SEJOY

SARS-CoV-2 Antigen Rapid Test Cassette
Package Insert

REF COVG-602ST

Specimens: Nasal Swab

Effective Date: 2021.11

EN

IVD

Version: Z
For self testing
Code: 4.15.03.0140-0

FREQUENTLY ASKED QUESTIONS

- When I am ready to start the test, what preparations do I need to do?

Regardless of whether you have symptoms or not, when you are ready to use this reagent, please do isolation and protection. Wear a face mask or cover your mouth and nose with a tissue when you are coughing and keep distance with other people.

- 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.

Antigen testing is typically used in the acute phase of infection, when samples are tested within seven days of the onset of symptoms in a suspected population.

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.
- Avoid touching the reagent membrane and sample well.
- Test for children and young people should be used with an adult.

KIT COMPONENTS

Materials Required and Provided

- SARS-CoV-2 Antigen Test Cassette
- Extraction Kit
- Sterile Swabs
- Package Insert
- Tube Holder
- Biohazard Waste Bag
- Qualification Certificate

Note: Components of different batches cannot be mixed.

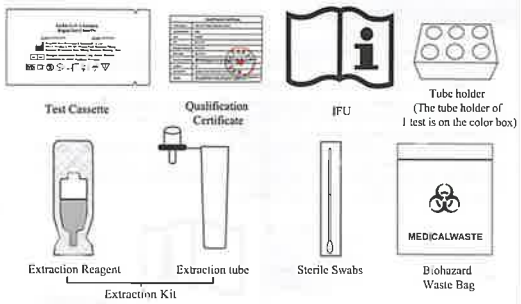
Materials Required but not Provided

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

DIRECTIONS FOR USE

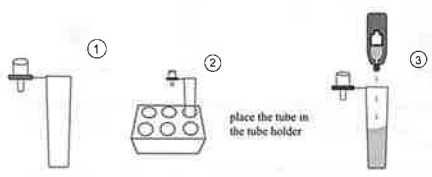
1. Preparation before the beginning

- Choose a location to do this test where it can sit UNDISTURBED for 15-30 minutes. Place the test cassette, sample extraction reagent and test components at room temperature for 15-30 minutes, and equilibrate to room temperature{15~30°C (59°F-86°F)}
- Wash your hands with soap and water for at least 20 seconds before testing. If soap and water are not available, use hand sanitizer with at least 60% alcohol.
- It is not recommended to clean the nasal cavity before the test to prevent the virus content from being too low. Unless the nasal cavity is too wet or dry, after cleaning the nasal cavity, take a sample at least 30 minutes later.
- Open your test kit, and you should have:

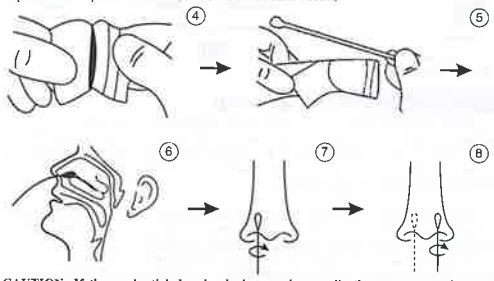


2. Sample collection

- Take out the Extraction Tube, open the lid and place the tube in the tube holder (see below).



- Take out the extraction reagent, tear it apart from the groove position, and turn the extraction reagent upside down, squeeze the bottle body. Squeeze all of the extraction Reagent into the extraction tube without touching the edge of the tube.
- 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.

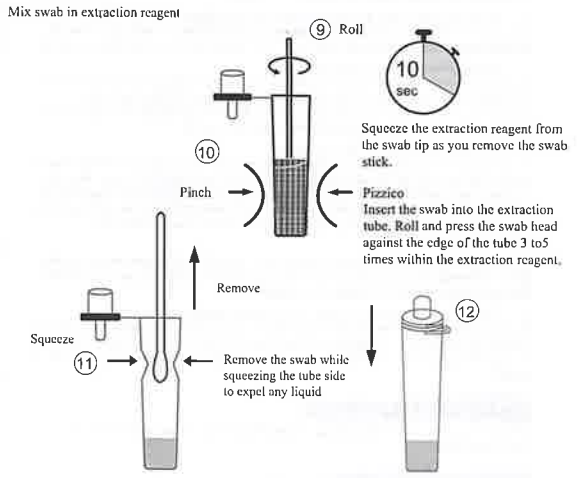


CAUTION: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab. When using swab, users should pay attention to the safety of sampling. Avoid inserting too deep into the nasal cavity, causing pain and bleeding.

3. Sample treatment

- Insert the swab into the Extraction tube and immerse the entire tip of swab into the extraction reagent.
- Soak the sampling swab below the liquid level of the extraction reagent. Rotate the swab and press for about 10 seconds.(Insert the swab into the extraction tube.Roll and press the swab head against the edge of the tube3 to 5 times within the extraction reagent)
- Squeeze the swab head against the inside of the extraction tube, then take out the swab and tighten the sampling tube.(Squeeze the extraction buffer from the swab tip as you remove the swab stick)

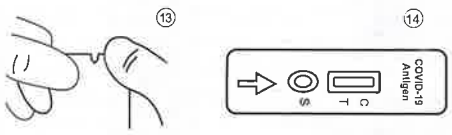
Mix swab in extraction reagent



4. Sample preservation: The sample can be stored at room temperature (15~30°C (59°F-86°F)) for one hour.

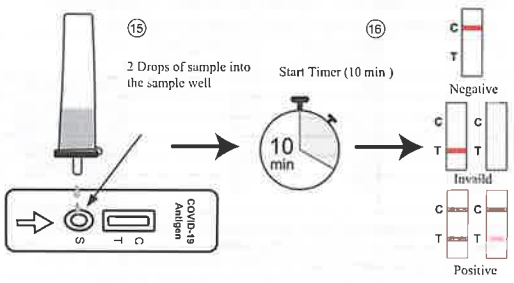
TEST PROCEDURE

- Open the aluminum foil pouch of the test cassette, place the test cassette on a flat surface.



- 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 10 minutes. The result obtained after 30 minutes is invalid.

Perform the test



DISPOSAL THE SAMPLE AND CLEAN-UP

- The test cassette, sample extraction reagent and disposable virus sampling swab are collected into the biohazard waste bag and dispose it according to local regulations.
- Re-apply hand sanitizer.

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

Store as packaged in the sealed pouch at room temperature or refrigerated (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.

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$_{50}$/ml.

Study on Interfering Substances

Test results will not be interfered by following substances at certain concentrations:

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 hydrochloride	15%

Cross-Reactivity

Test results will not be affected by other respiratory viruses and commonly encountered microbial flora and low pathogenic coronaviruses listed in table below at certain concentrations.

Name	Concentration
HCOV-HKU1	10^5TCID$_{50}$ /ml
Staphylococcus aureus	10^8TCID$_{50}$ /ml
Measles virus	10^5TCID$_{50}$ /ml
Mumps virus	10^5TCID$_{50}$ /ml
Mycoplasmal pneumonia	10^6TCID$_{50}$ /ml
Parainfluenzavirus, type2	10^5TCID$_{50}$ /ml
Human coronavirus OC43	10^5TCID$_{50}$ /ml
Human coronavirus 229E	10^5TCID$_{50}$ /ml
Influenza B Victoria STRAIN	10^5TCID$_{50}$ /ml
Influenza B YSTRAIN	10^5TCID$_{50}$ /ml
Influenza A H1N1 2009	10^5TCID$_{50}$ /ml
Influenza A H3N2	10^5TCID$_{50}$ /ml
H7N9	10^5TCID$_{50}$ /ml
H5N1	10^5TCID$_{50}$ /ml
Epstein-Barr virus	10^5TCID$_{50}$ /ml
Enterovirus CA16	10^5TCID$_{50}$ /ml
Human coronavirus NL63	10^5TCID$_{50}$ /ml
MERS coronavirus	10^5TCID$_{50}$ /ml
MERS CoV Florida/ USA-2_Saudi Arabia_2014	1.17 x 10^4TCID$_{50}$ /ml
Respiratory syncytial virus	10^5TCID$_{50}$ /ml
RSV-A 2006 Isolate	5.01 x 10^4TCID$_{50}$ /ml
RSV-B CH93-18(19)	1.55 x 10^3TCID$_{50}$ /ml

Clinical Performance

Clinical performance of SARS-CoV-2 Antigen Rapid Test Cassette has been determined by testing 109 positive and 300 negative specimens for SARS-CoV-2 antigen.

Analytical Results with correlation to Ct-values of the positive samples:

Ct-value	PCR confirmed sample number	Correct identified	RATE
≤30	82	82	100 % (Sensitivity)
≤32	94	92	97.9 % (Sensitivity)
≤34	102	98	96.1% (Sensitivity)
≤36	109	103	94.5 % (Sensitivity)
Negative	300	300	99.9% (Specificity)
total	409	403	98.5% (Total Accuracy)

The correlation between the Ct-values of the analyzed samples and the sensitivity reveals a sensitivity of 100% (95%CI* 95.5%-100.0%) for samples with a Ct-value of up to 30, the sensitivity reveals a sensitivity of 97.9 % (95%CI* 92.6%-99.4%) for samples with a Ct-value of up to 32, the sensitivity reveals a sensitivity of 96.1% (95%CI* 90.4%-98.5%) for samples with a Ct-value of up to 34. There is still a very good sensitivity of 94.5% (95%CI* 88.5%-97.5%) up to a Ct-value of 36. This is in line with expectations regarding viral detection by antigen rapid testing compared to PCR analysis. 99.9% (95%CI* 98.7%-100%)Specificity: In total 300 PCR confirmed negative samples: 300 PCR confirmed negative samples were correctly detected by The SARS-CoV-2 Antigen Rapid Test Cassette. There are no false positive cases. 98.5% (95%CI* 96.8%-99.3%) Accuracy: In total 409 PCR confirmed samples: 403 PCR confirmed samples were correctly detected by the SARS-CoV-2 Antigen Rapid Test Cassette.

The observed accuracy may vary depending on the prevalence of the virus in the population.The observed accuracy may vary depending on the prevalence of the virus in the population.

BIBLIOGRAPHY

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 coronavir uses. TrendsMicrobiol 2016;24:490-502.

Index of Symbols

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by date	2	Do not reuse
	Temperature limitation	LOT	Lot Number	REF	Catalogue number
CE 1434	Meet the requirements of 98/79/EC Directive		Manufacturer		Manufacturing date

EC REP **Shanghai International Holding Corp. GmbH (Europe)**
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