Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)

REF	Specifications
C8611CH	1 test/kit
C8610CH	5 tests/kit
C8602CH	20 tests/kit

- ◆ A rapid antigen test for the detection of SARS-CoV-2 in nasal swab.
- ◆ For self-testing use.
- ◆ Please read the instructions carefully before testing.

Operation Video

KIT CONTENTS

Test cassette | Elution tube | Disposable swab | Instructions for Use | Disposal bag | Timer (Not included)

PREPARATION

1. Remove secretions from the surface of the anterior nasal cavity before taking the sample. Wash your hands. Make sure they are dry before testing.

2. Read the instructions.

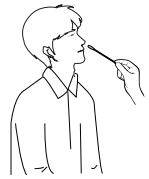
3. Check the expiration date printed on the foil pouch of the cassette.

4. Open the foil pouch and take out the cassette.

SAMPLE COLLECTION

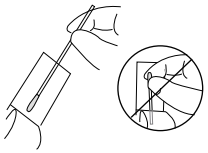
SELF COLLECTION

OPERATION BY ONE ADULT

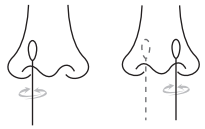


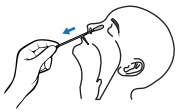
A sample of a nasal swab can be collected by a person 15 years of age older. Children aged 2 to 15 must be swabbed and tested by an adult (≥18 years old).

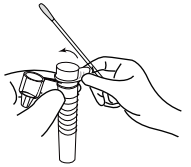
TEST PROCEDURE

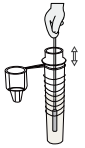
1. 
Open the package from the end of the cotton swab package, and take out the cotton swab. (**Note**: Don't touch the tips of the swab.)

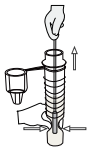
2. 
The tip of the swab should be inserted between 3 and 4 cm until resistance is felt. (**Note**: Do not insert the swab deeper if you feel strong resistance or pain.)

3. 
Roll the swab along the inner wall of the nostril 5 times. Using the same swab, repeat this process for the other nostril to ensure enough sample is taken from both nostrils.

4. 
Remove the cotton swab from the nostril.

5. 
Remove the white cap from elution tube.

6. 
Insert the sample swab into the tube (Immerse the sample part in the elution buffer), make sure the sample is removed into the sample eluent by rubbing and stirring the sampled swab up & down for 10 times.

7. 
Squeeze the tube and the swab to leave the eluent on the swab completely in the elution tube.

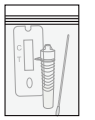
8. 
Discard the swab. Place the dropper tip on the tube and make sure the dropper tip is tightly capped.

9. 

Mix the sample by gently turning the tube upside down, squeeze the tube to dispense 4 drops (about 80 μL) into the sample well of the cassette, and start counting. (**Note**: Too large or too small drops can lead to errors or invalid test results.)

10. 

Visually read the result after 10 minutes. The result is invalid after 15 minutes.

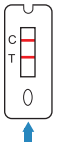
11. 
Please place the swab, tube and test cassette into the disposal bag after use.

(After opening the package, the test contents should be used within 1 hour to ensure the reliability of the result.)

INTERPRETATION OF RESULTS

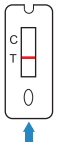
Negative

If you see only one red quality control line (C-line) in the result window, this may mean that you are negative or that the virus load is too low to be detected. Please continue to comply with all applicable rules regarding contact with others and protective measures. An infection can also be present if the test is negative. In case of suspicion, repeat the tests after 1-2 days, as the coronavirus cannot be accurately detected in all phases of an infection. Please avoiding to use the results to rule out SARS-CoV-2 infection for the purpose of travel accreditation, public event participation.

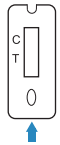


Positive

If you can see two clear red lines in both the control line (C-line) and the test line (T-line), your results are positive. There is currently a suspicion of a COVID-19 infection. Please contact a doctor or local health department immediately and have a PCR confirmatory test performed. Please follow local guidelines for self-isolation.



Invalid



Invalid

If you can't see the red line or only the T test line, but no quality control line (C-line), your results are invalid. This may have been caused by an incorrect test execution. Please repeat the test. If the test results remain invalid, contact a doctor or a COVID-19 test center.

INTENDED USE

The Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Self-testing Kit adopts the double antibody sandwich method for the qualitative detection of SARS-CoV-2 antigens in human nasal swab samples. Nasal swab samples may be self-collected by individuals over 15 years old. Individuals 2 to 15 years of age must be sampled and tested by an adult (≥ 18 years of age). This kit is not applicable to children under 2 years of age. You may test yourself at any time, whether you have symptoms or not. This kit is designed for self-testing and can be used as an auxiliary tool for the diagnosis of the current COVID-19 infection.

PRINCIPLE OF INSPECTION

The double antibody sandwich method is adopted for this product to implement determination in the form of solid phase immunochromatography.

SUMMARY

SARS-CoV-2 belongs to the broad family of viruses known as coronaviruses. The incubation period was 1-14 days, mostly 3-7 days. Common symptoms may include fever, dry cough and fatigue. Some patients have decreased sense of smell and taste as the first symptoms, while a few patients have symptoms such as stuffy nose, runny nose, sore throat, conjunctivitis, myalgia and diarrhea.

PRECAUTIONS

Do's during the test

You need to operate strictly according to the instructions of the kit
√ Children aged 2 to 15 must be swabbed and tested by an adult (≥18 years old).
√ Operate in strict accordance with the instructions.
√ Recover the test cassette and sample eluent fully to the room temperature(10°C~30°C) before use.
√ Leave test cassette sealed in its pouch until just before use.
√ Put the test cassette from the pouch on a flat, dry surface.
√ Only use the components provided. Do not replace the sample eluent by any other fluid.
√ After collecting the sample, immediately inserted it into the sample eluent.
√ Keep the test cassette on a flat surface , and please avoid moving the test cassette until the result is display.
√ Keep other substance away from the test during the testing.
√ Put it out of the reach of the children. To avoid putting it in their mouth and results to choking.
√ If your test results are positive, please isolate yourself and contact your doctor or local health department immediately.
√ Negative results should be treated as presumptive, and confirmation with another SARS-CoV-2 assay, if necessary, should be done. Please avoiding to use the results to rule out SARS-CoV-2 infection for the purpose of travel accreditation, public event participation.

Do not's during the test

× Do not use the kit if the pouch is damaged or open.
× Do not be reused or reused many times, this test box is for single use only.
× Do not test under direct sunlight, or put it under direct sunlight after open the pouch.
× Do not use kit past its expiration date.
× Do not use it on anyone under 2 years.
× Do not touch the tips of the swab, and ensure it does not touch any surface before use.
× Do not touch the sample eluent directly by any part of your body.

RESTRICTIONS

1. The kit is used for self-testing of individual nasal samples.
2. This kit is a self-testing in vitro diagnostic tool.
3. The operation should be carried out in strict accordance with the package insert, otherwise the test results will be inaccurate.
4. Please use the components provided in this kit. Do not replace the sample eluent by any other fluid.
5. Positive predictive value and negative predictive value depend to a large extent on the prevalence rate. When the SARS-CoV-2 activity is low / inactive and the prevalence rate is low, the positive results are more likely to be false positive results. If the prevalence of diseases caused by SARS-CoV-2 is high, false negative tests are more likely.
6. The kit is stored in a sealed state at 4°C to 30°C away from light for a validity period of 18 months. Once the package of the Test Cassette is opened (4°C~30°C, humidity <65%), it must be used within 1 hour.
7. Do not use the kit on the child under 2 years old.
8. If clinical symptoms such as fever persist but the results of multiple tests are all negative, please contact your doctor or local health department immediately.
9. If you have no fever or other symptoms but test positive, please contact your doctor or local health department immediately.
10. This kit has been used to detect a variety of pathogens without cross-reaction. Please refer to the section of Cross-Reaction for details. However, a positive test does not rule out the possibility of interference from other pathogens.
11. Please place the swab, tube and test cassette into the disposal bag after use, then treat this bag in strict accordance with the local regulations, and it should be put into corresponding marked dustbin.
12. Do not take the test result as the only guide to manage your situation. Please consult your doctor if your symptoms persist or become more severe.

INFORMATION FOR SELF TEST USERS

Please note, do not do a self-test in the following cases
× Anyone under 2 years old
× You are prone to nosebleed
× You have had a facial or head injury / surgery in last 6 months

PERFORMANCE CHARACTERISTICS

Clinical Performance

The novel coronavirus nucleic acid detection reagent already being on the market is used as a contrast reagent to test 1596 clinical samples in total, including 269 cases with positive nucleic acid results and 1327 cases with negative nucleic acid results.

Clinical Result for SARS-CoV-2 Antigen

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)	PCR Comparator		Subtotal
	Positive	Negative	
Positive	266	0	266
Negative	3	1327	1330
Subtotal	269	1327	1596
Sensitivity	98.88% (95% CI: 96.77% to 99.62%)		
Specificity	100.00% (95% CI: 99.71% to 100.00%)		
Accuracy	99.81% (95% CI: 99.45% to 99.94%)		

Limit of Detection (LOD)

The LOD of the product is determined after dilution of the SARS-CoV-2 positive specimen, and the value is 50 $TCID_{50}$/mL SARS-CoV-2.

Hook Effect

Severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) positive samples were selected and then diluted by multiples.There is no hook effect when testing the SARS-CoV-2 positive sample with concentration up to 4.0×10^5 $TCID_{50}$/mL.

Cross Reaction

Cross reactivity of this product was evaluated by testing pathogenic microorganisms with a variety of common cross reactions which easily cause the same and similar symptoms clinically, and the results show the following viruses and other micro-organisms have no cross reaction effect on the test results of the device.

S.N	Virus/Bacteria/Parasite name	Strain	Source/ Sample type	Wet-testing Concentration/ In silico testing	Cross Reactivity Results (Number of Positive/Total)
1	Human coronavirus	229E	Isolate	$1.6\times10^{2.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
2	Human coronavirus	OC43	Isolate	$1.6\times10^{2.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
3	Human coronavirus	NL63	Isolate	$1.6\times10^{3.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
4	MERS-coronavirus	EMC/2012	Inactivated virus	$1.6\times10^{2.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
5	Adenovirus	Serotype 5	Isolate	$1.6\times10^{2.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
6	Human metapneumovirus (hMPV)	TN/91-320	Isolate	$1.6\times10^{2.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
7	Human parainfluenza virus 1	HPIV1/FRA/292211 06/2009	Isolate	$8.9\times10^{2.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
8	Human parainfluenza virus 2	Greer	Isolate	$1.0\times10^{3.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
9	Human parainfluenza virus 3	NIH 47885	Isolate	$1.6\times10^{2.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
10	Human parainfluenza virus 4a	M-25	Isolate	$1.0\times10^{3.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
11	Human parainfluenza virus 4b	19503	Isolate	$1.6\times10^{2.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
12	Influenza A	A/California/07/2009	Isolate	$5.0\times10^{2.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
13	Influenza B	B/Hong Kong/330/2001 (Victoria Lineage)	Isolate	$1.6\times10^{2.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
14	Enterovirus	71/Tainan/4643/98	Isolate	$1.6\times10^{2.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
15	Respiratory Syncytial Virus A	1998/12-21	Isolate	$2.8\times10^{2.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
16	Rhinovirus	16	Isolate	$1.4\times10^{3.0}$ $TCID_{50}$/mL	No Cross-Reactivity (0/3)
17	*Haemophil fluenzae*	Type B CK(Lehmann and Neumann) Winslow *et al.*	Isolate	$>10^{4.0}$ cfu/vial*	No Cross-Reactivity (0/3)
18	*Streptococcus pneumoniae*	(Klein) Chester	Isolate	$1.0\times10^{6.0}$ cfu/mL	No Cross-Reactivity (0/3)
19	*Streptococcus pyogenes*	Typing strain T1 [NCIB 11841,SF 130] Rosenbach	Isolate	$1.0\times10^{6.0}$ org/mL	No Cross-Reactivity (0/3)
20	Pooled human nasal wash	N/A	Isolate	100%	No Cross-Reactivity (0/3)
21	*Bordetella pertussis*	18323 [NCTC 10739] (Bergey et al.) Moreno-Lopez	Isolate	$4.8\times10^{6.0}$ cells/mL	No Cross-Reactivity (0/3)
22	*Mycoplasma pneumoniae*	FH strain of Eaton Agent [NCTC 10119] Somerson *et al.*	N/A	$2.7\times10^{5.0}$ cfu/mL	No Cross-Reactivity (0/3)
23	*Chlamydia pneumoniae*	TW-183	Isolate	$9.1\times10^{5.0}$ IFU/mL	No Cross-Reactivity (0/3)
24	*Legionella pneumophila*	Philadelphia1, Brenner *et al.*	Isolate	$1.9\times10^{6.0}$ cfu/mL	No Cross-Reactivity (0/3)
25	*Staphylococcus aureus*	CDC 55, Rosenbach	Isolate	$6.5\times10^{6.0}$ cfu/mL	No Cross-Reactivity (0/3)
26	*Staphylococcus epidermidis*	1191 (Winslow and Winslow) Evans	Isolate	$7.7\times10^{6.0}$ cfu/mL	No Cross-Reactivity (0/3)
27	*Candida albicans*	Y537	Isolate	$1.0\times10^{6.0}$ cfu/mL	No Cross-Reactivity (0/3)

Interference Response

Interference verification is carried out for the product according to the maximum plasma concentration of common clinical therapeutic drugs in the following table under normal usage and dosages, and the results indicate that the product showcases good anti-interference performance.

S.N	Interfering Substances	Active Ingredient	Concentration	Interfering- Reactivity (Yes/No)
1	Whole Blood	Blood (human)	4 % V/V	No Interference (3/3)
2	Mucin	Mucin protein, Type I-S	0.5 % W/V	No Interference (3/3)
3	Chloraseptic	Benzocaine, Menthol	0.15 % W/V (1.5mg/mL)	No Interference (3/3)
4	Naso Gel (NeilMed)	Saline	5.0 % V/V	No Interference (3/3)
5	Nasal Spray	Phenylephrine	15.0 % V/V	No Interference (3/3)
6	Afrin	Oxymetazoline	15.0 % V/V	No Interference (3/3)
7	Zicam	Oxymetazoline, Hydrochloride	5.0 % V/V	No Interference (3/3)
8	Nasal Spray (Cromolyn)	Cromolyn sodium	15.0 % V/V	No Interference (3/3)
9	Alkalol	Galphimia glauca, Luffa operculata, Sabadilla	1:10 dilution	No Interference (3/3)
10	Sore Throat Phenol Spray	Phenol	15.0 % V/V	No Interference (3/3)
11	Tobramycin	Tobramycin	0.0004% W/V (4ug/mL)	No Interference (3/3)
12	Mupirocin	Mupirocin	1.0 % W/V (10mg/mL)	No Interference (3/3)
13	Fluticasone Propionate	Fluticasone propionate (glucocorticoid)	5.0 % V/V	No Interference (3/3)
14	Tamiflu	Oseltamivir	0.5 % W/V (5 mg/mL)	No Interference (3/3)

USABILITY STUDY

A user study found that the device performance was comparable when compared to lay users and professionals from a pool of 100 samples. Positive percent agreement is 100% and negative percent agreement is 100%. The overall agreement is 100%. The lay user's questionnaire and the professionals observation showed that the application of the kit was considered as very easy to perform by all the users (100%), none claimed for difficulty in performing the test by the kit. In conclusion, the usability performance of the kit has been validated.

BASIC INFORMATION

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EC REP
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* Disposable swabs included in this kit have been individually CE marked by a third manufacturer. See the swab label for details.

DATE OF APPROVAL AND REVISION OF INSTRUCTION

Approved on February 09, 2022;
Version number: VENA11;

GUIDE TO SYMBOLS

EC REP	Authorized representative in the European Community	REF	Catalogue number		Consult instructions for use
IVD	In vitro diagnostic medical device	LOT	Batch Code		Keep dry
	Temperature limit 4 ~ 30°C		Do not re-use		Keep away from sunlight
	Date of manufacture		Do not use if package is damaged.	CE 1434	CE Mark
	Contains sufficient for <n> tests		Manufacturer		
	Caution		Use-by date		

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