



SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay)

REF S3120E-1-H, S3120E-5-H

For in vitro (outside the body) diagnostic use only.
For self-testing use.
For use with nasal swab specimens.

Intended Use

The SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay) is a single-use, in vitro (outside the body) visually read rapid immunoassay that uses a human nasal swab specimen from those suspected of having symptoms of COVID-19 for the qualitative detection of nucleocapsid protein SARS-CoV-2 antigen (Ag). This test is authorized for home use with self-collected nasal swab specimens from individuals aged 17 years or older. Children under 17 years should be supported by an adult.

Summary and Explanation of The Test

The COVID-19 outbreak was first recognized in December 2019 and has since spread to all parts of the world. It has caused tremendous public health and economy challenges worldwide. The causative agent was identified as 2019-nCoV, subsequently designated SARS-CoV-2, which belongs to the species SARS-related coronavirus (SARSr-CoV).

SARS-CoV-2 is a kind of novel coronavirus of the genus β. In general, all people are susceptible to infection. 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.

Test Principle

The SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay) adopts latex immunochromatography technology and utilizes double-antibody-sandwich method to qualitatively detect SARS-CoV-2 antigen in human nasal swab sample. When the sample containing SARS-CoV-2 antigen is added into the test cassette, red reaction line will appear in the test band (T) which indicates the test is positive. When the sample does not contain SARS-CoV-2 antigen or the concentration of SARS-CoV-2 antigen is lower than the minimum detection concentration, no red reaction line will appear in the test band (T) which indicates the test is negative. Regardless of whether SARS-CoV-2 antigen is contained in the samples, there will be a red reaction line in the C region if the test was performed correctly, namely the quality control area. The control line is used for procedural control.

Components of the Diagnostic Kit

No.	Kit Component	1 Test/kit (REF: S3120E-1-H)	5 Tests/kit (REF: S3120E-5-H)
1	SARS-CoV-2-Antigen Test Cassette (with desiccant)	1 test/pouch × 1 pouch	1 test/pouch × 5 pouches
2	SARS-CoV-2 Sample Extraction Buffer	0.5 mL/tube × 1 tube	0.5 mL/tube × 5 tubes
3	Swab	1 device/kit	5 devices/kit
4	Plastic Waste Bag	1 device/kit	5 devices/kit

Materials Required but not provided:

- Timer

Storage Condition and Validity

- Store at 2-30°C in a dry and shady place.
- Avoid direct sunlight.
- The reagents and materials in the kit are stable until the expiration date printed on the outer packaging. Do not use the test kit beyond the expiration date.
- The test device should remain in its original sealed pouch until ready for use. After opening, the test device should be used immediately.

Warnings and Precautions

- Please read the instructions for use carefully before testing.
- Use only the SARS-CoV-2 Sample Extraction Buffer provided in the kit. Use of other liquids will lead to inaccurate results.
- Keep the SARS-CoV-2-Antigen Test Cassette on a flat surface until the result is available.
- The kit should be sealed and kept away from moisture. Reagents or specimens stored at low temperature should be balanced to room temperature before use.
- SARS-CoV-2-Antigen Test Cassette should be used as soon as possible after removal from aluminum foil pouch, so as to get the best performance.
- There should be no red lines on the test card before use.
- This test is only intended for detection of nucleocapsid proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Do not reuse the test kit.
- Do not use SARS-CoV-2-Antigen Test Cassettes which are damaged, or have an unclear label or expired.
- Do not eat the desiccant in the foil pouch.
- Do not dip the Swab into buffer or other liquid before inserting the Swab into the nose.
- Specimens with invalid results are recommended for retest.

- Clean up spills thoroughly using an appropriate disinfectant.
- Wash hands thoroughly before and after the test is completed.
- Dispose of kit components including the swabs in Plastic Waste Bag which has been provided in the kit.
- Dispose of the Plastic Waste Bag in household trash.
- Keep the kit components out of the reach of children and pets before and after use.
- Keep foreign substances away from the test during the testing process. Only for use outside the body.
- Sampling from anyone under the age of 17 should be performed under adult supervision. People who are unable to carry out the test on their own should seek support.
- There is a potential for fluorescent light to lead to a decrease in the intensity of the test line and false negative.

Limitations

1. Detection results should not be used alone for determining SARS-CoV-2 infection status, but should be combined with clinical observations, patient history, epidemiological information, and other laboratory evidence.
2. Positive test results do not rule out co-infections with other pathogens.
3. When the result of the test kit is positive, it is recommended to self-isolate, combine the results of other methods (such as PCR and CT imaging) for further confirmation and consult with the hospital or local public health prevention institutions for treatment.
4. A negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or a molecular assay if necessary for patient management. Therefore, a negative result does not constitute a travel authorisation.
5. A negative result may occur if the concentration of antigen in a specimen is below the limit of detection or if the specimen is collected or transported improperly.
6. Negative test results are not intended to rule out other pathogens infection.
7. This product is only used for the qualitative detection of the SARS-CoV-2-nucleocapsid protein in human nasal swabs, but not for quantitative detection.
8. The performance of the kit was evaluated using the test procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
9. Positive test results do not differentiate between SARS-CoV-2 and SARS-CoV.
10. If there are unknown interference in the specimen, it may cause false test results.
11. A confirmed diagnosis should only be made by a health care professional after all clinical and laboratory findings have been evaluated.
12. If you do not perform the test as per the instructions for use, you may get a false negative result.

FAQ

1. When should I get a test?

- You should get a test for any of the following:
- A) If you have symptoms of COVID-19, even after vaccination.
 - B) If you have had close contact (within 2 meters for a total of 15 minutes or more) with someone with confirmed COVID-19, even after vaccination.
 - C) If you took part in activities that put you at higher risk for COVID-19 because you could not socially distance as needed, such as travel, attending large social or mass gatherings, or being in crowded indoor settings.
 - D) If you have been asked or referred to get tested by your healthcare provider, or local or state health department.

2. How does the SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay) work?

If someone has COVID-19, SARS-CoV-2 (the virus that causes COVID-19) may be present in his (or her) nasal secretions. At this time, we collect the nasal swab sample and processed it, then add the processed sample to test window of the test cassette, the SARS-CoV-2-antigen in the sample will react with the SARS-CoV-2 antibody pre-coated in the test region (T), which finally produces a red reaction line in the T-region.

3. My test result is negative. Does it mean that I'm not infected with SARS-CoV-2? What should I do?

A negative test result does not completely eliminate the possibility of SARS-CoV-2 infection. A negative result may occur if the concentration of antigen in a specimen is below the limit of detection or if the specimen is collected or transported improperly. If symptoms continue, you should repeat the test after 1-2 days, as the coronavirus may not be detectable in the very early phases of infection. You are also advised to continue following local guidelines for self-isolation and consult your doctor. A negative result should not be used to change infection control behaviours, please continue to follow local social distancing guidelines to limit the spread of the virus.

4. My test result is positive. Does it mean I'm infected with SARS-CoV-2? What should I do?

A positive result indicate the presence of SARS-CoV-2 antigen. You should follow local guidelines for social distancing to limit the spread of the virus and contact your doctor or local health department immediately.

5. My test result is invalid. What should I do?

You should test again, using a new test kit and following the instruction. If the test result is still invalid, please stop using the kit and contact your local distributor or our Customer Helpline. Invalid result maybe occurred by not following the test procedure correctly, or the SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay) may be damaged before test.

Clinical Performance

The SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay) has been shown in clinical evaluations, performed by professional health care persons, with a sensitivity of 94.55% (95%CI: 88.51%-97.97%) and a specificity of 100.00% (95%CI: 99.20%-100.00%). Clinical specimens were determined to be positive or negative using an RT-PCR reference method.

SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay)	PCR		
	Positive	Negative	Total
Positive	104	0	104
Negative	6	460	466
Total	110	460	570
Sensitivity	94.55% (95%CI: 88.51%-97.97%)		
Specificity	100.00% (95%CI: 99.20%-100.00%)		
Overall percent agreement	98.95% (95%CI: 97.72%-99.61%)		

Analytical Performance

1. Limit of Detection (LoD)

The detection limit for the test is 80 TCID₅₀/mL.

2. Hook Effect

No hook effect occurs at the concentration of 1.0×10⁵ TCID₅₀/mL.

3. Cross-Reactivity

Cross-reactivity of the SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay) was evaluated by testing a panel of related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimens.

The test shows no cross-reactivity with the following pathogens.

Virus/Bacteria	Concentration Tested	Virus/Bacteria	Concentration Tested
Human coronavirus OC43	1.0 × 10 ⁶ TCID ₅₀ /mL	Enterovirus 70	4.0 × 10 ⁵ TCID ₅₀ /mL
Human coronavirus 229E	1.12 × 10 ⁶ TCID ₅₀ /mL	<i>Mycoplasma pneumoniae</i>	4.62 × 10 ⁶ CFU/mL
Human coronavirus NL63	1.2 × 10 ⁶ TCID ₅₀ /mL	<i>Chlamydia pneumoniae</i>	2.3 × 10 ⁶ CFU/mL
Human coronavirus HKU1	1×10 ⁶ TCID ₅₀ /mL	Measles Virus, Edmonston	1.0 × 10 ⁶ TCID ₅₀ /mL
MERS Coronavirus	1×10 ⁵ TCID ₅₀ /mL	Mumps virus	8.27 × 10 ⁶ TCID ₅₀ /mL
<i>Haemophilus influenzae</i>	1.0 × 10 ⁶ cells/mL	Epstein-Barr virus	3.46 × 10 ⁶ TCID ₅₀ /mL
Influenza A (H3N2)	1.8 × 10 ⁶ CEID ₅₀ /mL	<i>Staphylococcus aureus</i>	4.1 × 10 ⁶ CFU/mL
Influenza A (H1N1, 2009)	1.26 × 10 ⁶ TCID ₅₀ /mL	<i>Streptococcus pyogenes</i>	3.08 × 10 ⁶ CFU/mL
Influenza B (Y strain)	4.2 × 10 ⁷ CEID ₅₀ /mL	Respiratory syncytial virus	1.8 × 10 ⁵ TCID ₅₀ /mL
Influenza B (Victoria strain)	1.0 × 10 ⁵ TCID ₅₀ /mL	<i>Streptococcus pneumoniae</i>	1.42 × 10 ⁶ CFU/mL
Parainfluenza virus 1	4.2 × 10 ⁵ TCID ₅₀ /mL	<i>Candida albicans</i>	2.66 × 10 ⁶ CFU/mL
Parainfluenza Virus 2	1.07 × 10 ⁵ TCID ₅₀ /mL	<i>Metapneumovirus</i>	1.03 × 10 ⁵ TCID ₅₀ /mL
Parainfluenza virus 3	1.0 × 10 ⁶ TCID ₅₀ /mL	<i>Bordetella pertussis</i>	2.0 × 10 ⁶ CFU/mL
Parainfluenza virus 4	1.0 × 10 ⁵ TCID ₅₀ /mL	<i>Staphylococcus epidermidis</i>	1.0 × 10 ⁶ CFU/mL
Adenovirus Type 5	4.26 × 10 ⁷ TCID ₅₀ /mL	<i>Legionella pneumophila</i>	1.25 × 10 ⁶ CFU/mL
Adenovirus Type 7	2.42 × 10 ⁷ TCID ₅₀ /mL	Human Rhinovirus B70	1.0 × 10 ⁶ PFU/mL

4. Endogenous/Exogenous Interference Substances Studies

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay). No interference was seen with the following substances when tested at the concentration presented in the table below.

Substance	Concentration	Substance	Concentration
Blood	4%	Mucoprotein	0.5%
Tobramycin eye drops	5%	Fisherman's Friend	1.5 mg/mL
Gold Throat Spray (Menthol)	15%	Compound Benzocaine Gel	1.5 mg/mL
Mupirocin	10 mg/mL	Sodium chromoglycate eye drops	15%
Ice throat candy (menthol)	1.5 mg/mL	Sinex (phenylephrine hydrochloride)	15%
Tamiflu-oseltamivir	5 mg/mL	Afrin(oxymetazoline)	15%

Naphthalmezoline hydrochloride Nasal drops	15%	Fluticasone Propionate nasal spray	15%
Mucin: bovine submaxillary gland, type I-S	2.5 mg/mL	Human Anti-mouse Antibody (HAMA)	800 ng/mL
Nasal gel, Sodium Chloride	5%	Ceftriaxone	2.5 mg/mL
Nasal Spray (Cromolyn)	15%	Sore Throat Phenol Spray	15%
Zicam Drip Nasal Spray	5%	Nasal Spray (Alkalol)	10%
Nasal ointment, Mupirocin	12 mg/mL	Face cream	1%
Hand cream	5%		

Symbols

Symbols	Meanings	Symbols	Meanings
	In Vitro Diagnostic Medical Device		Date of Manufacture
	Use By		Consult Instructions for Use
	Temperature Limitation		Manufacturer
	Lot Number		Reference Number
	Number of Tests		Any Warnings and/or Precautions to Take
	Keep Away from Sunlight		Do not Re-use
	This product fulfills the requirements of the European Directive 98/79/EC for in vitro diagnostic medical devices		Keep Dry
	Authorized representative in the European Community		Do not use if package is damaged and consult instructions for use
	Medical Device		Sterilized using ethylene oxide

Customer Helpline

If you have any questions about the SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay) or your result, please contact our customer helpline on +86-731-88883176-6116 or send E-mail to info@sansure.com.cn or support@sansure.com.cn.

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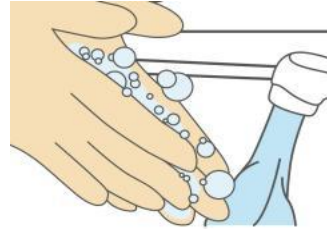
Video

Scan our QR Code with your smart phone to watch the instructions online.



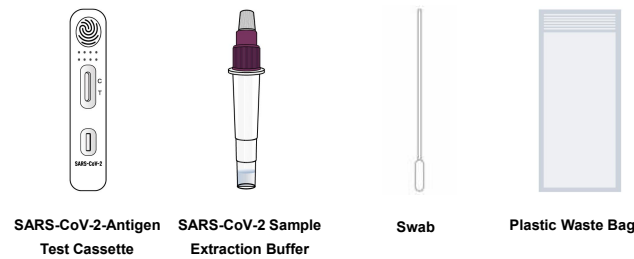
• Before Starting:

Wash or sanitize your hands. Make sure they are dry before starting.

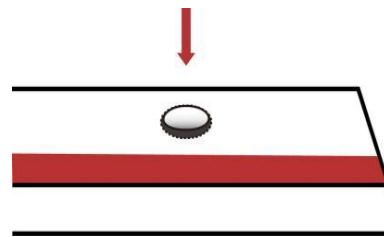


A. PREPARE FOR THE TEST

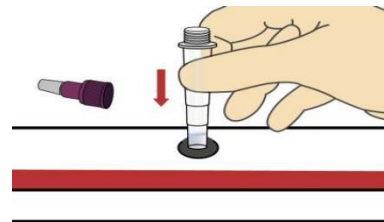
1. Remove the components from the box and identify the kit components.



2. Put the bottom of the kit packing box upright. You can see the circle(s), and then squeeze the paper out to make a tube holder.



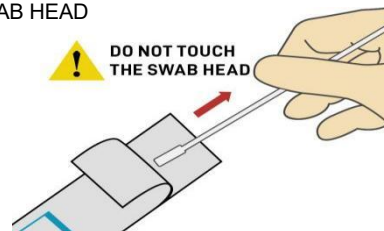
3. Remove the purple cap from extraction tube and place it in the tube holder.



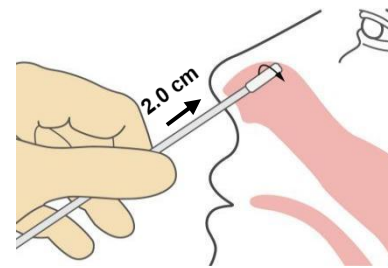
B. THE COLLECTION METHOD OF NASAL SWAB

! DO NOT TOUCH THE SWAB HEAD

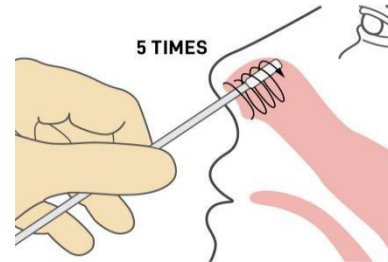
4. Take the Swab out.



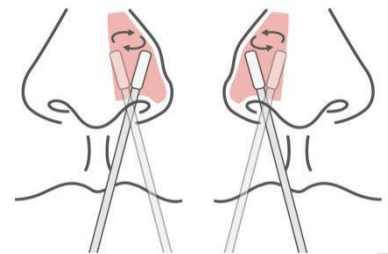
5. Carefully insert the Swab into left nostril about 2.0 cm.



6. Rotate the Swab, 5 times for the left nostril to ensure sufficient specimen collection.



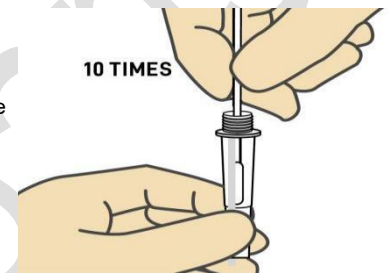
7. Using the same Swab, repeat step 5 and step 6 in your right nostril.



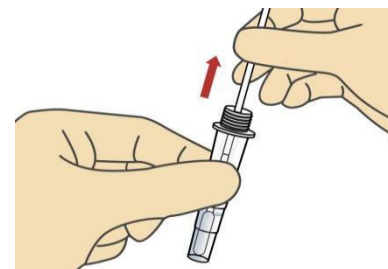
C. TEST PROCEDURE

! Please read the instructions carefully before testing. Samples to be tested, test reagents, and other test materials shall be balanced to room temperature. The test shall be conducted at room temperature.

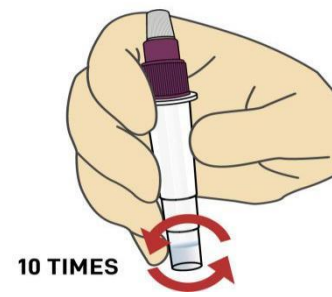
8. Place the Swab into the extraction tube filled with SARS-CoV-2 Sample Extraction Buffer. Stir Swab in the liquid for 10 times. Hold and squeeze the tube to mix the Swab and SARS-CoV-2 Sample Extraction Buffer well.



9. Squeeze out as much liquid as possible from the Swab and remove.



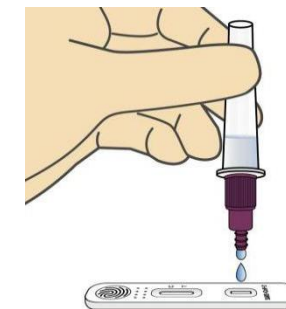
10. Screw up the purple cap tight onto the tube. Shake it gently for 10 times, and be careful not to turn it upside down, to mix the liquid thoroughly.



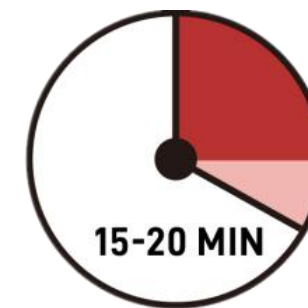
11. Take out the SARS-CoV-2-Antigen Test Cassette from the foil bag and place it flat on the table.



12. Remove the white cap off the extraction tube and turn the tube with samples upside down. Add 3 drops of processed sample to the sample window, and time it.



13. Read the test results within **15~20 minutes**, and the test results have no clinical significance after 20 minutes.



Note

Keep SARS-CoV-2-Antigen Test Cassette in sealed foil pouch prior to use. The cassette should be used within **120 minutes** once the foil pouch is opened. If the temperature is higher than 30°C or under conditions of high humidity (>70%RH), It should be used immediately after the foil pouch is opened.

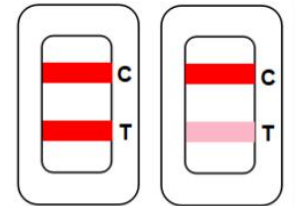
Interpretation of Test Results

Find result window and look carefully for red bands to appear.

Note: There should be no red lines on the test card before use.

Positive:

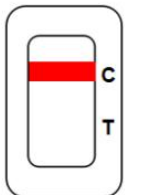
If you watch red bands appearing at both test band (T) and control band (C). This means that the sample contains SARS-CoV-2 antigen.



Note: Look Closely! Samples with low levels of antigen may give a faint sample line. **Even if the test line is very faint or not uniform the test result should be interpreted as a positive result.**

Negative:

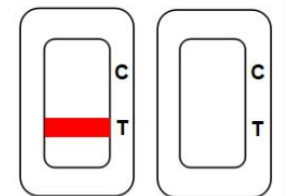
If you watch a red band appearing at control band (C) only, it means SARS-CoV-2 antigen is not detected.



Note: negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or a molecular assay if necessary for patient management.

Invalid:

No visible red band appear at control band (C). The test procedures may not be followed correctly, or the cassette is deteriorated. It is recommended to retest. Please perform a new test with a new sample and a new test cassette.



Disposal

1. Dispose of kit components including the swabs in Plastic Waste Bag which it provided in the kit.
2. Dispose of the Plastic Waste Bag in household trash.