Canadian Pharmacists Association | Association des pharmaciens du Canada

Neighbourhood Pharmacy Association of Canada | Association canadienne des pharmacies de quartier

RAPID TESTS TRAINING GUIDE

How to Administer Test

All persons administering a test should adhere to provincial/territorial guidelines. For further details, please refer to your provincial/territorial ministry of health.

1. Wear appropriate PPE, as outlined by your local provincial/territorial ministry of health (e.g., gloves, apron, mask, sneeze guard, etc.). Ensure testing area has been appropriately disinfected before each test. Open test.
2. Hold buffer bottle vertically and fill extraction tube with fluid until fill line. Place the extraction tube in tube rack.
3. Swab nose. Tilt head backwards (approx. 70°). Insert swab 2 cm into nostril and rotate swab 5 times against nasal wall. Repeat in other nostril with the same swab.
4. Insert used swab into extraction tube. Swirl swab on the sides of the extraction tube 5 times and squeeze out swab by holding the sides of the extraction tube with your fingers tightly. Break swab at breakpoint. Place cap on extraction tube and close tightly.
5. Open nozzle cap at the bottom of the extraction tube. Dispense 5 drops of extracted specimen onto the device. Leave test unmoved until ready to read (approx. 15–20 minutes). Close nozzle and begin disposal procedure.

For video instructions, please refer to Abbott video: https://alere.wistia.com/medias/82co9bznbc

How to Dispose of Test

1. Ensure both caps on the extraction tube are sealed tightly.
2. Dispose of both the extraction tube (with swab inside) and testing device into regular waste disposal or use a biohazard waste disposal process if one is available to you.
3. Clean area with disinfectant and follow proper doffing and disposing procedures for PPE. Ensure new PPE is used for each test procedure and patient.

For detailed disposal instructions, please refer to your local provincial/territorial health ministry website. Please note the Province of Ontario requires additional disposal steps, found here: https://covid-19.ontario.ca/provincial-antigen-screening-program

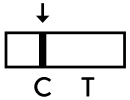
Keep rapid antigen test kits and solutions out of the reach of children and pets, before and after use. Keep test kit and kit components together and sealed until immediate use.

How to Interpret Test Results

Regardless of rapid test results, if you are experiencing any COVID-19 symptoms, follow all local public health guidelines.

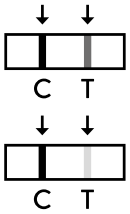
Negative

The presence of only the control line (C) and no test line (T) within the results window indicates a negative test result. A negative result is presumptive and is only valid the day of testing.



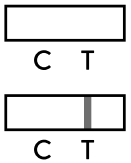
Positive

The presence of the control line (C) and test line (T) within the results window indicates a positive test result, regardless of which line appears first, or how faint. A positive result is presumptive and is only valid the day of testing.



Invalid

The presence of no lines within the results window, or the presence of only the test line (T) indicate an invalid test result. Reread instructions on administration before retesting the specimen with a new testing device.



For full details, please refer to the Abbott leaflet found inside the testing kit, and here: https://extranet.who.int/pqweb/sites/default/files/documents/EUL_0587_032_00_PanbioCOVID-19_AgRapidTestDevice_NASAL_ifu.pdf

For reporting instructions and requirements for positive cases, please refer to your local provincial/territorial ministry of health website.

Additional training resources: Some provinces also have specific guidance and training material on rapid testing, see: https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/testing-screening-contact-tracing/workplace/rapid-antigen-tests.html#a3

Abbott

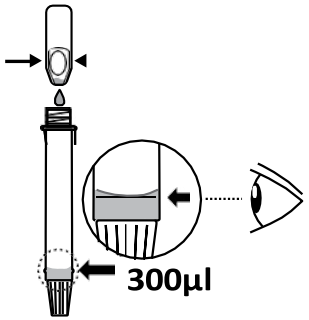
Panbio™

COVID-19 Ag Rapid Test Device (NASAL)

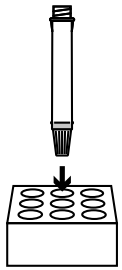
TEST PROCEDURE

1 Squeeze the liquid from the buffer bottle and fill the extraction tube with buffer fluid until it flows up to the fill-line of the extraction tube (300 µl). You will need to squeeze at least twice.

⚠ **Caution:** If the amount of buffer is excessive or insufficient, an improper test result may occur. The buffer fluid should be at or slightly above the fill line on the side of the tube.

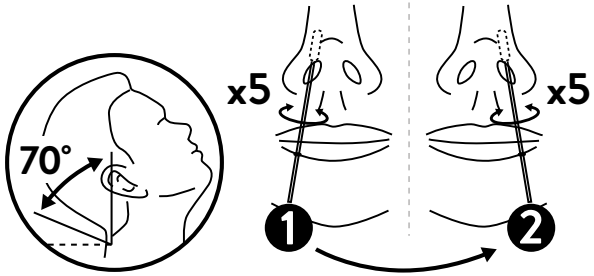


2 Place the extraction tube in the tube rack.

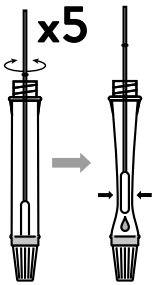


3 Tilt the patient's head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at the turbinates). Rotate the swab five times against the nasal wall. Using the same swab repeat the collection procedure with the second nostril. Slowly remove swab from the nostril.

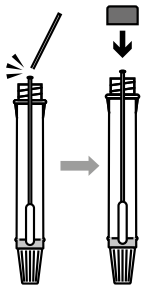
⚠ **Caution:** If the swab stick breaks during sample collection, repeat sample collection with a new swab.



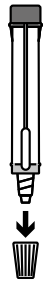
4 Insert the swab specimen in the extraction tube. Swirl the swab tip in the buffer fluid inside the extraction tube, pushing into the wall of the extraction tube at least five times and then squeeze out the swab by squeezing the extraction tube with your fingers.



5 Break the swab at the breakpoint and close the cap of extraction tube.

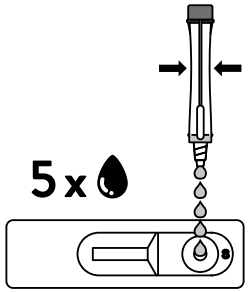


6 Open the dropping nozzle cap at the bottom of the extraction tube.

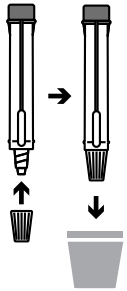


7 Dispense 5 drops of extracted specimens vertically into the specimen well (S) on the device. Do not handle or move the test device until the test is complete and ready for reading.

⚠ **Caution:** Bubbles that occur in the extraction tube can lead to inaccurate results. If you are unable to create sufficient drops, this may be caused by clogging in the dispensing nozzle. Shake the tube gently to release the blockage until you observe free drop formation.



8 Close the nozzle and dispose of the extraction tube containing the used swab according to your local regulations or biohazard waste disposal protocol.



9 Start timer. Read result at 15 minutes. Do not read results after 20 minutes.

10 Dispose of the used device according to your local regulations or biohazard waste disposal protocol.

Panbio™ COVID-19 Ag Rapid Test Device (Nasal). Abbott; 2020. Available from: https://extranet.who.int/pqweb/sites/default/files/documents/EUL_0587_032_00_PanbioCOVID-19_AgRapidTestDevice_NASAL_ifu.pdf. Accessed January 10, 2022.

May 2022 pharmacists.ca

STANDARD Q
COVID-19 Ag Nasal Test
EN

COVID-19 Antigen Nasal Test Quick reference instruction

Fast result in 15 minutes | Nasal Test SD BIOSENSOR

Study the Instructions for Use 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.

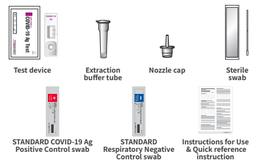
Video Guide

STEP 1 PREPARATION

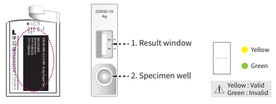
1 Wash your hands.

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

2 Check the kit contents before testing. Ensure all test components are at room temperature(15°C-30°C) for 30 minutes before use.



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.

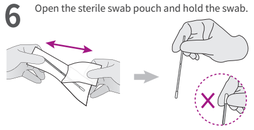


STEP 2 SPECIMEN COLLECTION

4 Open the Extraction buffer tube pouch and the seal of buffer tube.

5 Set the extraction buffer tube on the buffer tube rack.

6 Open the sterile swab pouch and hold the swab.



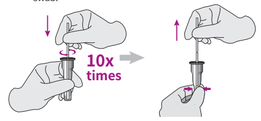
! Do not touch swab tip when handling swab specimen.

7 Tilt patient's head back slightly. While rotating the swab, insert swab approximately one inch (about 2 cm) into nostril until resistance is met at turbinates. Slowly rotate the swab in a circular path against the nasal wall at least 4 times for a minimum of 15 seconds. Repeat in other nostril using the same swab.

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

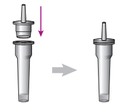
STEP 3 TEST PROCEDURE

8 Insert the sterile swab into the extraction buffer tube. While squeezing the extraction buffer tube, stir the sterile swab more than 10 times. Remove the sterile swab while squeezing the sides of the tube to extract the liquid from the sterile swab. Discard used swab.

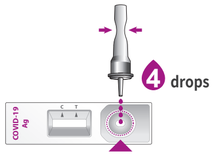


! In case of contact with your skin or eyes, wash immediately with plenty of water.

9 Press the nozzle cap tightly onto the tube.



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



! Do not squeeze out all of the liquid in the extraction buffer tube.

11 Read the test result in 15-30 min.

! 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 specimen 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.

For inquiries, please contact us at
help.covid19@sdbiosensor.com

Head office: C-4&5Floor, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA

EN Ref No. 09COV36D

STANDARD Q
COVID-19 Ag Nasal Test

STANDARD™ Q COVID-19 Ag Nasal Test

For prescription use only
For *in vitro* diagnostic use only
PLEASE READ CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

INTENDED USE

The STANDARD Q COVID-19 Ag Nasal Test is a lateral flow rapid chromatographic immunoassay for the qualitative detection of nucleocapsid antigen to SARS-CoV-2 present in human nasal samples. This test is intended for use, as an aid in detection of SARS-CoV-2 infection in individuals suspected of COVID-19 with clinical symptoms onset within 5 days.
Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in human nasal swab samples 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 definite cause of disease.
Negative results should be treated as presumptive, and 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. 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, and confirmed with a molecular assay, if necessary, for patient management.
The STANDARD Q COVID-19 Ag Nasal Test is intended for use in laboratory or POC settings by healthcare professionals, or self-collection under the supervision of a healthcare worker.

INTRODUCTION

Coronaviruses can cause a variety of acute and chronic diseases. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. In late 2019 a new coronavirus, later named SARS-CoV-2[1], was identified in a cluster of pneumonia cases, and the World Health Organization described the global SARS-CoV-2 situation as pandemic on March 11, 2020[2]. The disease associated with SARS-CoV-2 infection was named COVID-19 (COronaVIrus Disease 2019)[3].

PRINCIPLE OF THE TEST

The STANDARD Q COVID-19 Ag Nasal Test has two 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 samples. 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 sample 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.

Even if the test line is very faint or not uniform the test result should be interpreted as a positive result. If SARS-CoV-2 antigens are not present in the sample, no color appears in the test line. The control line is used for procedural control, and always appears if the test result is valid. If no control line is visible the test result should be considered as invalid.

ACTIVE COMPONENTS

- mAb anti-COVID 19 antibody
- mAb anti-Chicken IgY
- mAb anti-COVID-19 antibody-gold conjugate
- Purified chicken IgY-gold conjugate
- Recombinant COVID-19 nucleocapsid protein (positive controls)

KIT CONTENTS

Contents (Ref No. 09COV36D)	Quantity
Test device (individually in a foil pouch with desiccant)	25
Extraction buffer tube	25
Nozzle cap	25
Sterile swab	25
Buffer tube rack	1
STANDARD COVID-19 Ag Positive Control swab	1
STANDARD Respiratory Negative Control swab	1
Instructions for use & Quick reference guide	1

KIT STORAGE AND STABILITY

1. Store the kit at 2-30°C / 36-86°F out of direct sunlight.
2. Kit materials are stable until the expiration date printed on the outer box.
3. Do not freeze the kit.

MATERIALS REQUIRED BUT NOT SUPPLIED

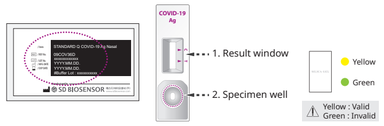
- Timer
- External controls: STANDARD COVID-19 Ag Control

WARNINGS AND PRECAUTIONS

1. Equilibrate the kit contents and specimens to operating temperature before testing.
2. Do not re-use the test kit.
3. Do not use the test kit if the pouch is damaged or the seal is broken.
4. Do not use the extraction buffer of another lot.
5. Do not smoke, drink or eat while handling the sample.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
7. Clean up spills thoroughly using an appropriate disinfectant.
8. Handle all samples as if they contain infectious agents.
9. Observe established precautions against microbiological hazards throughout testing procedures.
10. 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.
11. Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the desiccant beads change from yellow to green, the test device in the pouch should be discarded.

KIT PREPARATION

1. Carefully read instructions for using the STANDARD Q COVID-19 Ag Nasal Test.
2. Check the expiry date on the back of the foil pouch. Do not use the test if the expiry date has passed.



3. Open the foil pouch and remove the test device and the desiccant package. Use the test immediately after opening the pouch.
4. Ensure that the test device is undamaged and that the desiccant status indicator shows valid (yellow).
5. Perform a QC test as recommended in the EXTERNAL QUALITY CONTROL section and according to the Instructions for Use of the QC material.

SPECIMEN COLLECTION, TRANSPORT AND STORAGE

Nasal swab

1. Tilt patient's head back slightly
2. While rotating the swab, insert swab approximately one inch (about 2 cm) into nostril until resistance is met at turbinates.
3. Slowly rotate the swab in a circular path against the nasal wall at least 4 times for a minimum of 15 seconds.
4. Repeat in other nostril using the same swab.

Transport and storage

Samples should be tested as soon as possible after specimen collection.
Specimens in extraction buffer are stable for up to 1 hour at room temperature (20±5°C), up to four hours when stored refrigerated at 5±3°C. If stored frozen at -20°C, specimens in extraction buffer are stable for only one (1) freeze/thaw cycle.
Dry swab specimens are stable for 1 hour at room temperature (20±5°C).

TEST PROCEDURE

Prior to starting the procedure, test devices and reagents must be equilibrated to operating temperature (15-30°C/ 59-86°F) for at least 30 minutes prior to the test.

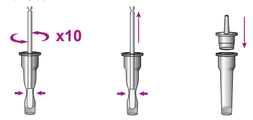
Preparation

Carefully open extraction buffer tube avoiding spillage.

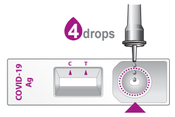
If buffer is spilled, do not use the tube.

Fresh specimen

1. Insert the swab from patient into an extraction buffer tube. While squeezing the buffer 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 specimen to the specimen well of the test device.
5. Read test result at 15-30 minutes.



- Place the test device on a flat surface
- Dispense the specimen at a 90 degree angle to allow for free falling drops and avoid bubbles.
- **Do not read test results after 30 minutes. It may give false results.**

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.

EXTERNAL QUALITY CONTROL

- Positive and negative controls are supplied with each kit.
- Positive and negative controls should be performed as real specimens.
- It is recommended that positive and negative controls be run once for each new lot, once for each untrained operator, as required by test procedures in these instructions and in accordance with local, state and federal regulations or accreditation requirements.

Preparing a QC

1. Place the test device on a flat surface and apply 3 drops of extracted sample at a 90 degree angle to the specimen well of the test device.
2. Read the test result in 15-30 minutes.

QC procedure

1. Check the expiry date on the foil pouch of the controls. Do not use the controls if the expiry date has passed.
2. Open the pouch of the positive or negative control and put the positive or negative control swab into an extraction buffer tube. Stir the swab more than 5 times.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
4. Press the nozzle cap tightly onto the tube.

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

Result	Interpretation
Positive result with positive control	Pass
Negative result with negative control	Pass
Negative result with positive control	Fail
Positive result with negative control	Fail
Control line not visible	Invalid. Repeat with a new test device.

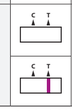
READING AND INTERPRETING RESULTS

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

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

* Use new test devices and new control for retest.

INTERPRETATION OF TEST RESULT

Test result	Example	Description
Negative*		1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is control line (C).
Positive*		2. A colored band will appear in the lower section of the result window. This band is test line of SARS-CoV-2 antigen (T).
Invalid		3. Retest: If the control line(C) is not appeared in the result window, it is an invalid result. Retest using a new specimen and device.

* Even if the control line or test line is faint or not uniform, the test should be considered to be performed properly and the test result should be interpreted.

LIMITATIONS

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. The test should be used for the detection of SARS-CoV-2 antigen in human nasal swab samples.
3. This test cannot be used for quantifying SARS-CoV-2 antigen concentration.
4. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
5. The immune response cannot be assessed with this test and needs other testing methods.
6. The test result should not be used as a sole basis for treatment or patient management decisions, and should be considered in the context of the patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
7. A negative result may occur if the concentration of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly. Therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by a molecular assay, if necessary for patient management.
8. Positive test results do not rule out co-infections with other pathogens.
9. Positive test results do not differentiate between SARS-CoV-2 and SARS-CoV.
10. Negative test results are not intended to rule in or rule out other coronavirus infection.
11. The performance of this device has not been assessed in a population vaccinated against COVID-19.

SPECIFIC PERFORMANCE DATA

Clinical evaluation

Clinical performance of the STANDARD Q COVID-19 Ag Nasal Test was evaluated using nasal swab samples from 696 subjects in a prospective study at a clinical center in Germany. The study cohort included adults at high risk for SARS-CoV-2 infection according to clinical suspicion. 311 subjects underwent nasal sampling performed by healthcare professionals and 385 subjects followed instructions to obtain a nasal swab sample by themselves. Self-collection was performed under the supervision of healthcare workers without interference or assistance. Test procedures and result reading were always performed by healthcare professionals. RT-PCR tests (Roche cobas® SARS-CoV-2 and TibMolbiol SARS-CoV-2 E-gene assay) using combined nasopharyngeal/oropharyngeal swab samples were used as the comparator methods. Nasal sampling always preceded the combined NP/OP sampling.

The following tables summarize the patient and performance characteristics of the STANDARD Q COVID-19 Ag Nasal Test. The relative sensitivity was 89.6 % (Ct value ≤ 30; 95 % CI: 79.7 % - 95.7 %) for professionally collected samples, and 89.1 % (Ct value ≤ 30; 95 % CI: 78.8 % - 95.5 %) for self-collected samples. For patients for whom days post symptom onset was known, and was 0-5 days, the relative sensitivity in comparison to RT-PCR was 86.7 % (95 % CI: 75.4 % - 94.1 %) for professionally collected nasal samples and 88.9 %(95 % CI: 77.4 % - 95.8 %) for self-collected nasal samples. The relative specificity in comparison to RT-PCR was 99.1 % (95 % CI: 96.9 % -99.9 %) for professionally collected nasal samples and 99.0 % (95% CI: 97.2 % -99.8 %) for self-collected nasal samples.
In total, nasal swab samples from 150 PCR-positive and 546 PCR-negative individuals were evaluated using the STANDARD Q COVID-19 Ag Nasal Test. The relative sensitivity and relative specificity were 82.7 % (95 % CI: 75.6 % - 88.4 %) and 99.1 % (95 % CI: 97.9 % - 99.7 %), respectively.

Summary of sample characteristics and performances:

	Overall	HCP-collection	Self-collection
N	696	311	385
Asymptomatic, n/N (%)	0/696 (2.9 %)	7/311 (2.3 %)	13/385 (3.4 %)
Symptomatic, n/N (%)	676/696 (97.1 %)	304/311 (97.7 %)	372/385 (96.6 %)
DPSO, median (range)	3 (0 - 27)	3 (0 - 15)	4 (0 - 27)
PCR positive, n/N (%)	150/696 (21.6 %)	77/311 (24.8 %)	73/385 (19.0 %)
PCR positive symptomatic, n/N (%)	147/150 (98.0 %)	75/77 (97.4 %)	72/73 (98.6 %)
PCR positive asymptomatic, n/N (%)	3/150 (2.0 %)	2/77 (2.6 %)	1/73 (1.4 %)
PCR negative, n/N (%)	546/696 (78.4 %)	234/311 (75.2 %)	312/385 (81.0 %)
PCR sample type	Combined OP/NP		

Relative sensitivity, % (95 % CI), N	**Professional collection**	**Self-collection**
NCt[a] ≤ 24	97.7 % (CI: 88.0 % - 99.9 %), 44	97.9 % (CI: 88.7 % - 99.9 %), 47
NCt[a] ≤ 27	93.1 % (CI: 83.3 % - 98.1 %), 58	94.7 % (CI: 85.4 % - 98.9 %), 57
NCt[a] ≤ 30	**89.6 % (CI: 79.7 % - 95.7 %), 67**	**89.1 % (CI: 78.8 % - 95.5 %), 64**
NCt[a] ≤ 33	87.1 % (CI: 77.0 % - 93.9 %), 70	84.5 % (CI: 74.0 % - 92.0 %), 71
All Ct values	83.1 % (CI: 72.9 % - 90.7 %), 77	82.2 % (CI: 71.5 % - 90.2 %), 73

a) for samples run on **cobas** the Target 2 (E gene) Ct values were used.

Relative specificity, % (95 % CI), N	**Professional collection**	**Self-collection**
All Ct values	99.1 % (CI: 96.9 % - 99.9 %), 234	99.0 % (CI: 97.2 % - 99.8 %), 312

Summary of all nasal samples evaluated and overall performance:

	PCR positive	PCR negative	Total
Antigen positive	124	5	129
Antigen negative	26	541	567
Total	150	546	696
Relative sensitivity	**82.7 % (95 % CI: 75.6 % - 88.4 %)**		
Relative specificity	**99.1 % (95 % CI: 97.9 % - 99.7 %)**		

ANALYTICAL PERFORMANCE

Limit of detection (LoD)

The SARS-CoV-2 positive specimen was prepared by spiking inactivated SARS-CoV-2 (2019-nCOV) NCCP 43326/2020/Korea strain in negative clinical matrix using SARS-CoV-2 negative nasal swab confirmed with PCR. LoD is determined as 9.25 x $10^{1.2}$ $TCID_{50}$/mL (146.6 $TCID_{50}$/mL) for direct nasal swab by testing serially diluted positive specimens.

Cross-reactivity

No cross-reactivity was observed for the following microorganisms at the indicated concentrations, with the exception of SARS-CoV. All microorganisms were spiked into negative clinical matrix for testing.

Virus/Bacteria	Concentration	Results
Extraction buffer with negative nasal matrix[a]	N/A	NEG
Human coronavirus 229E[b]	2.18 X 10^5 PFU/mL	NEG
Human coronavirus OC43[b]	4.06 X 10^7 PFU/mL	NEG
Human coronavirus NL63[b]	1.17 X 10^5 PFU/mL	NEG
MERS-coronavirus[b]	2.87 X 10^5 PFU/mL	NEG
SARS-coronavirus[c]	N/A	POS
Adenovirus Type1[b]	1.77 X 10^8 PFU/mL	NEG
Adenovirus Type2[b]	7.93 X 10^6 PFU/mL	NEG
Adenovirus Type5[b]	2.33 X 10^7 PFU/mL	NEG
Adenovirus Type6[b]	1.34 X 10^7 PFU/mL	NEG
Adenovirus Type7A[b]	9.74 X 10^4 PFU/mL	NEG
Adenovirus Type11[b]	1.34 X 10^7 PFU/mL	NEG
Adenovirus Type14[b]	1.69 X 10^5 PFU/mL	NEG
Adenovirus Type40[b]	2.62 X 10^6 PFU/mL	NEG
Human Metapneumovirus3 type B1[b]	1.50 X 10^6 PFU/mL	NEG
Human Metapneumovirus16 type A1[b]	6.58 X 10^6 PFU/mL	NEG
Parainfluenza virus 1[b]	2.13 X 10^8 PFU/mL	NEG
Parainfluenza virus 2[b]	8.68 X 10^5 PFU/mL	NEG
Parainfluenza virus 3[b]	4.55 X 10^6 PFU/mL	NEG
Parainfluenza virus 4A[b]	2.62 X 10^6 PFU/mL	NEG
Influenza A H1N1 pdm/Michigan/45/15[b]	8.68 X 10^5 PFU/mL	NEG
Influenza A H1N1 Brisbane/59/07[b]	4.99 X 10^5 PFU/mL	NEG
Influenza A H3N2 Singapore/INFIMH-16-0019/16[b]	3.22 X 10^4 PFU/mL	NEG
Influenza A H3N2 South Australia/55/14[b]	8.1 X 10^4 PFU/mL	NEG
Influenza A H3N2 Hong Kong/8/68[b]	3.45 X 10^5 PFU/mL	NEG
Influenza A H3N2 Victoria/361/11[b]	9.74 X 10^4 PFU/mL	NEG
Influenza B Massachusetts/2/12[b]	1.69 X 10^5 PFU/mL	NEG
Influenza B Malaysia/2506/04[b]	2.87 X 10^5 PFU/mL	NEG
Influenza B Lee/40[b]	1.69 X 10^5 PFU/mL	NEG
Influenza B Yamagata/16/88[b]	1.69 X 10^5 PFU/mL	NEG
Influenza B Victoria/2/87[b]	1.28 X 10^4 PFU/mL	NEG
Influenza B Texas6/11[b]	2.62 X 10^6 PFU/mL	NEG
Influenza B Colorado6/17[b]	3.22 X 10^4 PFU/mL	NEG
Influenza B Florida/02/06[b]	2.62 X 10^6 PFU/mL	NEG
Enterovirus type 68 09/2014 Isolate 4[b]	2.44 X 10^5 PFU/mL	NEG
Respiratory syncytial virus A[b]	2.62 X 10^6 PFU/mL	NEG
Respiratory syncytial virus B[b]	3.45 X 10^5 PFU/mL	NEG
Rhinovirus 1A[b]	2.44 X 10^6 PFU/mL	NEG
Rhinovirus A16[b]	8.68 X 10^6 PFU/mL	NEG
Rhinovirus B42[b]	7.24 X 10^5 PFU/mL	NEG
Haemophilus influenzae (NCCP 13815)[a]	N/A	NEG
Haemophilus influenzae (NCCP 13819)[a]	N/A	NEG
Haemophilus influenzae (NCCP 14581)[a]	N/A	NEG
Haemophilus influenzae (NCCP 14582)[a]	N/A	NEG
Streptococcus pneumoniae type1 (KCCM 41560)[a]	N/A	NEG
Streptococcus pneumoniae type2 (KCCM 40410)[a]	N/A	NEG
Streptococcus pneumoniae type3 (KCCM 41569)[a]	N/A	NEG
Streptococcus pneumoniae type5 (KCCM 41570)[a]	N/A	NEG
Streptococcus pyogenes (ATCC 12344)[a]	N/A	NEG
Candida albicans (ATCC 10231)[a]	N/A	NEG
Bordetella pertussis (NCCP 13671)[a]	N/A	NEG
Mycoplasma pneumoniae (ATCC 15531)[d]	N/A	NEG
Chlamydia pneumoniae (ATCC VR-2282)[d]	N/A	NEG
Legionella pneumophila (ATCC 33155)[a]	N/A	NEG
Staphylococcus aureus (NCCP 14647)[a]	N/A	NEG
Staphylococcus epidermidis (KCCM 35494)[a]	N/A	NEG

a) Bionote
b) Zeptometrix
c) BEI
d) ATCC

Human coronavirus HKU1, Mycobacterium tuberculosis, and Pneumocystis jirovecii (PJP) have not been tested. A low probability of cross-reactivity was determined for in-silico analysis.

Microbial interference

For microorganism that did not cross-react, additional microbial testing was performed and no microbial interference was found.

Endogenous / exogenous interference substances studies

There was no interference on the test result from potentially interfering substances listed below. SARS-CoV-2 positive and negative samples were tested.

a) Results from interference testing from SARS-CoV-2 negative samples:

Potential interfering substance	Concentration	Results
Whole blood (EDTA)	4%	NEG
Mucin	0.5%	NEG
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	NEG
Naso GEL (NeilMed)	5% v/v	NEG
CVS Health Nasal Drops (Phenylephrine)	15% v/v	NEG
Afrin (Oxymetazoline)	15% v/v	NEG
CVS Health Oxymetazoline	15% v/v	NEG
CVS Health Nasal Spray (Cromolyn)	15% v/v	NEG
Zicam	5% v/v	NEG
Homeopathic (Alkalol)	1:10 dilution	NEG
Sore Throat Phenol Spray	15% v/v	NEG
Tobramycin	4 µg/mL	NEG
Mupirocin	10 mg/mL	NEG
CVS Health Fluticasone Propionate	5% v/v	NEG
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	NEG

b) Results from interference testing with SARS-CoV-2 positive samples:

Potential interfering substance	Concentration	Viral strain level[e]	Results[f]
Whole blood (EDTA)	4%	SARS-CoV-2 cultured virus media[g]	POS
Mucin	0.5%	SARS-CoV-2 cultured virus media[g]	POS
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	SARS-CoV-2 cultured virus media[g]	POS
Naso GEL (NeilMed)	5% v/v	SARS-CoV-2 cultured virus media[g]	POS
CVS Health Nasal Drops (Phenylephrine)	15% v/v	SARS-CoV-2 cultured virus media[g]	POS
Afrin (Oxymetazoline)	15% v/v	SARS-CoV-2 cultured virus media[g]	POS
CVS Health Oxymetazoline	15% v/v	SARS-CoV-2 cultured virus media[g]	POS
CVS Health Nasal Spray (Cromolyn)	15% v/v	SARS-CoV-2 cultured virus media[g]	POS
Zicam	5% v/v	SARS-CoV-2 cultured virus media[g]	POS
Homeopathic (Alkalol)	1:10 dilution	SARS-CoV-2 cultured virus media[g]	POS
Sore Throat Phenol Spray	15% v/v	SARS-CoV-2 cultured virus media[g]	POS
Tobramycin	4 µg/mL	SARS-CoV-2 cultured virus media[g]	POS
Mupirocin	10 mg/mL	SARS-CoV-2 cultured virus media[g]	POS
CVS Health Fluticasone Propionate	5% v/v	SARS-CoV-2 cultured virus media[g]	POS
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	SARS-CoV-2 cultured virus media[g]	POS

e) In multiples of LoD
f) Detected X/3
g) Dilution 2.78 X $10^{2.2}$ $TCID_{50}$/mL

High-dose hook effect

SARS-CoV-2 cultured virus was spiked into negative clinical matrix. SARS-CoV-2 cultured virus did not show hook-effect up to 1 x $10^{6.2}$ $TCID_{50}$/mL.

REFERENCES

1. Gorbalenya et al. Nat Microbiol. 2020;5:536-44.
2. WHO. https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-March-2020. Accessed 6 Jan 2021.
3. WHO. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it. Accessed 6 Jan 2021.
4. https://www.idsociety.org/globalassets/idsa/practice-guidelines/covid-19/diagnostics/idsa-covid-19-guideline_dx_version-1.0.1.pdf, accessed 24 November 2020.

IVD

L20COV36CAR0
Issue date: 2021.11

SD Biosensor, Inc.
Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA
www.sdbiosensor.com

REF Reference number
IVD *In vitro* Diagnostics
Consult Instructions for Use
GTIN Global Trade Item Number
UDI Unique Device Identifier
CODE Manufacturer's batch code
Contains Sufficient for <n> Tests
Caution
Note
Do not re-use.
Temperature limit
Use-by date
LOT Batch code
Manufacturer
Keep product dry
Keep away from sunlight
Do not use if package is damaged

SD BIOSENSOR