SEJOY

SARS-CoV-2 Antigen Rapid Test Cassette （Saliva） Package Insert

REF COVG-602

Specimens: Saliva

Effective Date: 2022.5

Version: B

For self-testing.

IVD

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.

- Whether this kit is suitable for asymptomatic users?

Testing of asymptomatic individuals should be limited to contacts of confirmed or probable cases or suspected COVID-19 for other epidemiological reasons, and should be followed by confirmatory testing of additional molecular tests.

- Are there age and usage restrictions for the kit?

Children aged 2 to 15 years and older adults with limited ability to test themselves should be tested by an adult.

PACKAGE SPECIFICATIONS

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

INTENDED USE

This kit is used for in vitro qualitative determination of SARS-CoV-2 antigens in human saliva 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. Testing of asymptomatic individuals should be limited to contacts of confirmed or probable cases or suspected COVID -19 for other epidemiological reasons, and should be followed by confirmatory testing of additional molecular 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 b loody samples.
- Avoid touching the reagent membrane and sample well.
- Children aged 2 to 15 years and older adults with limited ability to test themselves should be tested by an adult.

KIT COMPONENTS

Materials Required and Provided

- SARS-CoV-2 Antigen Test Cassette
- Extraction Tube
- Extraction Reagent
- Saliva Collection kit
- Package Insert
- Qualification Certificate
- Workstation (Tube holder for 1 test/pack on color box)

Note: Components o f different batches cannot be mixed.

Materials Required but not Provided

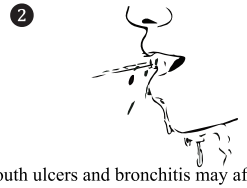
The timer and Disinfection products, such as hand sanitizer, rubbing alcohol, soap, etc.

DIRECTIONS FOR USE

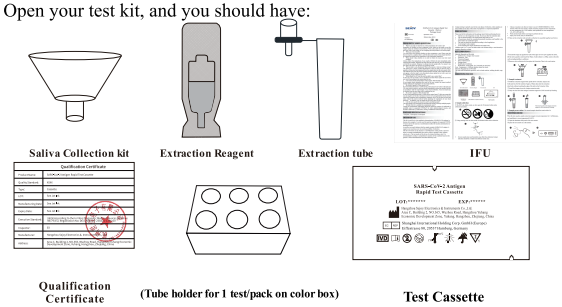
1. Sample collection

① Do NOT eat, drink, smoke, or chew gum for 30 minutes before saliva collection procedure.

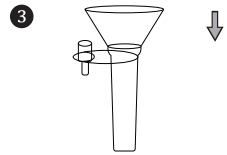
② Using running water to clean mouth 30 minutes before saliva collection.



- Severe mouth ulcers and bronchitis may affect the collection Contact infection should be avoided from different tested ones.
- 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 and dry hands before you begin to perform the test.
- Open your test kit, and you should have:

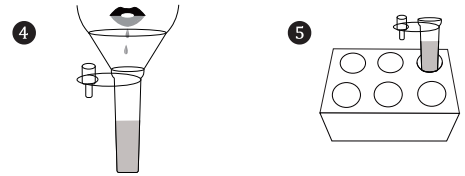


③ Take out the extraction tube and saliva collection kit, assemble together (see below).



④ Extend the tongue tip against the teeth of the upper or lower jaw togather the saliva, till the saliva quantity could reach the 300μL of saliva (there is a 300μL scale on the tube wall) excluding bubbles is sufficient.

⑤ Remove saliva collection kit, then place the Extraction Tube in the work station.

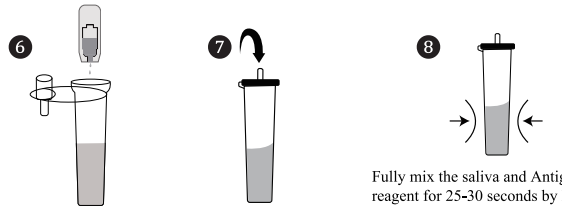


2. Sample treatment

⑥ Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let all of the solution (Approx, 500μL) drop into the extraction tube freely without touching the edge of the tube to the Extraction Tube.

⑦ Install the dropper tip on the Antigen extraction tube.

⑧ Fully mix the saliva and Antigen extraction reagent for 25-30 seconds by Pinching.



Fully mix the saliva and Antigen extraction reagent for 25-30 seconds by Pinching.

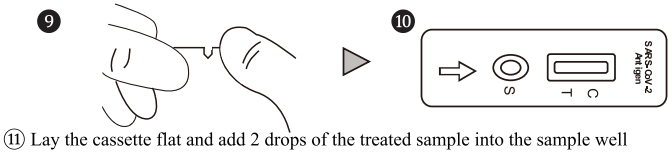
3. Sample preservation: The treated sample should be tested within 1h.

TEST PROCEDURE

Place the test cassette, sample extraction reagent at room temperature for 15-30minutes, and equilibrate to room temperature(15-30°C).

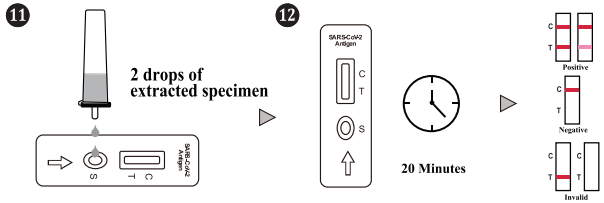
⑨ Open the aluminum foil pouch of the test cassette.

⑩ place the test cassette on a flat surface.



⑪ Lay the cassette flat and add 2 drops of the treated sample into the sample well of the test cassette.

⑫ Read the test result after adding the sample for 20 minutes. The result obtained after 30 minutes is invalid.



DISPOSAL THE SAMPLE AND CLEAN-UP

- The test cassette, sample extraction reagent and disposable virus sampling saliva collection kit 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 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.

It is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative. If you experience symptoms such as headaches, migraines, fever, loss of sense of smell or taste. Follow the guidance from your local Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

If your first test result is negative, however you have doubts about it, you can test again with a new test or repeat the test after 1-2 days, as the corona virus cannot be precisely detected in all phases of an infection.

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 saliva. 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 24 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. The user should not take any decision of medical relevance without first consulting his or her medical practitioner.
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 sample 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).

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD)

SARS-CoV-2 Antigen Rapid Test Cassette has been confirmed can be detect SARS-CoV-2 at 400$TCID_{50}$/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%
Quinine	1mg/ml	Penicillin G Potassium salt	3ug/ml
Ethanol	15%	Cholesterol	3ug/ml
Maltose	1mg/ml	Xylitol	1mg/ml
Trehalose	10mg/ml	Theophylline	1mg/ml
Niacin	1mg/ml	Sucrose	10mg/ml
Lidocaine	10mg/ml		

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
Epstein-Barr virus	$10^5$$TCID_{50}$/ml
Measles virus	$10^5$$TCID_{50}$/m
Mumps virus	$10^5$$TCID_{50}$/m
Paraimfluenzavirus,type2	$10^5$$TCID_{50}$/m
Influenza B Victoria STRAIN	$10^5$$TCID_{50}$/m
Influenza B YSTRAIN	$10^5$$TCID_{50}$/m
Influenza A H1N1 2009	$10^5$$TCID_{50}$/m
Influenza A H3N2	$10^5$$TCID_{50}$/m
H7N9	$10^5$$TCID_{50}$/m
H5N1	$10^5$$TCID_{50}$/m
Enterovirus CA16	$10^5$$TCID_{50}$/m
Respiratory syncytial virus	$10^5$$TCID_{50}$/m
MERS coronavirus	$10^5$$TCID_{50}$/m
Human coronavirus NL63	$10^5$$TCID_{50}$/m
Human coronavirus OC43	$10^5$$TCID_{50}$/m
Human coronavirus 229E	$10^5$$TCID_{50}$/m
CoV-NP HKU1	$10^5$$TCID_{50}$/m
Mycoplasma pneumoniae	10^9 CFU/ml
Staphylococcus aureus	10^9 CFU/ml
Herpes simplex virus type I	$2.0*10^4$$TCID_{50}$/mL
Herpes simplex virus type II	$2.0*10^4$$TCID_{50}$/mL
Parainfluenza virus type I	$5.0*10^3$$TCID_{50}$/mL
Parainfluenza virus type III	$5.0*10^3$$TCID_{50}$/mL

The following are cross-trial data conducted in clinical validation:

Strains	Quantity	Sejoy Ag TestResult
Influenza A Virus	5	100% (5/5)
Influenza B Virus	5	100% (5/5)
Adenovirus	12	100% (12/12)
Adenovirus and Parainfluenza virus-3 coinfection	2	100% (2/2)
Adenovirus and Coronavirus (NL-63, 229E) coinfection	2	100% (2/2)
Adenovirus and Rotavirus coinfection	1	100% (1/1)
Respiratory syncytial virus, RSV	17	100% (17/17)
RSV and Parainfluenza virus-3 coinfection	2	100% (2/2)
Metapneumovirus	3	100% (3/3)
Rotavirus	19	100%(19/19)
Rotavirus and Coronavirus(NL-63, 229E) coinfection	1	100%(1/1)
Coronavirus(NL-63, 229E)	4	100%(4/4)
Streptococcus pneumoniae	2	100%(2/2)
Streptococcus group A	2	100%(2/2)

Hook Effect

The hook effect here refers to the false negative result of the reagent when the content of the substance to be detected in the sample is too high.

SARS-CoV-2 Antigen Rapid Test Cassette has been confirmed that when the concentration of inactivated virus culture fluid is below $4.0\times10^6$$TCID_{50}$/ml, there is no HOOK effect.

Clinical Performance

Clinical performance of SARS-CoV-2 Antigen Rapid Test Cassette has been determined by testing 140 positive and 300 negative specimens for SARS-CoV-2 antigen.

- Below is the full data on clinical performance:

The positive coincidence rate is 81.43% (95%CI:73.98%-87.50%), and the negative coincidence rate is＞99.99% (95%CI:98.78%-100.00%).

	PCR confirmed sample number	Correct identified	RATE
Positive sample	140	114	81.43%
Negative sample	300	300	100%
total	440	414	94.09%

81.43% Positive coincidence rate: In total 140 PCR confirmed positive samples: 114 PCR confirmed positive samples were correctly detected by The SARS-CoV-2 Antigen Rapid Test Cassette. There are 26 false negative cases.

＞99.99% Negative coincidence rate: 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 0 false positive cases.

94.09% Total coincidence rate: In total 440 PCR confirmed samples: 414 PCR confirmed samples were correctly detected by the SARS-CoV-2 Antigen Rapid Test Cassette.

- When the CT value is less than or equal to 25, the positive detection rate is as follows:

The positive coincidence rate is 90.08% (95%CI:83.46%-94.24%).

	PCR confirmed sample number	Correct identified	RATE
Positive sample	121	109	90.08%

90.08% Positive coincidence rate: In total 121 PCR confirmed positive samples: 109 PCR confirmed positive samples were correctly detected by The SARS-CoV-2 Antigen Rapid Test Cassette. There are 12 false negative cases.

The observed total coincidence rate 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 coronaviruses. TrendsMicrobiol 2016;24:490-502.

Index of Symbols

	Consult instructions for use		Contains sufficient for <n> tests	EC REP	Authorized representative		Keep away from sunlight
IVD	In vitro diagnostic medical device		Use-by date		Do not re-use		Keep dry
	Temperature limit	LOT	Batch code	REF	Catalogue number		Do not use if package is damaged
	Manufacturer		Date of manufacture	CE 2934	Meet the requirements of 98/79/EC Directive		

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

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

CE 2934