



# SARS-CoV-2 Antigen Rapid Test Cassette Package Insert

REF COVG-602ST

Specimens: Nasal Swab

Effective Date: 2021.03

Version: 02



## FREQUENTLY ASKED QUESTIONS

• When can I test myself?  
You can always test yourself whether you have symptoms or not. Please note that the test result is a snapshot that is valid for this point in time. Tests should therefore be repeated according to the regulations of the responsible authorities.

• What should I pay attention to in order to obtain the most exact test result possible?

Always follow the instructions of use exactly. Perform the test immediately after collecting the sample. Dispense the drops from the test tube only into the designated well of the test cassette. Dispense two drops from the sample tube. Too many or too few drops can lead to an incorrect or invalid test result.

• The test strip is very discolored. What is the reason or what am I doing wrong?

The reason for a clearly visible discoloration of the test strip is that too large a quantity of drops has been dispensed from the sample tube into the test cassette well. The indicator strip can only hold a limited amount of liquid. If the control line does not appear or the test strip is very discolored, please repeat the test with a new test kit according to the instructions for use.

• What should I do if I took the test but didn't see a control line?  
In this case, the test result is to be considered invalid. Please repeat the test with a new test kit according to the instructions for use.

• I am unsure of the interpretation of the results. What should I do?  
If you cannot clearly determine the result of the test, contact the nearest medical facility applying the regulations of your local authority.

• My result is positive. What should I do?  
If a horizontal colored line is visible in the control area (C) as well as in the test area (T), your result is positive and you should immediately contact the medical facility in accordance with the requirements of your local authorities. Your test result may be checked and the next steps will be explained to you.

• My result is negative. What should I do?  
If only a horizontal colored line is visible in the control area (C), this may mean that you are negative or that the viral load is too low to be recognized by the test. If you experience symptoms such as headaches, migraines, fever, loss of sense of smell and taste, contact the nearest medical facility applying the regulations of your local authority. In addition, you can repeat the test with a new test kit.

• Can this test cassette be reused or used by multiple people?  
This test cassette is for one-time use and cannot be reused or used by multiple people.

• Why do I swab both nostrils?  
Swabbing both nostrils gives you the best chance of collecting sufficient sample to generate an accurate result. It has been observed in some cases that only one nostril has detectable virus, so it is important to collect from both nostrils. Correct swabbing is important to obtain a correct result.

## PACKAGE SPECIFICATIONS

1 test/pack, 3 tests/pack, 5 tests/pack, 7 tests/pack, 25 tests/pack

## INTENDED USE

This kit is used for in vitro qualitative determination of SARS-CoV-2 antigens in human anterior nasal swab samples. It can be used for rapid investigation of suspected COVID-19 cases, and can be used as a reconfirmation method for nucleic acid detection in discharged cases.

A positive test result indicates that the sample contains SARS-CoV-2 antigen. A negative test result does not rule out the possibility of infection.

This kit is for home use by laymen in a non-laboratory setting (such as person's

home or certain non-traditional sites such as offices, sporting events, airports, schools etc.). The test results of this kit are for clinical reference only. It is recommended to conduct a comprehensive analysis of the condition based on the patient's clinical manifestations and other laboratory tests.

## PRECAUTIONS

Please read all the information in this package insert before performing the test.

- The kit is in vitro diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until ready to use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infection agent.
- The used test should be discarded according to local regulations.
- Avoid using bloody samples.
- Wear gloves when handling the samples, avoid touching the reagent membrane and sample well.

## KIT COMPONENTS

- SARS-CoV-2 Antigen Test Cassette
- Extraction Buffer with Integrated Extraction Tube
- Sterile Swabs
- Package Insert
- Work Station
- Biohazard Waste Bag
- Qualification Certificate

**Note:** Components of different batches cannot be mixed.

## SPECIMEN REQUIREMENTS

### 1. Sample collection

- Choose a location to do this test where it can sit UNDISTURBED for 20 minutes. Bring the test components to room temperature {15~30°C (59°F~86°F)}.
- Wash and dry hands before you begin to perform the test.
- Open your test kit, and you should have:



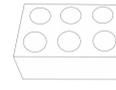
Test Cassette



Qualification Certificate



IFU



Work Station



Extraction Tube

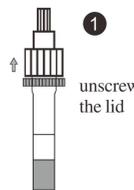


Sterile Swabs

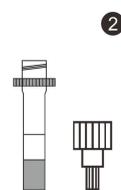


Biohazard Waste Bag

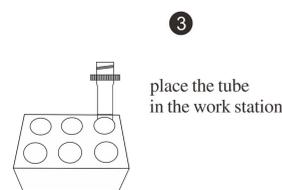
- Take out the Extraction Tube, unscrew the lid and place the tube in the work station (see below).



1 unscrew the lid



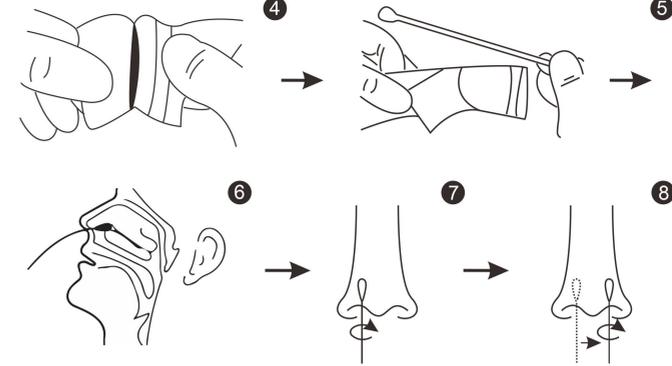
2



3 place the tube in the work station

- Remove the swab from the container, being careful NOT to touch the soft end, which is the absorbent tip.
- Gently insert the swab into one nostril for 2-4cm (1-2cm for children) until you feel a bit of resistance.

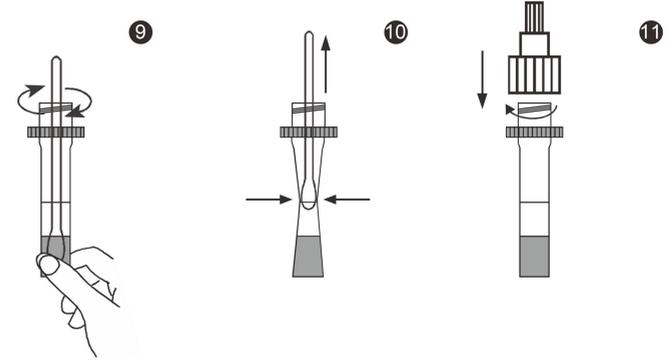
- Using medium pressure, rub the swab slowly in a circular motion around the inside wall of your nostril 5 times within 7-10 seconds.
- Repeat the same process with the same swab in the other nostril.



**CAUTION:** If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.

### 2. Sample treatment

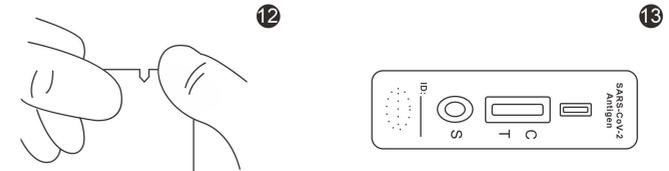
- Insert the swab into the Extraction tube and immerse the entire tip of swab into the extraction buffer.
- Soak the sampling swab below the liquid level of the extraction reagent. Rotate the swab and press for about 10 seconds.
- Squeeze the swab head against the inside of the extraction tube, then take out the swab and tighten the sampling tube.



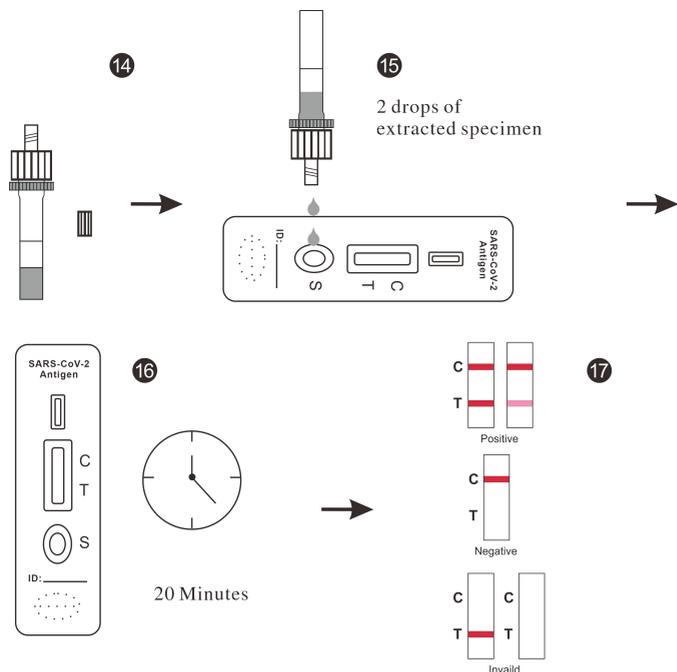
- 3. **Sample preservation:** The treated sample should be tested within 1h.

## TEST PROCEDURE

- Place the test cassette, sample extraction reagent at room temperature for 15-30 minutes, and equilibrate to room temperature (15-30°C).
- Open the aluminum foil pouch of the test cassette, place the test cassette on a flat surface.



- Unscrew the small cap at the top of the extraction buffer tube. Lay the cassette flat and add 2 drops of the treated sample into the sample well of the test cassette. Read the test result after adding the sample for 20 minutes. The result obtained after 30 minutes is invalid.

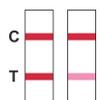


**INTERPRETATION OF RESULTS**

**NEGATIVE RESULT:** One colored line appears in the control line region (C). No line appears in the test region (T). A negative result indicates that SARS-CoV-2 antigen is not present in the specimen, or is present below the detectable level of the test.



**POSITIVE RESULT:** Two lines appear. One colored line should be in the control region (C) and another apparent colored line should be in the test region (T). A positive result indicates that SARS-CoV-2 was detected in the specimen.



**INVALID RESULT:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



**NOTE:** The intensity of the color in test line region (T) will vary depending on the concentration of SARS-CoV-2 Antigen present in the specimen. Therefore, any shade of color in the test line region(T) should be considered positive.

**PRINCIPLE OF THE ASSAY**

The SARS-CoV-2 Antigen Rapid Test Cassette is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in human Nasal swabs. In this test, antibody specific to the N protein of SARS-CoV-2 is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to N protein of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N protein of SARS-CoV-2 on the membrane and generate one colored line in the test regions. The presence of this colored line of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

**STORAGE AND STABILITY**

The validity period is 18 months if this product is stored in an environment of 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** The manufacture date and expiration date is labelled in the sealed pouch. Do not use beyond the expiration date.

**LIMITATIONS OF THE TEST**

1. The test result of this kit is not the only confirmation indicator of clinical indication. The infection should be confirmed by a specialist along with other laboratory results, clinical symptoms epidemiology, and additional clinical data.
2. The test results are related to the quality of sample collection, processing, transportation and storage. Any errors may lead to inaccurate results. If cross-contamination is not controlled during the sample processing, false positive results may occur.
3. In the early stages of infection, low levels of antigen expression can result in negative results.
4. A negative result obtained from this kit should be confirmed by PCR. A negative result may be obtained if the concentration of the SARS-CoV-2 present in the swab is not adequate or is below the detectable level of the test.
5. The negative results are not intended to exclude other non 2019-nCov virus infections.
6. A negative test result does not rule out a coronavirus infection and does not exempt you from the applicable rules for spread control (e.g. contact restrictions and protective measures).
7. Excess blood or mucus on the swab specimen may interfere with performance and may yield a false positive result.

**PERFORMANCE CHARACTERISTICS**

**Limit of Detection (LoD)**  
SARS-CoV-2 Antigen Rapid Test Cassette has been confirmed can be detect SARS-CoV-2 at 400TCID<sub>50</sub>/ml.

**Study on Interfering Substances**  
The potential interfering substances listed below do not interfere.

Interfering substance	Conc.	Interfering substance	Conc.
Whole Blood	4%	Compound Benzoin Gel	1.5mg/ml
Ibuprofen	1mg/ml	Cromolyn glycate	15%
tetracycline	3ug/ml	chloramphenicol	3ug/ml
Mucin	0.5%	Mupirocin	10mg/ml
Erythromycin	3ug/ml	Oseltamivir	5mg/ml
Tobramycin	5%	Naphazoline Hydrochlo-ride Nasal Drops	15%
menthol	15%	Fluticasone propionate spray	15%
Afrin	15%	Deoxyepinephrine hydro-chloride	15%

**Cross-Reactivity**

There is no cross-reaction and no interference with the potentially cross-reactive microorganisms listed below.

Name	Concentration
HCOV-HKU1	10 <sup>5</sup> TCID <sub>50</sub> /ml
Staphylococcus aureus	10 <sup>6</sup> TCID <sub>50</sub> /ml
Group A streptococci	10 <sup>6</sup> TCID <sub>50</sub> /ml
Measles virus	10 <sup>5</sup> TCID <sub>50</sub> /ml
Mumps virus	10 <sup>5</sup> TCID <sub>50</sub> /ml
Adenovirus type 3	10 <sup>5</sup> TCID <sub>50</sub> /ml
Mycoplasmal pneumonia	10 <sup>6</sup> TCID <sub>50</sub> /ml
Parainfluenzavirus,type2	10 <sup>5</sup> TCID <sub>50</sub> /ml
Human metapneumovirus	10 <sup>5</sup> TCID <sub>50</sub> /ml
Human coronavirus OC43	10 <sup>5</sup> TCID <sub>50</sub> /ml
Human coronavirus 229E	10 <sup>5</sup> TCID <sub>50</sub> /ml
Bordetella parapertusis	10 <sup>6</sup> TCID <sub>50</sub> /ml
Influenza B Victoria STRAIN	10 <sup>5</sup> TCID <sub>50</sub> /ml
Influenza B YSTRAIN	10 <sup>5</sup> TCID <sub>50</sub> /ml
Influenza A H1N1 2009	10 <sup>5</sup> TCID <sub>50</sub> /ml

Influenza A H3N2	10 <sup>5</sup> TCID <sub>50</sub> /ml
H7N9	10 <sup>5</sup> TCID <sub>50</sub> /ml
HSN1	10 <sup>5</sup> TCID <sub>50</sub> /ml
Epstein-Barr virus	10 <sup>5</sup> TCID <sub>50</sub> /ml
Enterovirus CA16	10 <sup>5</sup> TCID <sub>50</sub> /ml
Rhinovirus	10 <sup>5</sup> TCID <sub>50</sub> /ml
Respiratory syncytial virus	10 <sup>5</sup> TCID <sub>50</sub> /ml
Streptococcus pneumoni-ae	10 <sup>6</sup> TCID <sub>50</sub> /ml
Candida albicans	10 <sup>6</sup> TCID <sub>50</sub> /ml
Chlamydia pneumoniae	10 <sup>6</sup> TCID <sub>50</sub> /ml
Bordetella pertussis	10 <sup>6</sup> TCID <sub>50</sub> /ml
Pneumocystis jiroveci	10 <sup>6</sup> TCID <sub>50</sub> /ml
Mycobacterium tubercu- losis	10 <sup>6</sup> TCID <sub>50</sub> /ml
Legionella pneumophila	10 <sup>6</sup> TCID <sub>50</sub> /ml
Human coronavirus NL63	10 <sup>5</sup> TCID <sub>50</sub> /ml
MERS coronavirus	10 <sup>5</sup> TCID <sub>50</sub> /ml

**HOOK effect**

When the virus content in the sample to be tested reaches 4.0\*10<sup>5</sup>TCID<sub>50</sub>/ml, the test result still does not show the HOOK effect.

**Clinical Performance**

Clinical performance of SARS-CoV-2 Antigen Rapid Test Cassette has been determined by testing 116 positive and 214 negative specimens for SARS-CoV-2 antigen. The sensitivity is 97.4% (95%CI\*:90.39%-98.61%), and the specificity is 99.1%(95%CI\*:98.20%-99.87%).

SARS-CoV-2 Antigen Rapid Test Cassette	Method	PCR Test Results		Total Results
	Results	Positive	Negative	
	Positive	113	2	115
	Negative	3	212	215
	Total Results	116	214	330

Relative Sensitivity :97.4%(95%CI\*:90.39%-98.61%)

Relative Specificity:99.1%(95%CI\*:98.20%-99.87%)

\*Confidence Intervals

**IBIBLIOGRAPHY**

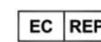
- 1.Weiss SR,Leibowitz JZ.Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164
- 2.Cui J,Li F,Shi ZL.Origin and evolution of pathogenic coronaviruses.Nat Rev Microbiol 2019;17:181-192.
- 3.Su S,Wong G,Shi W,et al.Epidemiology,genetic recombination,and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502.

**Index of Symbols**

	Consult instructions for use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by date		Do not reuse
	Temperature limitation		Lot Number		Catalogue number
	For self-testing		Manufacturer		Manufacturing date



**Hangzhou Sejoy Electronics & Instruments Co.,Ltd.**  
Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China  
Website: www.sejoy.com



**Shanghai International Holding Corp. GmbH (Europe)**  
Eiffestrasse 80, 20537 Hamburg, Germany