InstantSure Covid-19 Ag CARD
SELF-TEST Instruction for Use

LAY TEST FOR ANTERIOR NASAL SWAB SPECIMENS

This instruction for use (IFU) must be read carefully prior to use. Instruction for use must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions for use.

PRODUCT NAME

InstantSure Covid-19 Ag CARD

PACKING SPECIFICATION

1test/kit, 5 tests/ kit, 20 tests/ kit.

INTENDED USE

This kit is used for in vitro qualitative detection of SARS-CoV-2 antigen in human nasal swabs from individuals suspected of COVID-19 within the first seven days of symptom onset. InstantSure Covid-19 Ag CARD shall not be used as sole basis to diagnose or exclude SARS-CoV-2 infection.

SUMMARY

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.

MATERIALS SUPPLIED

1. Main components:

Specification / component	1test/kit	5tests/kit	20 tests/kit
Test Card	1	5	20
Collection tubes include extraction solution	1	5	20
Specimen Collection Swab	1	5	20
Hermetic Bag	1	5	20
Package Insert	1	1	1
Work Station	The box	The box	1

CAUTION:The components in different batches of the kit cannot be mixed.

MATERIALS REQUIRED BUT NOT PROVIDED

• Timer• Sanitizer

IMPORTANT INFORMATION BEFORE EXECUTION

1.Read this instruction guide carefully.

2.Do not use the product if the pouch is damaged or the seal is broken.

3.Kits should be stored at 2°C~30°C, in a cool, dark, dry place, valid for 24 months, forbidden to store under 2°C and avoid using expired products.

4.The test card should be in aluminum foil bag after opening, to the specified environment (temperature 2°C~35°C, humidity 40%~60%) used within 1 hour.

5.Handle all specimens as potentially infectious.

6.Inadequate or inappropriate specimen collection, storage, and transport may yield inaccurate test results.

7.Use the swabs included in the test kit to ensure optimal performance of the test.

8.Correct specimen collection is the most important step in the procedure. Make sure to collect enough specimen material (nasal secretion) with the swab, especially for anterior nasal sampling.

9.Blow the nose several times before collecting specimen.

10.Apply the drops of test specimen only to the specimen well (S).

11.Too many or too few drops of extraction solution can lead to an invalid or incorrect test result.

12.Children under 14 years of age should be assisted by an adult.

13.MFD date and EXP date: marked on the label.

LIMITATIONS

1.The test is to be used exclusively for the qualitative detection of SARS-CoV-2 viral antigen cannot be determined as part of this test.

2. Proper specimen collection is critical. Failure to follow the procedure may result in inaccurate test results.

3. Improper collection, storage, or even freezing and thawing of the specimen can lead to inaccurate test results.

4. If the viral load of the specimen is below the detection limit of the test, the test may produce a negative result.

5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should be made by the physician after evaluation of all clinical and laboratory results.

6. A negative result does not exclude viral infection except for SARS-CoV-2 and should be confirmed by molecular diagnostic methods (e.g. PCR) if COVID-19 is suspected.

7. A positive result does not rule out an additional infection with other disease-causing agents.

8. The InstantSure Covid-19 Ag CARD can detect both viable and non-viable SARS-CoV-2 material. The performance of the InstantSure Covid-19 Ag CARD is dependent on viral load and may not correlate with other diagnostic methods performed on the same specimen.

9. Users should test specimens as soon as possible after specimen collection and within one hour of specimen collection.

10. Sensitivity for nasal swabs may be lower than nasopharyngeal swabs.

11. It could be possible that virus mutations might be detected with lower sensitivity or not at all.

12. The amount of antigen in a sample may decrease as the duration of illness increased. Specimens collected after day 5-7 of illness are more likely to be tested negative compared to a RT-PCR assay.

13. The Kit was validated with the swabs provided. Use of alternative swabs may result in false negative results.

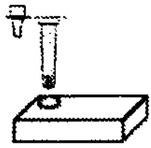
14.

PREPARATION

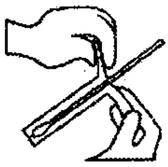
1. Wash your hands.
2. Clear clean and dry a flat surface.
3. Check the kit contents.
4. Make sure that nothing is damaged or broken.
5. Have a timer ready.
6. Blow your nose several times before taking the sample.
7. Wash your hands again.

PROCEDURE

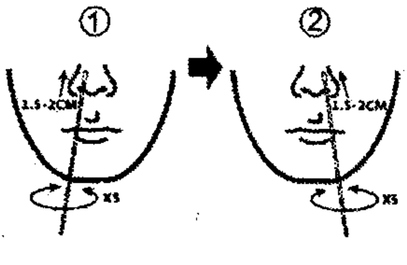
This test is suitable for people of all ages. The recommended operators are aging from 14-90,Children under 14 years of age should be tested by an adult. Do not continue the test if the child feels any pain.

1. 

Take out a collection tube and fix it on the extraction tube rack.

2. 

Take the swab out of its packaging, being careful not to touch the soft end, which is the absorbent tip. **CAUTION: Never touch soft, fabric tip of the swab with your hands.**

3. 

Carefully insert the entire absorbent tip of the swab into one nostril (approximately 1.5 to 2 cm) and firmly lift the nasal wall by rotating the swab five times against the nasal wall. Slowly withdraw the swab from the nostril. (This step should take about 15 seconds, making sure to collect the mucus and cells).

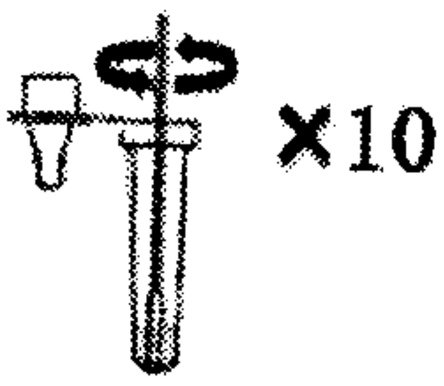
Repeat the above procedure for the other nostril with the same swab.

CAUTION: This may feel uncomfortable. Do not insert any deeper if you feel strong resistance or pain.

4. 

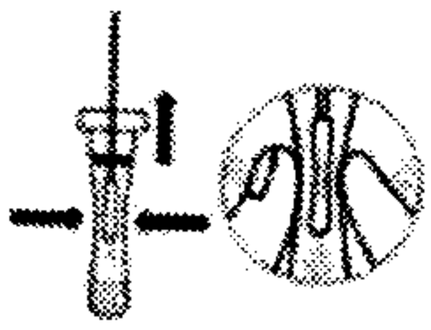
Tear off the aluminum foil film sealing the collection tube.

5.



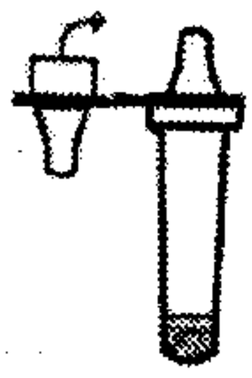
Completely immerse the swab head in the extraction solution in the collection tube. Completely mix the solution by rotating the swab forcefully against the side of the tube at least 10 times (while submerged) and squeeze the tube 5 times by hand to ensure that the sample on the sampling swab is fully eluted into the extraction solution. **Leave the swab in the collection tube for one minute.**

6.



Squeeze the swab head along the inner wall of the collection tube to keep the liquid in the tube as much as possible.

7.



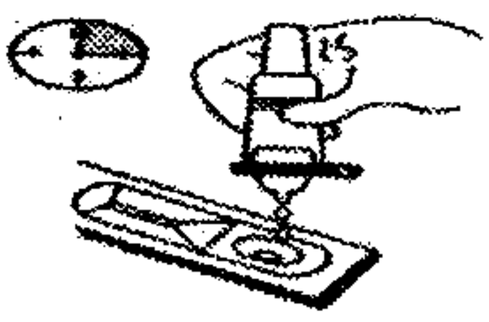
Discard the swab and cover the dropper tip.

8.

Remove the test card from the foil pouch and place on a clean dry surface.

CAUTION: Once opened, the test card must be used immediately.

9.



3 drops

Unscrew the first lid of the extraction tube (the white one),dispense 3 drops of the specimen into the circular sample well on the card. Read the results at 15~20 minutes. Do not interpret the results after 20 minutes.

CAUTION: The formation of air bubbles in the specimen well (S) must be avoided.

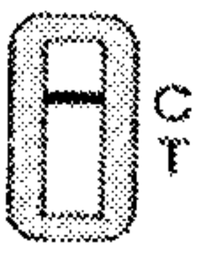
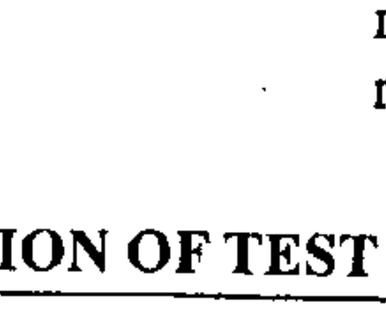
10.

After the test is completed, sterilize test cards, samples, and cotton swabs with a recommended and approved disinfectant.

Put the sterilized test cards, samples, and swabs into a disposable sealed bag that protects against biological hazards

Dispose of the packaging in the form recommended or in accordance with local authority regulations

INTERPRETATION OF TEST RESULTS

Negative		If one colored band appears in the Control Zone (C) and no colored band appears in the Test Zone (T) within 15-20 minutes, the test result is negative.
Positive		If two colored bands appear, with one colored band in the Control Zone (C) and another in the Test Zone (T) within 15-20 minutes, the test result is positive **CAUTION :No matter how faint the colored band is in the Test Zone(T), the result should be considered as positive.**
Invalid		If no color line appears in the control area(C) within 15-20 minutes, the test is invalid. Repeat the test with a new test card.

FREQUENTLY ASKED QUESTIONS (FAQ)

1.How does the detection work?
The N protein of the SARS-CoV-2 virus reacts with the stripe-like coating of the test line and, if present, results in a color change, i.e. a red line appears. Therefore, if the sample does not contain any viral proteins or antigens, there will be no red test line (T).

2.When should/can I test myself?
You can test yourself whether you have symptoms or not. Studies show that earlier testing within the first 4 days of illness typically means a higher viral load, which is easier to detect. Since the test result is a snapshot valid for that point in time, testing should be repeated as recommended by local authorities.

3.What can affect my test result? What should I pay attention to?
Be sure to blow your nose multiple times before collecting the specimen.
Be sure to visibly collect sample material (nasal secretions).
Perform the test immediately after taking the sample.
Follow the instructions for use carefully.
Apply the drops of extraction solution only to the sample well (S).
Too many or too few drops of extraction solution can lead to an invalid or incorrect test result.

4.The test strip is clearly discolored or smudged? What is the reason for this?
Please note that the test card should not be used with more than 3 drops of sample, as the liquid absorption of the test strip is naturally limited/ If the control line does not appear or the test strip is badly smudged or discolored, making it unreadable, please repeat the test according to the instructions.

5.I have taken the test, but I don't see a control line (C). What should I do?
Your test result is invalid. Observe the answer to question 4 and repeat the test according to the instructions for use.

6.I am unsure about reading the result. What should I do?
For the result to be positive, 2 straight horizontal lines must be clearly visible with the full width of the cassette. If you are still unsure about the results, contact the nearest health facility according to the recommendations of your local authorities.

7.My result is positive. What should I do?
If your result is positive and the test kit clearly indicates the control line as well as the test line, then the result must be confirmed by a PCR test. You should immediately contact the nearest medical facility (e.g. your family doctor) by telephone, as recommended by your local authorities. The medical facility will explain the ap)propriate next steps to take. Avoid contact with other people until the result of the PCR test is available.

8. My result is negative. What should I do?
If the test kit only clearly shows the control line, this may mean that you are negative or that the viral load is too low to be detected. If you experience symptoms (headache, fever, migraine, loss of sense of smell or taste, etc.), please consult your primary care physician, or the nearest health care facility as recommended by your local authorities. If you are not sure, you can repeat the test. Even with a negative result, continue to adhere to social distancing rules, contact restrictions, and hygiene measures.

9.How can I dispose of the product?
The test kit may be disposed of with normal household waste in accordance with the apolicable local regulations.

PERFORMANCE CHARACTERISTIC

1. Performance- LoD

The lowest detection limit of the InstantSure Covid-19 Ag Card is 1.6×10^2 TCID 50 /mL.

2. Performance-Clinical

The clinical performance of InstantSure COVID-19 Ag CARD was established in prospective studies with nasal swabs collected from 600 individual symptomatic patients (within 7 days of onset) and asymptomatic patients who were suspected of COVID-19.

Summary data of InstantSure COVID-19 Ag CARD as below:
The RT-PCR cycle threshold (Ct) is the relevant signal value. Lower Ct value indicate higher viral load. The sensitivity was calculated for the different Ct value range (Ct value≤33 and Ct value≤37).

COVID-19 Antigen		Clinical diagnosis PCR Ct≤33		Total
		Positive	Negative	
SAIER TECH®	Positive	262	2	264
	Negative	10	313	323
Total		272	315	587
PPA(Ct≤33): 96.32%(262/272), 95%CI (93.34%-98.22%) NPA(Ct≤33): 99.37%(313/315),, 95%CI(97.73%-99.92%)				

COVID-19 Antigen		Clinical diagnosis PCR Ct≤37		Total
		Positive	Negative	
SAIER TECH®	Positive	265	2	267
	Negative	20	313	333
Total		285	315	600
PPA(Ct≤37): 92.98%(265/285), 95%CI (89.37%-95.66%) NPA(Ct≤37): 99.37%(313/315),, 95%CI(97.73%-99.92%)				

3. Cross-reactivity

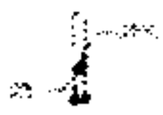
No.	Virus name	Test conc.
1	Human coronavirus 229E	1.6×10^5TCID$_{50}$/mL
2	Human coronavirus OC43	1.6×10^4TCID$_{50}$/mL
3	Human coronavirus NL63	1.6×10^3TCID$_{50}$/mL
4	MERS-coronavirus (Irradiated)	8.9×10^4TCID$_{50}$/mL
5	Adenovirus	1.6×10^5TCID$_{50}$/mL
6	Human metapneumovirus (hMPV)	1.6×10^5TCID$_{50}$/mL
7	Human parainfluenza virus 1	8.9×10^5TCID$_{50}$/mL
8	Human parainfluenza virus 2	1.0×10^5TCID$_{50}$/mL
9	Human parainfluenza virus 3	1.6×10^5TCID$_{50}$/mL
10	Human parainfluenza virus 4 a	1.6×10^3TCID$_{50}$/mL
11	Human parainfluenza virus 4 b	5.0×10^5TCID$_{50}$/mL
12	Influenza A	5.2×10^5TCID$_{50}$/mL
13	Influenza B	1.8×10^5TCID$_{50}$/mL
14	Enterovirus	1.6×10^5TCID$_{50}$/mL
15	Respiratory Syncytial Virus A	2.8×10^5TCID$_{50}$/mL
16	Rhinovirus 16	5×10^3TCID$_{50}$/mL
17	Haemophilus influenzae	800 cfu/vial
18	Streptococcus pneumoniae	4.25×10^5CFU/mL
19	Streptococcus pyogenes	800 cfu/vial
20	Bordetella pertussis	4.8×10^6CFU/mL
21	Mycoplasma pneumoniae	3.0×10^5CFU/mL
22	Chlamydia pneumoniae	9.1×10^6IFU/mL
23	Legionella pnuemophila	3.9×10^5CFU/mL
24	Staphylococcus aureus	800 cfu/vial
25	Staphylococcus epidermidis	800 cfu/vial
26	Candida albicans	N/A

4. Interference Substances

The test results do not be interfered with the substance at the following concentration:

No.	Substances	Conc.
1	Whole Blood	4%
2	Chloraseptic(Menthol/Benzocaine)	1.5mg/mL
3	Naso GEL(NeiMed)	5% v/v
4	CVS Nasal Drops (Phenylephrine)	15% v/v
5	Afrin (Oxymetazoline)	15% v/v
6	CVS Nasal Spray (Cromolyn)	15% v/v
7	Zicam	5% v/v
8	Homeopathic (Alkalol)	1:10 dilution
9	Sore Throat Phenol Spray	15% v/v
10	Tobramycin	4 µg/mL
11	Mupirocin	10 mg/mL
12	Fluticasone Propionate	5% v/v
13	Tamiflu (Oseltamivir Phosphate)	5 mg/mL
14	Mucin	0.5%

SYMBOLS

Symbol	Used for	Symbol	Used for
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Tests per kit		Authorized representative in the European Community
	Please don't reuse it		Don't use the product when the package is damaged