Product Insert

IVD CE 0123

COVID-19 Ag Test Kit

【Version No】 0003

【Issued Date】 2021-04-28

【Packaging Specifications & REF ID】

1 test/kit(BE0081), 5 tests/kit(BE0082), 10 tests/kit(BE0083), 20 tests/kit(BE0080).

【Intended Use】

The COVID-19 Ag Test Kit is intended for self testing the SARS-CoV-2 nucleocapsid protein. This test is authorized for self-collected human anterior nasal (AN) swab specimens from individuals who are suspected of COVID-19 within the first seven (7) days of symptom onset.

Individuals under the age of 18 completed the sampling and testing accompanied by their parents or guardians.

【Summary and Explanation】

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

【Principle of the procedure】

The COVID-19 Ag Test Kit is based on the principle of lateral flow colloidal gold immunoassay, which is intended for the qualitative detection of nucleocapsid protein from SARS-CoV-2 in anterior nasal (AN) swab specimens from individuals who are suspected of COVID-19 within the first seven (7) days of symptom onset. When the sample is added to the sample well, the nucleocapsid protein in the sample reacts with the gold-labeled antibody. It forms an immuno-complex, which flows onto the nitrocellulose membrane. When the immuno-complex reaches the T Line (Test band), it reacts with the COVID-19 antibody pre-coated on the nitrocellulose membrane then develops color on the T Line (Test band), which indicates a positive result. Regardless of whether the sample contains nucleocapsid protein, the gold labeled quality control antigen will bind to the coated antibody at the C band and develop color.

【Reagents and Materials Provided】

Component	Description	1 test/kit		5 tests/kit		10 tests/kit		20 tests/kit	
		BE0081		BE0082		BE0083		BE0080	
		Quantity	Specification	Quantity	Specification	Quantity	Specification	Quantity	Specification
Test Cassette	Foil pouched test device containing one reactive strip. Each strip has COVID-19 antibody, quality control antigen and antibody.	1	Individual package	5	Individual package	10	Individual package	20	Individual package
Specimen Collection Swab	For sample collection and transfer.	1	-----	5	5 per bag	10	10 per bag	21	21 per bag
Lysis Buffer	Buffer with 0.05% Proclin 300 and 0.1-5.0% SDS.	1	0.6 mL per tube	5	0.6 mL per tube	10	0.6 mL per tube	21	0.6 mL per tube
Nozzle Cap with Protective Cover	Components for Test	1 Copy	-----	5	5 per bag	10	10 per bag	21	21 per bag

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Component	Description	1 test/kit		5 tests/kit		10 tests/kit		20 tests/kit	
		BE0081		BE0082		BE0083		BE0080	
		Quantity	Specification	Quantity	Specification	Quantity	Specification	Quantity	Specification
Product Insert	Instructions for use	1 Copy	-----	1 Copy	-----	1 Copy	-----	1 Copy	-----
Medical waste bag	For collecting medical waste	1	-----	5	-----	10	-----	20	-----
Quick User Guide	Guide use	1	-----	1	-----	1	-----	1	-----

Materials Required but not Provided

The timer and Disinfection products, such as hand sanitizer, rubbing alcohol, soap, etc

【Warnings and Precautions】

1. This kit is for *in vitro* diagnostic use.
2. If uncertain how to proceed, scan QR code to watch operation video or contact Technical Assistance, contact information as shown on packing box.
3. Do not use cassettes which are damaged or have an unclear label or expired.
4. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
5. When collecting anterior nasal (AN) swab sample, use the Specimen Collection Swab supplied in the kit. Use of alternative swabs may result in false test results.
6. Samples with invalid results must be retested.
7. The cassette is for one time use only. The used test Cassette, used lysis buffer, used nozzle cap with protective Cover and used specimen collection swab should be treated as potential bio-hazardous materials.
8. Do not eat the desiccant in the foil pouch.
9. Do not reuse the used Test Cassette, fixed Lysis buffer, used Nozzle and used Specimen Collection Swab.
10. Do not interchange or mix components from different kit lots.
11. Wash hands thoroughly use hand sanitizer or soap before and after handling.
12. After the test, dispose the used test Cassette, used lysis buffer, used nozzle cap with protective Cover and used specimen collection swab into the medical waste bag.
13. When the test result is close to the critical value and the user is unable to determine the test result, it is recommended to go to the hospital for professional diagnosis. Interpretation of critical value: when the operation is correct, the color of control band is normal, and the color of test band is very weak, which leads to the unavailability of correct interpretation by the layman.
14. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. The agent detected may not be the definite cause of the disease. Persons who test positive should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary and for public health reporting.
15. Negative results should be treated as presumptive, and do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.
16. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay, if necessary, for patient management.

【Storage and Stability】

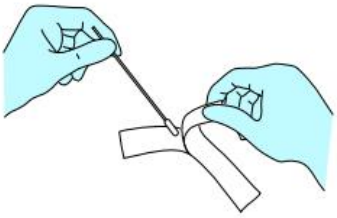
Store at room temperature (2-30℃ or 35.6-86℉) in a dry shady place. Avoid direct sunlight.
18 months of shelf life (production date to expiration date).

【Sample Collection】

Sample Collection for anterior nasal swab

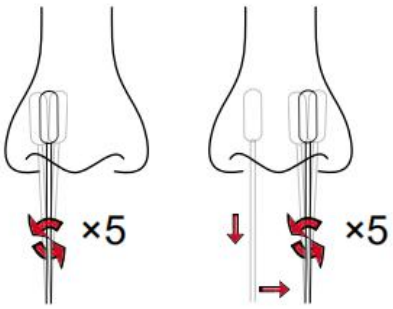
Take a specimen collection swab from the pouch. Carefully insert the swab into one nostril of the patient about 2-3 cm. Slowly scrape the nasal wall for 5 times. Repeat this process at the other nostril by using the same swab to ensure that an adequate sample is collected from both nasal cavities. Then slowly take out the specimen collection swab from the nostril. It is recommended to hold your breath when taking an anterior nasal swab.

Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results.

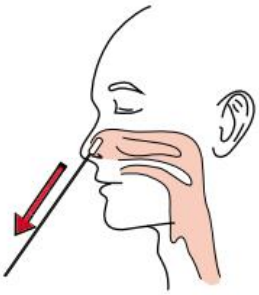


1. Take a specimen collection swab from the pouch.

2. Carefully insert the swab into one nostril of the patient about 2-3 cm.



3. Slowly scrape the nasal wall for 5 times. Repeat this process at the other nostril by using the same swab to ensure that an adequate sample is collected from both nasal cavities.



4. Then slowly take out the specimen collection swab from the nostril. It is recommended to hold your breath when taking an anterior nasal swab.

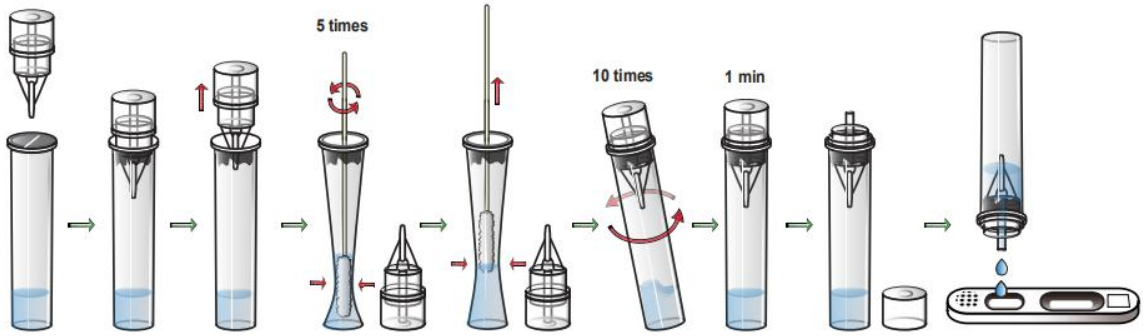
【Test Procedure】

Caution: Please read the product insert of the kit carefully. Before starting the test, wash your hands use hand sanitizer.

1. Pierce the sealing membrane of lysis buffer tube with the tip of nozzle cap.
2. Unplug the nozzle cap from the tube and place it on the workbench with the protective cover facing down. Be careful not to touch the nozzle tip to avoid contamination.Insert the swab into the lysis buffer tube. Squeeze the tube and stir the swab for 5 times.
3. Keep squeezing the tube and remove the swab. Make sure all the liquid from the swab is removed.
4. Install the nozzle cap with the protective cover facing up. Mix the tube by gently shaking for 10 times. Let stand for 1 minute.
5. Remove the protective cover. Add three drops of processed specimen vertically into the sample

well, and then let stand for 15 minutes.

6. Read the test result immediately, the test result will be invalid after 30 minutes.

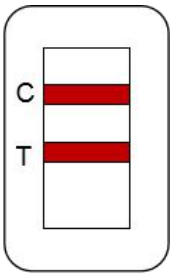
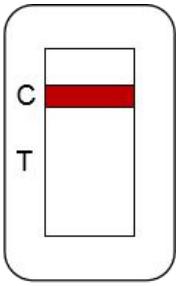


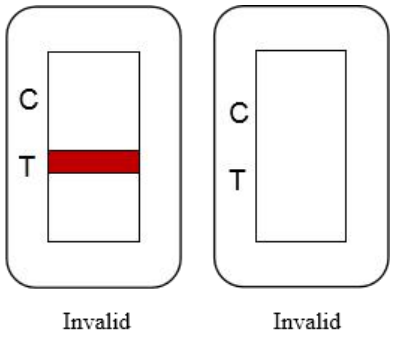
Caution: Keep the COVID-19 Ag Test Cassette in sealed foil pouch prior to use. Under the condition of 45-65% humidity and 15-25°C, the cassette should be used within 30 minutes once the foil pouch is opened. If the temperature ≥ 30℃ or under conditions of high humidity, it should be used within 5 minutes after the foil pouch is opened.

【Disposal】

Discard all materials in a safe and acceptable manner and in compliance with all federal, state, and local regulations.

【Interpretation of Results】

Positive: colored bands appear at both test band (T) and control band (C).	 Positive
Negative: colored band appears at control band (C) only.	 Negative

Invalid: no visible colored band appears at the control band. The test procedures may not be followed correctly, or the cassette has deteriorated. It is recommended to retest the specimen.	

Note: The color intensity of the test band (T) may vary according to the concentration of antigen in the sample. The lower the concentration, the weaker the intensity. The determination of a positive result should be based on the presence of the test band (T) and control band (C), regardless of whether the test band (T) is weaker than the control band (C).

If the test results are positive, be sure to isolate from other people. Don't visit or invite others, don't go to the store, wear masks around the house and follow the distance rules. Contact your family doctor and / or health department immediately for further instructions. The positive test should be confirmed by PCR. As a precaution, please inform your contact about potential infection.

Although the test result is negative, the infection prevention rules must be observed.

【Limitations of the Procedure】

1. The test results of this product are for diagnostic aid only and cannot be used as the sole basis for confirming or excluding the diagnosis. To achieve diagnostic purposes, the results should always be assessed in combination with clinical examination, medical history, and other laboratory data.
2. This product is only used for the qualitative detection of the SARS-CoV-2 nucleocapsid protein in human anterior nasal swab, but not for quantitative detection.
3. This product is only for the initial screening test. The disease diagnosis should be made in conjunction with clinical observations, patient history, epidemiological information, and other laboratory evidence.
4. Subject to the limitations of the assay methodology, the questionable results should be verified with RT-PCR.
5. Positive test results do not rule out co-infections with other pathogens.
6. Cross reactive cause by SARS-coronavirus Tor2 and Human coronavirus HKU1 may lead positive results.
7. False test results may occur if a specimen is improperly collected, transported, or handled.
8. False-negative test results may occur if the level of an antigen in a sample is below the detection limit of the test.
9. False positive results may occur, particularly in individuals without COVID-19 symptoms and/or individuals who live in areas with low numbers of COVID-19 infections and without known exposure to COVID-19.
10. Negative results should be treated as presumptive, and confirmation with another SARS-COV-2 assay, if necessary, should be done.
11. Faint visible band should be interpreted as positive.

12. Samples and kits should be treated as potential sources of infection.
13. Positive test results do not differentiate between SARS-coronavirus Tor2 and SARS-CoV-2.
14. Positive test results do not differentiate between Human coronavirus HKU1 and SARS-CoV-2.
15. The prevalence of infection will affect the test's predictive values.
16. Positive and negative predictive values are highly dependent on prevalence. False-negative test results are more likely during peak activity when the prevalence of the disease is high. False-positive test results are more likely during the periods of low SARS-CoV-2 activity when prevalence is moderate to low.
17. In order to ensure the validity of the test, the C-band was added as the quality control band.

【Clinical Performance】

The study is intended to evaluate if an untrained user (self-tester) can perform the test autonomously. The performance of the COVID-19 Ag Test Kit in possible home use / personal use were evaluated and the reproducibility of the results in comparison to a professional user was be verified. The self-tester must take a sample from the anterior nasal part of the nose, perform the test and understand the results correctly. The whole study is supervised by the Physician and is monitored so that an objective and neutral assessment by a specialist is ensured. Supporting documents are solely the IFU and the Quick-User-Guide.

The observation of the Physician is that among the sample group 88.0% of the self-test-participants conducted the test correctly. The average score of self-test-participants answers from questionnaire of 89.0% and an average score of the self-Testing procedure by Physician assessment of 90.0% results in a Usability Score of 90.0%.

Self-Testing by Subject	Testing of Subject by Doctor		
Positive	True Positive	False Positive	Total
	13	0	13
Negative	False Negative	True Negative	Total
	0	95	95
Total	13	95	108
Positive Percent Agreement (PPA)	100.0% (95% CI: 71.66% to 100.00%)		
Negative Percent Agreement (NPA)	100.0 % (95% CI: 95.16% to 100.00%)		
Overall percent agreement	100.0%		
Result reproductivity	100.0%		
Subject has done Test correctly according to the Physician's Assessment	88.0%		

Average Score of Subject Answers from Questionnaire	89.0%
Average Score of the Self Testing Procedure by Physician's Assessment	90.0%
Usability Score	90.0%

In this clinical study, 500 participants were tested with COVID-19 Ag Test Kit and RT-PCR. It includes 364 negative samples and 136 positive samples. An RT-PCR assay is utilized as the comparator method for the study. The performance of the COVID-19 Ag Test Kit as compared to the RT-PCR comparator method are presented in the table below:

The COVID-19 Ag Test Kit (Anterior nasal swab)	RT-PCR		
Positive	True Positive	False Positive	Total
	112	1	113
Negative	False Negative	True Negative	Total
	24	363	387
Total	136	364	500
Positive Percent Agreement (PPA)	82.4% (95% CI: 74.68% to 88.15%)		
Negative Percent Agreement (NPA)	99.7 % (95% CI: 98.24% to 99.99%)		
Overall percent agreement	95.0%		

*CI: Confidence Interval

【Analytical Sensitivity】

Limit of detection (LOD)

The confirmed LOD for the COVID-19 Ag Test Kit are showed as follow.

Matrix	LOD Concentration $TCID_{50}$/mL	Number of Positive/Total	% Detected
Anterior nasal swab	$8.0 \times 10^{2.0}$	20/20	100 %

【Analytical Specificity】

Cross Reactivity and Microbial Interference

The table below summarizes the data from the cross reactivity studies and microbial interference studies:

Virus/Bacteria/Parasite name	Strain	Source/ Sample type	Test Concentration	Cross Reactivity Results	Interference Results
Human coronavirus	229E	Isolate	$1.4 \times 10^{5.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Human coronavirus	OC43	Isolate	$1.4 \times 10^{5.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Human coronavirus	NL63	Isolate	$1.4 \times 10^{3.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
MERS-coronavirus	EMC/2012	Inactivated virus	$1.4 \times 10^{5.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Adenovirus	Serotype 5	Isolate	$1.4 \times 10^{5.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Human metapneumovirus (hMPV)	TN/91-320	Isolate	$1.4 \times 10^{5.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Human parainfluenza virus 1	HPIV1/FRA/292211 06/2009	Isolate	$1.4 \times 10^{5.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Human parainfluenza virus 2	Greer	Isolate	$1.4 \times 10^{5.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Human parainfluenza virus 3	NIH 47885	Isolate	$1.4 \times 10^{5.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Human parainfluenza virus 4a	M-25	Isolate	$1.0 \times 10^{3.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Human parainfluenza virus 4b	19503	Isolate	$1.4 \times 10^{5.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference

Virus/Bacteria/Parasite name	Strain	Source/ Sample type	Test Concentration	Cross Reactivity Results	Interference Results
Influenza A	A/California/07/2009	Isolate	$1.4 \times 10^{5.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Influenza B	B/Hong Kong/330/2001 (Victoria Lineage)	Isolate	$1.4 \times 10^{5.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Enterovirus	71/Tainan/4643/98	Isolate	$1.4 \times 10^{5.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Respiratory Syncytial Virus A	1998/12/21	Isolate	$1.4 \times 10^{5.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Rhinovirus	16	Isolate	$1.4 \times 10^{5.0}$ $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Haemophilus influenzae	Type B CK (Lehmann and Neumann) Winslow *et al*.	Isolate	$1.0 \times 10^{6.0}$ cells/mL	No Cross-Reactivity	No Interference
Streptococcus pneumoniae	(Klein) Chester	Isolate	$1.0 \times 10^{6.0}$ cfu/mL	No Cross-Reactivity	No Interference
Streptococcus pyogenes	Typing strain T1 [NCIB 11841, SF 130] Rosenbach	Isolate	$1.0 \times 10^{6.0}$ org/mL	No Cross-Reactivity	No Interference
Pooled human nasal wash	N/A	Isolate	100%	No Cross-Reactivity	No Interference
Bordetella pertussis	18323 [NCTC 10739] (Bergey *et al*.) Moreno-Lopez	Isolate	$1.0 \times 10^{6.0}$ cells/mL	No Cross-Reactivity	No Interference
Mycoplasma	FH strain of Eaton	N/A	$1.0 \times 10^{6.0}$ cfu/mL	No Cross-Reactivity	No Interference

Virus/Bacteria/Parasite name	Strain	Source/ Sample type	Test Concentration	Cross Reactivity Results	Interference Results
pneumoniae	Agent [NCTC 10119] Somerson *et al*.				
Chlamydia pneumoniae	TW-183	Isolate	1.0 x $10^{6.0}$ IFU/mL	No Cross-Reactivity	No Interference
Legionella pnuemophila	Philadelphia1, Brenner *et al*.	Isolate	1.0 x $10^{6.0}$ cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus aureus	CDC 55, Rosenbach	Isolate	1.0 x $10^{6.0}$ cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus epidermidis	1191 (Winslow and Winslow) Evans	Isolate	1.0 x $10^{6.0}$ cfu/mL	No Cross-Reactivity	No Interference
Candida albicans	Y537	Isolate	1.0 x $10^{6.0}$ cfu/mL	No Cross-Reactivity	No Interference

To predict the potential of Cross Reactivity with SARS-CoV-2 of organisms that were not available for wet testing, in silico analysis using the Basic Local Alignment Search Tool (BLAST), available on the web on the National Center for Biotechnology Information (NCBI), was used to assess the degree of protein sequence homology. The analysis procedure was first, downloaded all subjects of amino acid sequences of each substance from the NCBI database or directly searched on the database by limiting specific organism and then executed Protein-protein BLAST (blastp) to the SARS-CoV-2 nucleocapsid protein (Sequence ID: YP_009724397.2).

- The homology between SARS-CoV-2 nucleocapsid protein and SARS-coronavirus Tor2 nucleocapsid protein (Sequence ID: YP_009825061.1) is high at 91% identities and 94% positives on 100% query coverage. The cross reactivity between two substances cannot be ruled out. The microbial interference was not identified.
- No significant similarity was found between SARS-CoV-2 nucleocapsid protein and *Mycobacterium tuberculosis* with Protein-protein BLAST searched 1,781 *Mycobacterium tuberculosis* proteins. Thus homology-based cross reactivity can be ruled out. The microbial interference was not identified.
- The homology between SARS-CoV-2 nucleocapsid protein and Human coronavirus HKU1 nucleocapsid protein (Sequence ID: YP_173242.1) is at 37% identities and 54% positives of 82% query coverage. Homology is relatively low, but the cross reactivity cannot be ruled out. The microbial interference was not identified.
- No significant similarity was found between SARS-CoV-2 nucleocapsid protein and *Pneumocystis jirovecii* (PJP) with Protein-protein BLAST searched 3,776 Pneumocystis jirovecii proteins. The

weak or no cross reactivity is predicted between the two substances. Thus homology-based cross reactivity can be ruled out. The microbial interference was not identified.

【Endogenous Interfering Substances Studies】

Endogenous interference substances studies of the COVID-19 Ag Test Kit were evaluated by testing the following substances listed in the table. Each substance was tested in triplicate (3) with 3x LOD, inactivated SARS-CoV-2 virus (NR-52286). All samples tested produced expected results, demonstrating that the COVID-19 Ag Test Kit performance was not affected by any of the 14 potentially interfering substances listed in the table below at the concentrations tested.

The table below summarizes the data from the endogenous interference substances studies:

Potential Interfering Substances	Active Ingredient	Test Concentration	Results
Whole Blood	Blood (human)	4.0 % V/V	No Interference
Mucin	Mucin protein, Type I-S	0.5 % W/V	No Interference
Chloraseptic	Benzocaine, Menthol	0.15 % W/V	No Interference
Naso Gel (NeiMed)	Saline	5.0 % V/V	No Interference
Nasal Spray	Phenylephrine	15.0 % V/V	No Interference
Afrin	Oxymetazoline	15.0 % V/V	No Interference
Zicam	Oxymetazoline, Hydrochloride	5.0 % V/V	No Interference
Nasal Spray (Cromolyn)	Cromolyn sodium	15.0 % V/V	No Interference
Alkalol	Galphimia glauca, Luffa operculata, Sabadilla	1:10 dilution	No Interference
Sore Throat Phenol Spray	Phenol	15.0 % V/V	No Interference
Tobramycin	Tobramycin	0.0004% W/V	No Interference
Mupirocin	Mupirocin	1.0 % W/V	No Interference
Fluticasone	Fluticasone propionate	5.0 % V/V	No Interference

Propionate	(glucocorticoid)		
Tamiflu	Oseltamivir	0.5 % W/V (5 mg/mL)	No Interference

【High-dose Hook Effect】

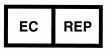
No high dose hook effect was observed when tested with up to a concentration of $1.5\times10^{5.0}$ $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus.

【REFERENCES】

1. Baker, S., Frias, L., and Bendix, A. Coronavirus live updates: More than 92,000 people have been infected and at least 3,100 have died. The US has reported 6 deaths. Here's everything we know. Business Insider. March 03, 2020.

2. Lauer, S.A., et. al. The incubation period of Coronavirus disease 2019 (COVID-19) from publicly reported confirmed cases: estimation and application, Ann Intern Med. 2020.

【SYMBOL】

SYMBOL	DESCRIPTION
	Manufacturer
	Authorized representative in the European Community
	*In Vitro* Diagnostic Medical Device
	Batch Code
	Use-by date
	Temperature Limitation
	CE Mark
	Catalogue number
	Biological risks
	Do not re-use
	Contains Sufficient for <n> Tests
	Date of manufacture
	Keep Away From Sunlight
	Consult instructions for use
	Keep Dry
SYMBOL	DESCRIPTION

Manufactured by: Guangdong Wesail Biotech Co., Ltd.

CE 0123

Address: 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China

Tel: 86-769-22890969 E-mail:customer@wesailbio.com

Website: http://en.wesailbio.com

EC REP Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

E-mail: peter@lotusnl.com

Specimen Collection Swab

Manufactured by: Shenzhen KangDaAn Biological Technology co., Ltd

CE 0197

Address: East-1, 3rd floor, Building 2, Shunheda factory, Liuxiandong industrial zone, Xili street, Nanshan district, Shenzhen.

Tel: +86-755-82836262 Fax:+86-755-83426595

Website: www.kdasw.com

EC REP Share Info Consultant Service LLC Repräsentanzbüro

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