to 1 hour or at 2-8°C (36-46 °F) for up to 12 hours prior to testing.

⚠ In case of using VTM/UTM samples, avoid multiple freeze/thaw cycles.

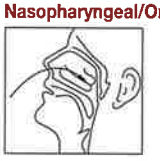
<Assay Procedure>

Preparation of Extraction solution



Open the sealed cover.

Nasopharyngeal/Oropharyngeal swab



Nasopharyngeal swab collection

[Optional]
Oropharyngeal swab collection

Collect the specimens from the patient using provided swab

Mix the swab with extraction solution

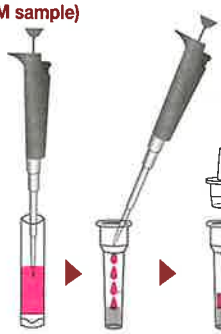
Place the cap

Add 4 drops (~100 $\mu\ell$) of the solution into the sample well

Read the test results

Preparation of Extraction solution (VTM/UTM sample)

Open the sealed cover and pull out the Extraction solution 200 $\mu\ell$ from the extraction tube.



Fill 200 $\mu\ell$ VTM or UTM specimen

Place the cap

Mix strongly

⚠ **When using samples from viral/universal transport media, it may cause inaccurate results due to decreasing the sensitivity of the test.**

Add 4 drops (~100 $\mu\ell$) of the mixture into the sample well

Read the test results