STANDARD Q

COVID-19 Ag Home Test

EN

COVID-19 Antigen Home TestQuick reference instruction

Fast result in 15 minutes | Nasal Test

SD BIOSENSOR

Study the Instructions for Use and User Manual thoroughly before using Quick Reference Instructions. This is not a complete Instructions for Use.

After looking at the diagram below and familiarizing yourself with how to use it, follow the instructions below.

Video Guide

STEP 1 PREPARATION

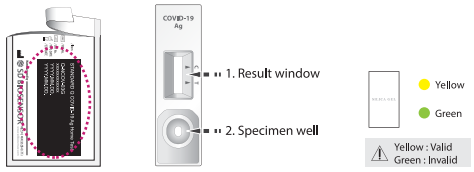
1 Wash your hands.

! It is recommended to wear gloves when using the product.

2 Check the kit contents before testing.

Test device | Solution tube & Nozzle cap | Sterile swab | Instructions for Use & Quick reference instruction

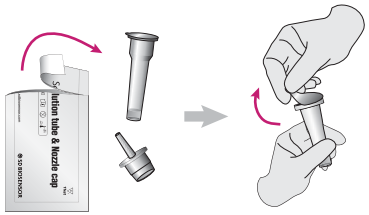
3 Check the expiry date at the back of the foil pouch. After open the foil pouch, check the test device and the desiccant pack in the foil pouch.



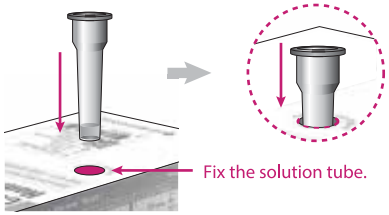
Foil pouch | Test device | Desiccant

STEP 2 SAMPLE COLLECTION

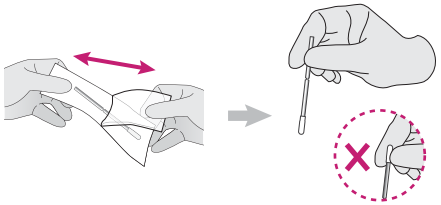
4 Open the Solution tube & Nozzle cap pouch and the seal of solution tube.



5 Set the solution tube on the stand hole of the package.

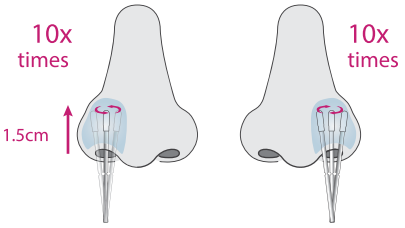


6 Open the sterile swab pouch and hold the swab.



! Do not touch swab tip when handling swab sample.

7 Insert the sterile swab and rotate for both side of nostrils. The sterile swab should be entered in less than one inch (about 1.5cm) into nostril parallel to the palate until resistance is met at turbinates.

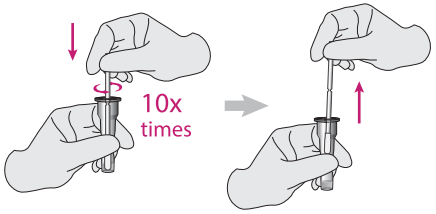


Right nostril | Left nostril

! Do not soak the swab in the solution tube or other liquid until you put it into the nasal cavity.

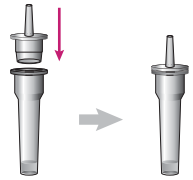
STEP 3 TEST PROCEDURE

8 Insert the swab into an solution tube. While squeezing the solution tube, stir the swab more than 10 times. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

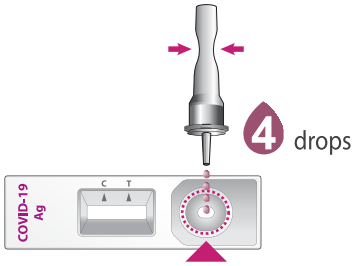


! In case of contact with your skin or eyes, wash immediately with plenty of water.

9 Press the nozzle cap tightly onto the tube.



10 Apply 4 drops of extracted sample to the sample well of the test device.



! Do not squeeze out all of the solution in the solution bottle.

11 Read the test result in 15 minutes.

Read in 15 minutes

! Do not read test results after 30 minutes.

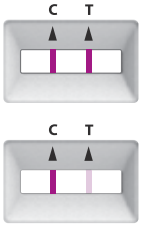
STEP 4 INTERPRETATION OF TEST RESULT

Negative

Negative result: A colored band will appear only control line(C) on the result window.

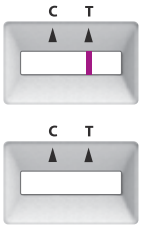
Positive

Positive result: Colored bands will appear both control line(C) and test line(T) on the result window.



Invaild

Retest: If the control line(C) is not appeared in the result window, it is an invalid result. Retest using a new sample and device.



* Positive results should be considered in conjunction with the clinical history and other data available.
* Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.

Biomedia SPD Scientific

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EN | FEF Q-NCOV-03G

Cat. No. 09COV130H

STANDARD Q

COVID-19 Ag Home Test

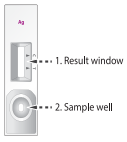
STANDARD™ Q COVID-19 Ag Home Test

SELF-DIAGNOSTIC TEST

Fast results in 15 minutes | Nasal Test

Video Guide

Foil pouch



Test device

Desiccant

COVID-19 Antigen Test
Instructions for Use

SD BIOSENSOR

Product name: STANDARD™ Q COVID-19 Ag Home Test
Model name: STANDARD™ Q COVID-19 Ag Home Test (Q-NCOV-03G)
Intended use: STANDARD Q COVID-19 Ag Home Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigen present in human nasal sample. It provides only an initial screening test result. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

[When to use this kit]
Do use
- If you want to diagnosis current COVID-19 infection.
- If you are concerned that you may have COVID-19.

Do not use
- If you can't collect sample in the recommended way.
- If you are prone to nosebleeds.

EXPLANATION AND SUMMARY

Introduction

Coronavirus is a single-stranded positive-sense RNA virus with an envelope of about 80 to 120 nm in diameter. Its genetic material is the largest of all RNA viruses and is an important pathogen of many domestic animals, pets, and human diseases. It can cause a variety of acute and chronic diseases. Common symptoms in people infected with coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. "2019-nCoV" was discovered because of Wuhan Viral Pneumonia cases in 2019 and on January 12, 2020, World Health Organization (WHO) confirmed that it can cause colds like Severe Acute Respiratory Syndrome (SARS), and Middle East Respiratory Syndrome (MERS).

Test Principle

STANDARD Q COVID-19 Ag Home Test has two pre-coated lines, "C" Control line, "T" Test line on the surface of the nitrocellulose membrane. Both the control line and test line in the result window are not visible before applying any sample. Mouse monoclonal anti-SARS-CoV-2 antibody is coated on the test line region and mouse monoclonal anti-Chicken IgY antibody is coated on the control line region. Mouse monoclonal anti-SARS-CoV-2 antibody conjugated with color particles are used as detectors for SARS-CoV-2 antigen device. During the test, SARS-CoV-2 antigen in the sample interact with monoclonal anti-SARS-CoV-2 antibody conjugated with color particles making antigen-antibody color particle complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the mouse monoclonal anti-SARS-CoV-2 antibody. A colored test line would be visible in the result window if SARS-CoV-2 antigens are present in the sample. The intensity of colored test line will vary depending upon the amount of SARS-CoV-2 antigen present in the sample. If SARS-CoV-2 antigens are not present in the sample, then no color appears in the test line. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

CONTENTS

Test device, Solution tube & Nozzle cap, Sterile swab, Instructions for use & Quick reference instruction

INSTRUCTION FOR USE

Sample Collection

[Nasal swab]
1. Open the seal of solution tube and set the solution tube on the stand hole of the package.
2. Open the sterile swab pouch.
3. Tilt head back 70 degrees.
4. While rotating the swab, insert it less than one inch (about 1.5 cm) into nostril parallel to the palate until resistance is met at turbinates.
5. Rotate the swab 10 times against nasal wall.
6. Repeat in other nostril using the same swab.

Preparation

1. Carefully read instructions for using the STANDARD Q COVID-19 Ag Home Test.
2. Check the expiry date at the back of the foil pouch. Do not use the kit, if expiry date has passed.
3. Check the test device and the desiccant pack in the foil pouch.

Test Procedure

1. Insert the swab into an solution tube. While squeezing the solution tube, stir the swab more than 10 times.
2. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
3. Press the nozzle cap tightly onto the tube.
4. Apply 4 drops of extracted sample to the sample well of the test device.
5. Read the test result in 15 minutes.

⚠ Do not read test results after 30 minutes. It may give false

INTERPRETATION OF TEST RESULT

Results	Example	Interpretation of results
Negative		Negative result: A colored band will appear only control line(C) on the result window.
Positive		Positive result: Colored bands will appear both control line(C) and test line(T) on the result window.
Re-test		Retest: If the control line(C) is not appeared in the result window, it is an invalid result. Retest using a new sample and device.

* Positive results should be considered in conjunction with the clinical history and other data available.
* Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.

KIT STORAGE AND STABILITY

Store the kit at 2-30°C / 36-86°F out of direct sunlight. Kit components can be stably used until the expiration date printed on the external box. Do not store the kit frozen.

PRECAUTIONS FOR USE

1. This product should be used for in vitro diagnosis.
2. COVID-19 self-diagnosis test is a novel coronavirus antigens diagnosis medical device using the nasal.
3. Since the SARS-CoV-2 antigen rapid test is a screening test, it is recommended to conduct the test periodically.
4. Before testing, read the instruction for use and follow the test procedure.
5. This product has been clinically evaluated on patient sample after the onset of COVID-19 symptoms, and was not clinically evaluated on asymptomatic patients.
6. After testing, wash or disinfect your hands thoroughly with soap and running water.

Precautions for Results Review

1. It is not possible to accurately diagnose SARS-CoV-2 infection only with the result of this product. When subject to a thorough examination, the doctor must make the final decision by considering clinical symptoms after performing a confirmation test with an approved RT-PCR product (except for emergency screening).
2. If the concentration of SARS-CoV-2 antigen in the sample is less than the detection limit of the test, or if it is collected or transported improperly, a false negative result may appear. Therefore, the possibility of SARS-CoV-2 infection cannot be eliminated with a negative result.
3. This product only checks the presence of SARS-CoV-2 antigen, and there is no correlation between the strength of the test line and the concentration of SARS-CoV-2 antigen.
4. If there is a mutation in the binding area of the monoclonal antibody contained in this product, the sensitivity may be reduced.
5. This product cannot distinguish between SARS-CoV and SARS-CoV-2 antigens.
6. This product only checks the presence of SARS-CoV-2 antigen, and there is no correlation between the strength (or measured value) of the test line and the concentration of SARS-CoV-2 antigen.
7. Sample collected after 6 days from the onset of symptoms may have false negative results.

AFTER THE TEST

After the test, follow the follow-up instructions below.

Check for Positive COVID-19 Result

If you have a positive result, it is very likely that you have COVID-19.

[What you need to do]
1. You should self-isolate to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result).
2. Consult a healthcare professional as soon as possible. Your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, and your symptoms, possible exposures, and geographic location of places you have recently traveled.

Check for Negative COVID-19 Result

A negative test result means that the SARS-CoV-2 antigen that causes COVID-19 was not found in your sample. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause your recent illness.

[What you need to do]
Please consult a healthcare professional if you develop symptoms, symptoms persist or become more severe. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, duration of illness, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Check for Invalid Result

An invalid test result means that the your test has experienced an error as below.

[The reason for the error occurred]
- When tested without proper understanding of how to use it
- When the insufficient or excessive sample is used
- When the user checks the result at the wrong reading time

[What you need to do]
When your test has experienced an error, you will need to retest with a new test or consult a healthcare professional. Until confirming the new test result, you need to do self-isolate at home. If you have any questions, please contact us to helpline 1-888-885-6121 / email (help.covid19@sdbiosensor.com) and website (www.sdbiosensor.com).

USER SAFETY

[What you need to know]
Older adults and people who have severe underlying medical conditions like heart or lung disease or diabetes seem to be at higher risk for developing more serious complications from COVID-19 illness.

[High risk groups]
People aged 65 years and older
- People in nursing homes or long-term care facilities
- People of all ages with underlying medical conditions, particularly if
- they are not well controlled:
  - Cancer
  - Chronic obstructive pulmonary disease
  - Chronic kidney disease
  - Immunocompromise such as those post solid-organ transplant
  - Obesity (BMI >30)
  - Serious heart conditions such as heart failure, coronary artery disease, cardiomyopathies
  - Sickle cell disease
  - Type II Diabetes
  - Immunocompromised
  - Asthma (Moderate-severe)
  - Cerebrovascular disease (affecting blood vessels to the brain)
  - Cystic fibrosis
  - High blood pressure
  - Immunocompromised (weakened immune system) from blood or bone marrow transplants, immune deficiencies, HIV, use of corticosteroids, use of other immune weakening medications
  - Neurologic conditions such as dementia
  - Liver disease
  - Pregnancy
  - Pulmonary fibrosis
  - Smoking
  - Thalassemia
  - Type I Diabetes

[When to seek emergency medical attention]
Look for emergency warning signs* for COVID-19. If someone is showing any of these signs, seek emergency medical care immediately:
- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion
- Inability to wake or stay awake
- Bluish lips or face

*This is not an exhaustive symptom list. Please call your medical provider for any other symptoms that are severe or concerning to you.

Call 911 or call ahead to your local emergency facility:
Notify the operator that you are seeking care for someone who has or may have COVID-19.

FAQS

What are the known and potential risks and benefits of this test?

Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test results (see Results section).
  - Potential benefits include:
    The results, along with other information, can help your healthcare provider make informed recommendations about your care.
  - The results of this test may help limit the spread of COVID-19 to your family and others in your community.
  - You have the option to refuse this test. However, your doctor has prescribed this test because they believe it could help with your care.

MORE ABOUT THE TEST

1. This product contains small amounts of animal sourced materials.
2. If you have any questions about the product, please contact your local distributor.
3. You can also visit www.sdbiosensor.com for product demonstrations.

COVID-19 INFORMATION

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness although some people infected with COVID-19 may have no symptoms at all. Serious outcomes of COVID-19 can include hospitalization or even death. Older adults and people of any age with underlying medical conditions have a higher risk of severe illness from COVID-19. A full list of symptoms of COVID-19 can be found here: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html COVID-19 is contagious and can be spread even before a person shows symptoms of being sick (e.g. fever, coughing, difficulty breathing). Some people may test positive for COVID-19, but not have symptoms of infection. These people are considered asymptomatic but may still be able to transmit infection to others. Studies have suggested that asymptomatic infection may be common.

What are common symptoms of COVID-19?
Symptoms may appear 2-14 days after exposure and may include fever, cough, shortness of breath, fatigue, muscle or body aches, headaches, loss of sense of taste or smell, sore throat, congestion or a runny nose, nausea or vomiting and diarrhea. It is possible for an infected person to experience no symptoms at all.

How does the virus spread?
The virus that causes COVID-19 is thought to spread mainly from person to person, mainly through respiratory droplets produced when an infected person coughs or sneezes. These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs. These respiratory droplets contain virus particles which can also survive on surfaces for several hours. This is another important source of spread with COVID-19 when people touch these infected surfaces and then touch their faces (mouth, nose, eyes). Spread is more likely when people are in close contact with one another (within about 6 feet). COVID-19 seems to be spreading easily and sustainably in the community ("community spread") in many affected geographic areas. Community spread means people have been infected with the virus in an area, including some who are not sure how or where they became infected.

I tested positive for COVID-19. When can I be with others again? If you have no symptoms at time of testing and continue to have no symptoms:
- After self-isolating for 10 days since your positive test result.

If you have symptoms at time of testing or develop symptoms:
- After self-isolating for at least 10 days since symptoms first appeared and;
- At least 24 hours with no fever (without fever-reducing medications) and;
- Other symptoms of COVID-19 have improved (excluding loss of taste and smell, which may persist for weeks or months after recovery) For the most current information on CDC recommendations regarding self-isolation, visit (https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/isolation.html)

What can I do to stay healthy during the COVID-19 pandemic?
To protect your friends, family, community, and yourself, follow these hygiene practices to help stop the spread of infections.
- Clean and wash your hands often with soap and water or an alcohol-based hand sanitizer.
- Clean all frequently touched surfaces daily with household disinfectants.
- Wear a face covering if you must be around other people in public places, in close contact with people outside of your household or where social distancing of 6 ft is difficult to maintain.
- Sneeze or cough into your elbow or into a tissue. Discard the tissue after using and wash your hands.
- Avoid close contact with people who are sick. This is especially important if you are in the high-risk group.
- If you become sick, avoid other household members where possible isolate yourself in your own room and avoid sharing bathrooms and personal items such as cups, plates and cutlery.

When should I seek medical attention?
If you develop any of the emergency warning signs (refer to User Safety section) for COVID-19 you must seek medical attention.
Emergency warning signs include*:
- Trouble breathing
- Persistent chest pain
- New confusion or inability to wake up or stay awake
- Bluish lips or face

In addition, if you are in the high-risk group (refer to User Safety section) or your symptoms are persisting or worsening, or you have concerns you should seek medical attention.
* This list is not all inclusive. Please see your healthcare professional for any other symptoms that are severe or concerning. For up-to-date information on COVID-19 please visit the CDC COVID-19 website: https://www.cdc.gov/coronavirus/2019-ncov/index.html

DISPOSAL

Dispose of all samples and materials used to perform the test in general waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.

SPECIFIC PERFORMANCE DATA

Clinical evaluation

The clinical performance of the STANDARD Q COVID-19 Ag Home Test for patient self-testing was evaluated using nasal swab samples collected from 146 (of which, 139 within 7 days post symptom onset) study participants in a prospective study at a clinical center in Germany. The clinical evaluations were performed independently from the manufacturer and distributor within a collaboration between the university hospitals Charité in Berlin and Heidelberg. The study cohort included symptomatic adults (aged 18 to 68) who were clinically suspected of having a SARS-CoV-2 infection. In the patient self-testing group, the study participants followed written instructions with illustrations for taking a nasal swab sample and performing the test themselves. The samples were collected and the tests performed under the observation of healthcare professionals, who did not intervene at any stage. PCR tests using combined deep nose/deep throat swab samples were used as a comparative method. Nasal sampling by the self-testers always preceded the combined deep nose/deep throat sample collection for RT-PCR comparison. A SARS-CoV-2 infection was diagnosed (using PCR) in 27.4 % of the patients. The clinical performance of the STANDARD Q COVID-19 Ag Home Test was also evaluated for professional testing following patient self-collection and professional collection of nasal swab samples in the same clinical center. 229 adults who were clinically suspected of having a SARS-CoV-2 infection were included in the prospective study. 133 study participants (there of 126 within 7 days post symptom onset) underwent nasal sampling performed by healthcare professionals and 96 study participants (thereof 83 within 7 days post symptom onset) followed instructions for collecting their nasal swab samples themselves. Self-collection was performed under the supervision of healthcare professionals. PCR tests were performed as described above.

TEST SENSITIVITY AND SPECIFICITY

In the self-testing study, the STANDARD Q COVID-19 Ag Home Test correctly identified 91.2 %(CI: 76.3 % - 98.1 %) of infected study participants with a relatively high viral load (Ct≤ 30). Individuals with a high viral load are considered to be at higher risk of being infectious and transmitting the virus to others. For all study participants, the antigen rapid test correctly identified 82.5 % (CI: 67.2 % - 92.7 %) of infected study participants and 100.0 % (CI: 96.5 % - 100.0 %) of non-infected study participants. In all 3 cohorts together, 110 PCR-positive and 263 PCR-negative study participants were evaluated using the STANDARD Q COVID-19 Ag Home Test. For patients with a relatively high viral load (Ct ≤ 30), the relative sensitivity was 91.1 % (95 % CI: 83.8 % - 95.8 %, N=101). For all samples, the overall relative sensitivity and the overall relative specificity were 86.4 %(95 % CI: 78.5 % - 92.2 %) and 99.6 % (95 % CI: 97.9 % - 100.0 %), respectively. For patients tested within 7 days post symptom onset (DPSO), the relative sensitivity was 87.4 % (95 % CI: 79.4 % - 93.1 %) and the relative specificity was 99.6 % (95 % CI: 97.7 % - 100.0 %).

BIBLIOGRAPHY

1. Clinical management of severe acute respiratory infection when novel coronavirus(nCoV) infection is suspected. Interim guidance. WHO.2020
2. Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR.2020
3. Diagnosis and treatment of pneumonia caused by new coronavirus (trial version 4) National Health Commission. 2020

SYMBOL

REF	Reference number	⚠	Caution		Use by	LOT	Batch code		Consult Instructions for Use	⊗	Do not re-use
IVD	In vitro Diagnostics		Note		Manufacturer		Date of manufacture		Contains Sufficient for <n> Tests		Keep away from sunlight
	Indicate that you should keep the product dry		To indicate the temperature limitations in which the transport package has to be kept and handled.				Do not use if packaging is damaged				

	Antigen positive/ PCR positive	Antigen negative/ PCR negative	Relative sensitivity (95% confidence interval)	Relative specificity (95% confidence interval)
Self Testing**	33 out of 40	105 out of 105	82.5 % (67.2 % - 92.7 %)	100 % (96.5 % -100 %)
Self collection	31 out of 34	61 out of 62	91.2 % (76.3 % - 98.1 %)	98.4 % (91.3 % - 100 %)
Professional collection*	31 out of 36	96 out of 96	86.1 % (70.5 % - 95.3 %)	100 % (96.2 % - 100 %)
Combined*,**	95 out of 110	262 out of 263	86.4 % (78.5 % - 92.2 %)	99.6 % (97.9 % - 100 %)
Ct ≤ 30***	92 out of 101	n.a.	91.1 % (83.8 % - 95.8 %)	n.a.
DPSO ≤ 7*,**	90 out of 103	242 out of 243	87.4 % (79.4 % - 93.1 %)	99.6 % (97.7 % - 100 %)

*One sample was excluded from the analysis because the PCR test result was not available.
**One sample (PCR negative) was excluded from the analysis because the antigen test result was not available.
***Ct values are commonly used to estimate the amount of the viral material in samples. A low Ct value suggests the presence of a lot of viral material, and a high Ct value suggests the presence of lower levels of viral material.

NOTE

"STANDARD™Q COVID-19 Ag Test has received Provisional Authorisation from the Health Sciences Authority in Singapore"

IVD

Manufactured by **SD Biosensor, Inc.**
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