EN REF Q-NCOV-08G

Cat.no: 09COV174D

STANDARD Q

COVID-19 Ag Test 2.0

STANDARD™ Q COVID-19 Ag Test 2.0

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

EXPLANATION AND SUMMARY

■ Intended use

The STANDARD Q COVID-19 Ag Test 2.0 is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first six (6) days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. The STANDARD Q COVID-19 Ag Test 2.0 does not differentiate between SARS-CoV and SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities. All negative results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19. The STANDARD Q COVID-19 Ag Test 2.0 is intended for use by medical professionals or operators who are proficient in performing tests in a point of care setting. The STANDARD Q COVID-19 Ag Test 2.0 is only for *in vitro* diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

■ Introduction

Coronaviruses are enveloped positive-stranded RNA viruses belonging to the Order of *Nidovirales*. In late 2019 a new coronavirus was identified in a cluster of pneumonia cases. The novel coronavirus, now known as SARS-CoV-2, has been classified as a member of the *Sarbecovirus* subgenus under the *Betacoronavirus* genus, and the disease associated with SARS-CoV-2 infection has been named COVID-19 (COronaVIrus Disease 2019). Due to the rapid rise in the number of cases and the scale of worldwide spread, the World Health Organization (WHO) described the SARS-CoV-2 situation as pandemic on March 11, 2020. The clinical presentation of SARS-CoV-2 can range from asymptomatic infection to severe disease and even death. Symptoms of patients with confirmed SARS-CoV-2 infection vary from fever and dry cough to shortness of breath or difficulty in breathing. In addition, diarrhea and a loss of taste or smell have been reported after a SARS-CoV-2 infection. Symptom onset may appear up to 14 days after exposure to the virus.

■ Test principle

The STANDARD Q COVID-19 Ag Test 2.0 has 2 pre-coated lines: a "C" Control line and a "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 specimens. 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 the SARS-CoV-2 antigen device. During the test, the SARS-CoV-2 antigen in the specimen interacts with monoclonal anti-SARS-CoV-2 antibody conjugated with color particles making an antigen-antibody color particle complex. This complex migrates on the membrane via capillary action to the test line, where it is captured by the mouse monoclonal anti-SARS-CoV-2 antibody. A colored test line becomes visible in the result window if SARS-CoV-2 antigens are present in the sample.

ACTIVE COMPONENTS

- mAb anti-SARS-CoV-2 antibody
- mAb anti-Chicken IgY
- mAb anti-SARS-CoV-2 antibody-gold conjugate
- Purified chicken IgY-gold conjugate
- Recombinant SARS-CoV-2 nucleocapsid protein
- BSA (Bovine Serum Albumin)

KIT CONTENTS

No	Contents
1	25x Test device (individually in a foil pouch with desiccant)
2	25x Extraction buffer tube
3	25x Nozzle cap
4	25x Sterile swab
5	1x Buffer tube rack
6	1x STANDARD COVID-19 Ag Positive Control swab
7	1x STANDARD COVID-19 Ag Negative Control swab
8	1x Instructions for use & Quick reference instructions

MATERIALS REQUIRED BUT NOT PROVIDED

1. Personal protective equipment per local recommendations or requirements (i.e. gown/lab coat, face mask, face shield/eye goggles and gloves)
2. Timer
3. Biohazard waste container

※ Additional external positive/negative quality controls (STANDARD COVID-19 Ag Control; REF No. C-NCOV-03G) can be purchased separately.

STORAGE AND STABILITY

Store the kit at 36-86 °F / 2-30 °C and protect from direct sunlight. The expiry date of the materials is indicated on the external packaging. Do not freeze the kit.

WARNINGS AND PRECAUTIONS

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If you have had symptoms longer than 6 days you should consider testing at least three times over five days with at least 48 hours between tests.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Bring the kit contents and specimens to operating temperature (15-30°C/59-86 °F) before testing.
- Do not smoke, drink or eat while testing.
- Do not use the control swabs for sample collection from patients.
- If there is evidence of microbial contamination in the reconstituted control in the extraction buffer, discard the control.
- Wear protective clothing, mask, and gloves when handling specimens and reagents. Wash hands thoroughly after the tests are done.
- Handle and dispose of all specimens, controls and materials used in testing as though they contain infectious agents.
- Dispose of all samples and materials used to perform the test as biohazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not open the kit contents until ready for use.
- Do not touch the swab tip.
- Testing should commence immediately after opening the sealed pouches.
- **Do not read test results before 20 minutes or after 30 minutes. Results read before 20 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.**
- The control line may show up within a few minutes of starting the test. It may take up to 20 minutes for a test line to show up.
- Make sure there is sufficient light when testing and reading the test results.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- In the event of a spillage, ensure it is cleaned thoroughly using a suitable disinfectant.
- If you suspect the presence of blood on the swab, discard the swab, make sure you are not bleeding, and repeat the test with a fresh swab.
- Remove any piercings from the nose before starting the test.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin and eyes. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin and eyes, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

Chemical dadf/ CAS	Hazard Category (mixture)	Hazard Statement for Mixture	Labeling of Harm(s)
Sodium chloride / 7647-14-5 L-Arginine / 74-79-3	Category 2	Eye irritation	May cause eye irritation
Polidocanol / 9002-92-0 ProClin® 300	Category 3	Skin irritation	Causes mild skin irritation

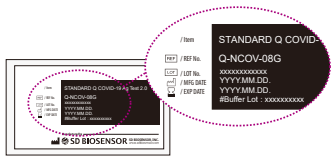
- If the reagent solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice. https://www.poison.org/contact-us or 1-800-222-1222.
- For more information on EUAs please visit:
- https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-fr amework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

PREPARATION AND SPECIMEN COLLECTION FOR COVID-19 Ag TEST

■ Preparation

1. Bring test kit to room temperature (59-86 °F / 15-30 °C).
2. Wash your hands with soap and water, or use hand sanitizer before performing the test. Make sure you rinse thoroughly and your hands are dry before starting.

3. Check test expiry date on the back of the foil pouches. Do not use if the expiry date has passed.



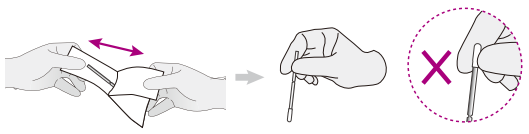
Testing should commence immediately after opening of the test device pouch.

4. Open the foil pouch by tearing along the tear- line. Remove the test device and desiccant package from the foil pouch. Place the test device on a flat surface.
5. Ensure that the test device is intact and that there are no green beads in the desiccant package (white and yellow beads are expected).

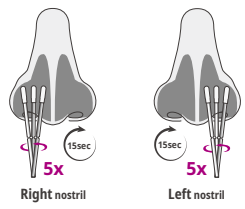
Do not open the desiccant package.

■ TEST PROCEDURE

1. Remove the swab from the packaging. Ensure that you only touch the handle of the swab and not the soft pad at the tip.



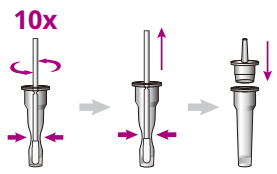
2. Holding the stick end of the swab, gently insert the foam end of the swab into the nostril approximately ¾ of an inch. Rotate the swab at least 5 times, brushing against the inside walls of the nostril, for a total of 15 seconds.
   **** Do not just spin the swab.****
   Using the same swab, repeat in the second nostril.
   ****Swab both nostrils.****



Inaccurate test results may occur if the nasal swab specimen is not properly collected.

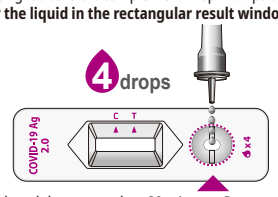
With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child's head while swabbing.

3. Carefully open the extraction buffer tube avoiding spillage. If any liquid spills, do not use the tube.
4. Insert the swab into the extraction buffer tube until the soft pad is in the liquid. Squeeze the tube at the bottom and stir the swab **more than 10 times while squeezing the tube.** Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Dispose of the swab and seal the tube securely with the nozzle cap.
   ****Ensure that the nozzle cap is securely fitted before proceeding to the next step.****

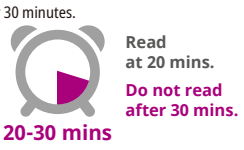


Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

5. Hold the tube upright above the sample well. Drop 4 drops onto the sample well.
   ****Do not apply the liquid in the rectangular result window****



6. Set the timer and read the test result at 20 minutes. Do not read the result before 20 minutes or after 30 minutes.



Do not move or lift the test device during this time.

INTERNAL QUALITY CONTROL

A control line is used in the test as a procedural control. A visible control line confirms that the lateral flow of the test is successful but is not the confirmation that the specimen and buffer have been applied properly.

CIRCUMSTANCES FOR RUNNING QUALITY CONTROL TESTS

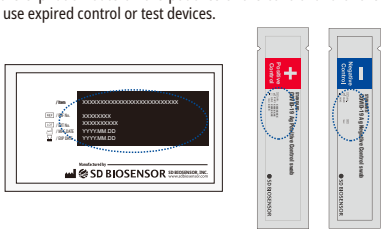
It is important to perform quality control tests with positive and negative control materials to ensure your system is working properly. It is recommended that positive and negative controls be run:

- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit storage area falls outside of 2°-30°C (35°-86°F), and
- At periodic intervals as dictated by the user facility, country, state or local regulations and policies :
- Control tests may be ran prior to performing each serial testing on patient specimens.
- Serial testing of STNADARD Q COVID-19 Ag Test 2.0 should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals.

PREPARATION AND PERFORMING A QUALITY CONTROL TEST

■ Preparation

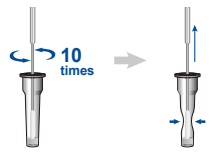
1. Bring the STANDARD™ COVID-19 Ag Test 2.0 and the STANDARD™ COVID-19 Ag Control swab to operating temperature (15-30°C / 59-86°F) at least 30 minutes prior to the test.
2. Carefully read the Instructions for Use for the STANDARD™ COVID-19 Ag Test 2.0.
3. Check the expiration date on the pouches of the control and of the test device. Do not use expired control or test devices.



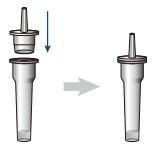
■ Test Procedure

1. Insert the positive or negative control swab into an extraction buffer tube which is in the STANDARD Q COVID-19 Ag Test 2.0. Stir the swab at least ten times while squeezing the sides of the buffer tube.

   Warning: Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

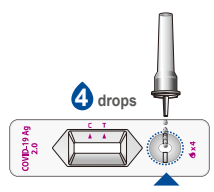


2. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
3. Press the nozzle cap tightly onto the tube.



4. Apply 4 drops of the prepared control mixture into the specimen well of the test device.
5. Read the results in accordance with the Instructions for Use accompanying the STANDARD Q COVID-19 Ag Test 2.0.

   Warning: Read the results at 20 minutes. Do not read before 20 minutes or after 30 minutes. Even faint lines should be considered as a valid result.



INTERPRETATION OF TEST RESULTS

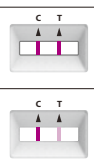
■ COVID-19 Ag Test Interpretation

Inaccurate test interpretations may occur if results are read before 20 minutes or after 30 minutes.

Look at the result window and locate the letters C and T on the top side of the window. A colored line should always appear at the C position; this is the control line and signals that the test is working properly.

Test result	Example	Description
Negative		**Negative result** If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. **To increase the chance that the negative result for COVID-19 is accurate, you should:** • **Test again in 48 hours if the individual has symptoms on the first day of testing.** • **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider. All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Positive		**Positive result** If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible, colored test (T) line with the control line (C) should be read as positive. **Repeat testing does not need to be performed if patients have a positive result at any time.**

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive). Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the STANDARD Q COVID-19 Ag Test 2.0 should self-isolate and seek follow up care with their physician or healthcare provider as 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.

Invalid		**Invalid result** If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device. If your test result is still invalid, please contact SD BIOSENSOR COVID-19 Support : ts@sdbiosensor.com, +82-80-970-9700

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

■ Quality Control Test Interpretation

STANDARD COVID-19 Ag Positive Control			
Result		Interpretation	Follow up
Test Line (T)	Control Line (C)		
Positive	Positive	Pass	-
Negative	Positive	Invalid	Retest*
No control line (C)		Invalid	Retest*

STANDARD COVID-19 Ag Negative Control			
Results		Interpretation	Follow up
Test Line (T)	Control Line (C)		
Negative	Positive	Pass	-
Positive	Positive	Invalid	Retest*
No control line (C)		Invalid	Retest*

* Use new test devices and new control for retesting. If the invalid control test result recurs, contact SD BIOSENSOR Customer Service Center: ts@sdbiosensor.com

LIMITATION OF TEST

1. For *in vitro* diagnostic use.
2. For prescription use only.
3. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected in December 2021 and February -March 2022. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
4. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
5. All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
6. If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
7. If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
8. This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
9. Incorrect test results may occur if a specimen is incorrectly collected or handled.
10. This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
11. This device is only used for testing direct human anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.
12. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after six days since symptoms onset are more likely to be negative compared to RT-PCR.
13. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected improperly.
14. The performance of the STANDARD Q COVID-19 Ag Test 2.0 was evaluated using the procedures provided in these Instructions for Use (IFU) only. Modifications to these procedures may alter the performance of the test.
15. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
16. Test results must be evaluated in conjunction with other clinical data available to the physician.
17. Positive test results do not rule out co-infections with other pathogens.
18. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

CONDITIONS OF AUTHORIZATION FOR LABORATORIES

The Standard Q COVID-19 Ag Test 2.0 Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website:

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical- devices/invitro-diagnostics-euas

However, to assist in using Standard Q COVID-19 Ag Test 2.0 ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

- Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in the Standard Q COVID-19 Ag Test 2.0 Instructions for Use and Quick Reference Instructions. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) or SD Biosensor, Inc. (via email: ts@sdbiosensor.com or via phone by contacting SD Biosensor at +82-80-970-9700) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- SD Biosensor, Inc., authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation."

SPECIFIC PERFORMANCE DATA

■ Clinical Evaluation

The STANDARD Q COVID-19 Ag Test 2.0 is identical to the Pilot COVID-19 At-Home Test and therefore, the clinical performance is based on the clinical study conducted with this test. The test was evaluated in a prospective, all comer's study was evaluated in a prospective, all- comer's study at 5 clinical sites in the United States. Patients or legal guardians of patients above 2 years of age visiting the study sites seeking testing and presenting symptoms suspicious of COVID-19 were approached to participate in the study. Those beyond 7 days since the onset of symptoms were excluded. Participants aged 14 years or older followed the Quick Reference Instructions provided in the test kit to self-collect an anterior nasal (nares) swab sample and performed the test using the STANDARD Q COVID-19 Ag Test 2.0. Participants younger than 14 years of age were sampled and tested by an adult participant (e.g., parent or legal guardian). A bilateral mid-turbinate nasal swab sample was also taken from each study participant by a healthcare professional for testing on a high- sensitivity, FDA EUA-authorized RT-PCR method as the comparator. In total, 168 participants were enrolled in this study, and valid rapid antigen and RT-PCR results were obtained for 158 participants. The STANDARD Q COVID-19 Ag Test 2.0 correctly identified 41 out of 44 SARS-CoV-2-positive individuals, and 114 out of 114 SARS-CoV-2-negative individuals. The relative diagnostic sensitivity and specificity of STANDARD Q COVID-19 Ag Test 2.0 were calculated in comparison to the comparator method and summarized in the tables below.

Performance summary against an authorized RT-PCR comparator method.

		RT-PCR Results		
		Positive	Negative	Total
SARS-CoV-2 Antigen Test Results	Positive	41	0	41
	Negative	3**	114	117
	Total	44	114	158
Relative sensitivity		93.2 % (95 % CI*: 81.8 to 97.7 %)		
Relative specificity		100 % (95 % CI*: 96.7 - 100 %)		

* The two-sided 95% confidence interval was calculated using the Wilson Method.
** The three discordant (false-negative) samples were re-tested on a different high-sensitivity, FDA EUA- authorized RT-PCR method, and all samples tested negative on this.

SD BIOSENSOR

Relative sensitivity stratified by days post symptoms onset.

DPSO	RT-PCR Positives	Rapid Antigen Positives
0-1	3	2
2	17	15
3	10	10
4	12	12
5	1	1
6	1	1
All	44	41

Performance stratified by age groups

Age group	RT-PCR Positives	Rapid Antigen Positives
< 14	6	5
14 - 24	8	8
>24 - 64	29	27
≥ 65	1	1
All	44	41

Another prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive. At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule. Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 -48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test. Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in the following table.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined:

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING Second Result Day 3			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Test	3 Test	1 Test	2 Test	3 Test
0	9/97 (9.3 %)	35/89 (39.3 %)	44/78 (56.4 %)	34/57 (59.6 %)	47/51 (92.2 %)	44/47 (93.6 %)
2	17/34 (50.0 %)	23/34 (67.6 %)	25/32 (78.1 %)	58/62 (93.5 %)	59/60 (98.3 %)	43/43 (100 %)
4	16/21 (76.2 %)	15/20 (75.0 %)	13/15 (86.7 %)	55/58 (94.8 %)	53/54 (98.1 %)	39/40 (97.5 %)
6	20/28 (71.4 %)	21/27 (77.8 %)	16/18 (88.9 %)	27/34 (79.4 %)	26/33 (78.8 %)	22/27 (81.5 %)
8	13/23 (56.5 %)	13/22 (59.1 %)	4/11 (36.4 %)	12/17 (70.6 %)	12/17 (70.6 %)	7/11 (63.6 %)
10	5/9 (55.6 %)	5/8 (62.5 %)		4/9 (44.4 %)	3/7 (42.9 %)	

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

■ Analytical performance

[Limit of Detection (LoD)]

The SARS-CoV-2 positive specimen was prepared by spiking inactivated SARS-CoV-2 (isolate USA-WA1/2020) into pooled negative nasal matrix (PNM) that was confirmed to be negative with PCR. A serial dilution of specimens was tested by applying a sample volume of 50 µL to each nasal swab before elution and sample application was performed according to the test procedure described in the IFU. The LoD was determined to be 1.4 x 10^3 $TCID_{50}$/mL. Based upon the testing procedure for this study the LoD of 1.4 x 10^3 $TCID_{50}$/mL equates to 7.0 x 10^1 $TCID_{50}$/swab

[Omicron Testing]

The performance of this test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Specimen pools were prepared by the RADx team using pooled clinical samples from currently circulating Omicron strains and tested by RADx® to assess performance with the Omicron variant. Results from this dilution series cannot be compared to any devices tested with a different specimen pool and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, the STANDARD Q COVID-19 Ag Test 2.0 detected 100% of live virus Omicron samples at a Ct-value of 27.7 (n=5). Testing was also compared to two additional EUA authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values higher than 27.7) were not detected by the STANDARD Q COVID-19 Ag Test 2.0 in this study.

Omicron Live Pool 1		Test Assay #1	Test Assay #2	STANDARD Q COVID-19 Ag Test 2.0
Dilutions	Avg N2 Ct (N=9)	Percent Positive N=5	Percent Positive N=5	Percent Positive N=5
Dilution 1	19.4	100	100	100
Dilution 2	20.6	100	100	100
Dilution 3	21.6	100	100	100
Dilution 4	22.4	100	100	100
Dilution 5	23.3	100	100	100
Dilution 6	24.5	0	100	100
Dilution 7	25.6	0	100	100
Dilution 8	26.5	0	0	100
Dilution 9	27.7	0	0	100
Dilution 10	28.5	0	0	0
Dilution 11	29.4	0	0	0
Dilution 12	30.3	0	0	0

[Cross-reactivity]

No cross-reactivity was observed for the following organisms at the indicated concentrations, except for SARS-coronavirus, which exhibited cross-reactivity when tested at 1.58 x 10^4 $TCID_{50}$/mL. A titration of SARS-CoV was performed to determine the concentration at which cross reactivity was no longer observed. Cross reactivity was no longer observed for SARS-CoV at 1.58 x 10^1 $TCID_{50}$/mL. These results are not unexpected as the STANDARD Q COVID-19 Ag Test 2.0 targets the nucleocapsid protein, which is present in both the SARS-CoV and SARS-CoV-2 viruses and is highly homologous.

Microorganism / Specimen	Concentration Tested for Cross Reactivity	Result
Human coronavirus 229E	1.43 × 10^5 $TCID_{50}$/mL	NEG
Human coronavirus OC43	8.50 × 10^4 $TCID_{50}$/mL	NEG
Human coronavirus NL63	1.17 × 10^5 $TCID_{50}$/mL	NEG
SARS-coronavirus	1.58 × 10^4 $TCID_{50}$/mL	POS
SARS-coronavirus (1:1000)	1.58 x 10^1 $TCID_{50}$/mL	NEG
MERS-coronavirus	1.43 × 10^5 $TCID_{50}$/mL	NEG
Adenovirus	1.43 × 10^5 $TCID_{50}$/mL	NEG
Human metapneumovirus 4 Type B2	1.43 × 10^5 $TCID_{50}$/mL	NEG
Parainfluenza virus 1	5.50 × 10^5 $TCID_{50}$/mL	NEG
Parainfluenza virus 2	1.43 × 10^5 $TCID_{50}$/mL	NEG
Parainfluenza virus 3	1.43 × 10^5 $TCID_{50}$/mL	NEG
Parainfluenza virus 4b	1.43 × 10^5 $TCID_{50}$/mL	NEG
Influenza A	1.43 × 10^5 $CEID_{50}$/mL	NEG
Influenza B	1.43 × 10^5 $TCID_{50}$/mL	NEG
Enterovirus 68	1.43 × 10^5 $TCID_{50}$/mL	NEG
Respiratory syncytial virus	1.43 × 10^5 PFU/mL	NEG
Rhinovirus	1.43 × 10^5 $TCID_{50}$/mL	NEG
Haemophilus influenzae	1.00 ×10^6 CFU/mL	NEG
Streptococcus pneumonia	1.00 × 10^6 CFU/mL	NEG
Streptococcus pyogenes	2.59 × 10^6 CFU/mL	NEG
Candida albicans	1.00 × 10^6 CFU/mL	NEG
Bordetella pertussis	1.00 × 10^6 CFU/mL	NEG
Mycoplasma pneumonia	2.57 × 10^8 CFU/mL	NEG
Chlamydia pneumoniae	1.00 × 10^6 IFU/mL	NEG
Legionella pneumophila	1.00 × 10^6 CFU/mL	NEG
Mycobacterium tuberculosis	1.00 × 10^8 CFU/mL	NEG
Pneumocystis carinii	1.00 × 10^6 nuclei/mL	NEG
P. jiroveci-S. cerevisiae	8.10 × 10^5 CFU/mL	NEG
Staphylococcus aureus subsp. aureus	1.00 × 10^6 CFU/mL	NEG
Staphylococcus epidermidis	1.00 × 10^6 CFU/mL	NEG
Pooled Negative Matrix	N/A	NEG

MICROBIAL INTERFERENCE

For the microorganisms which did not demonstrate cross-reactivity, additional microbial interference testing with SARS-CoV-2 positive samples spiked into pooled negative nasal matrix were performed and no microbial interference was observed.

ENDOGENOUS / EXOGENOUS CROSS-REACTIVITY STUDY

No cross-reactivity was observed for the following substances at the indicated concentrations. Each substance was spiked into pooled negative nasal matrix for testing.

Potentially Interfering Substance	Concentration	Result
Human Whole Blood (EDTA tube)	4% v/v	NEG
Mucin (Porcine Stomach, type II)	0.5%	NEG
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	NEG
Naso GEL (NeilMed)	5% v/v	NEG
Nasal Drops (Phenylephrine)	15% v/v	NEG
Nasal Spray (Oxymetazoline)	15% v/v	NEG
Nasal Spray (Cromolyn)	15% v/v	NEG
Zicam	5% v/v	NEG
Homeopathic (Alkalol)	10% v/v	NEG
Sore Throat Phenol Spray	15% v/v	NEG
Tobramycin	4 µg/mL	NEG
Mupirocin	10 mg/mL	NEG
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	NEG
Fluticasone Propionate	5% v/v	NEG
Body & Hand Lotion (Cerave)	0.5% w/v	NEG
Body Lotion with 1.2% Dimethicone	0.5% w/v	NEG
Hand Lotion (Eucerin)	5% w/v	NEG
Hand Sanitizer with Aloe, 62% Ethyl Alcohol	5% v/v	NEG
Hand Sanitizer Cream Lotion (Vaseline)	15% v/v	NEG
Hand Sanitizer, 80% Ethanol, Fast Drying	15% v/v	NEG
Hand Soap Liquid Gel (Soft Soap)	10% w/v	NEG

ENDOGENOUS / EXOGENOUS INTERFERENCE SUBSTANCES STUDY

For the substances listed above, additional endogenous / exogenous interference studies were performed with samples containing SARS-CoV-2 in pooled negative nasal matrix. Each substance was spiked into a positive sample and no endogenous / exogenous interference was found, except for hand soap liquid gel, which caused a false negative result at a concentration of 10% w/v and 5% w/v. A positive result (no interference) was observed at a concentration of 1% w/v.

HIGH-DOSE HOOK EFFECT

SARS-CoV-2 cultured virus was spiked into pooled negative nasal matrix. SARS-CoV-2 cultured virus did not show hook effect at the virus stock concentration of 2.80 x 10^6 $TCID_{50}$/mL.

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