GenBody COVID-19 Ag

EN IVD CE

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

2020.11.11 (Rev.3.1)

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. Fill the Extraction tube with Extraction solution up to the buffer line (400 ㎕).
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 ㎕) 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]

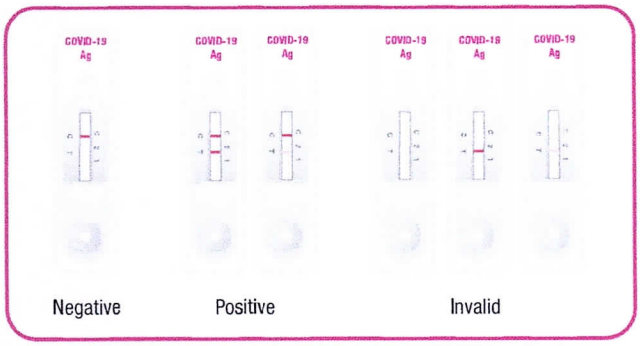
1. Place all specimens, test devices, and Extraction solution at room temperature prior to testing (15~30min).
2. Place the device on a flat surface.
3. Fill the Extraction tube with Extraction solution up to 4 drops (~100 ㎕).
4. Using pipette, add 100 ㎕ VTM (or UTM) sample in the Extraction tube, then, mix strongly.
5. Add 100 ㎕ of the mixture to the sample well [S].
6. 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.



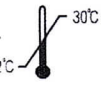
[Use analyzer]

- 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 12 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 evaluation for the GenBody COVID-19 Ag Test for rapid detection of SARS-CoV-2 antigen was conducted at the 2 sites in Korea and U.S.A. and, 351 residual and selected specimens in VTM from persons. The clinical evaluation were compared to Korean MFDS EUA and FDA EUA authorized molecular assays.

		Real-Time PCR		Total
		Positive	Negative	
GenBody COVID-19 Ag	Positive	72	2	74
	Negative	3	274	277
Total		75	276	351

- Sensitivity = 96.0% (95% CI = 88.75% to 99.17%)
- Specificity = 99.28% (95% CI = 97.41% to 99.91%)

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.

CE

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REF COVAG025

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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