REF

COV-S23010H1E

COV-S23010H2E

COV-S23010H5E

COV-S23010H20E

COVID-19 Antigen Home Test

(Nasal swab)

Version 3.1 Revision date:08/15/2023

1. INTENDED USE

COVID-19 Antigen Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 virus that causes COVID-19 in nasal swab samples from individuals suspected of COVID-19 within 7 days of symptom onset and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection. The test is intended for serial testing of symptomatic individuals for use at least twice with 48 hours between tests, or for serial testing of asymptomatic individuals for use at least three times with 48 hours between tests.

This device is authorized for home-use in a non-laboratory setting with direct anterior nasal (nares) swab samples for:

- Unobserved self-collection for individuals aged 18 years or older
- Adult supervised self-collection for individuals for ages 14 or older
- Adult collecting from individuals aged 2 years or older

COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

People who test positive with the COVID-19 Antigen Home Test should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or co-infection with other viruses. People who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have a SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. 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 an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

The COVID-19 Antigen Home Test is intended for self-use and/or, as applicable for an adult lay user testing for another person aged 2 years or older in a non laboratory setting.

The COVID-19 Antigen Home Test is only for use under the Health Canada Interim Order.

2. EXPLANATION OF THE TEST

The COVID-19 Antigen Home Test is an immunochromatographic assay for the direct and qualitative detection of the nucleocapsid protein antigens from SARS-CoV-2 in anterior nasal swab specimens.

The COVID-19 Antigen Home Test is comprised of a sample collection (nasal swab), Sample Buffer Tube, and Test Cassette with a test strip. The Test Strip is composed of several materials which, in combination, can detect SARS-CoV-2 antigens.

The sample should be collected with the provided nasal swab. The swab containing the sample is then added directly into the Sample Buffer Tube containing Sample Buffer and mixed. Remove the swab, Insert the nozzle to the buffer tube, and add the sample mixture liquid into the sample well on the test cassette. The sample mixture liquid will move up the Test Strip across the nitrocellulose membrane containing two reagent lines, contacting the Test Line first and then the Control Line. If SARS-CoV-2 antigen is present in the sample, it will bind to the anti-SARSCoV-2 conjugate particles and then be captured on the Test Line, forming a colored line indicating a SARS-CoV-2 antigen positive test result. The sample mixture liquid will continue to move up the Test Strip and will bind to the Control Line, forming a colored line, to indicate the test was run correctly and establishes assay validity. The Control Line will appear on all valid tests whether the Test Line gives a reactive or non-reactive result. If a colored Control Line does not appear, the test is invalid, and the specimen must be retested. The liquid will continue to be drawn up to the absorbent pad of the Test Strip until the color on the membrane has cleared within 15 minutes after the start of the test.

3. MATERIAL

Materials Provided

Material	1Test Kit	2 Test Kit	5 Test Kit	20 Test Kit
Test device	1	2	5	20
Nasal swab	1	2	5	20
Package insert	1	1	1	1
Extraction buffer	1	2	5	20
Tube Holder	0	0	1	1

Materials Required But Not Provided

Clock, timer, or stopwatch

4. PRECAUTIONS

Read the COVID-19 Antigen Home Test Package Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results.

- For in vitro diagnostic use only.
- For use with anterior nasal swab specimens.
- Do not use the kit or components beyond the expiration date.
- Do not use this test on anyone under 2 years of age.
- Children aged 2 to 13 years of age should be tested by an adult.
- You should wear a face mask if swabbing others.
- Use a separate test for each person.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- 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.
- Test components are single-use. Do not reuse.
- Do not use the Extraction Buffer if it is discolored or turbid.
- All specimens must be mixed thoroughly before testing to ensure a representative sample.
- Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity. Inaccurate or inappropriate specimen collection, storage, and transport may yield false-negative test results.
- Inadequate or improper nasal swab sample collection may yield false-negative test results.
- Do not touch the swab tip (specimen collection area) when handling the swab.
- The test is intended to be read in 15 minutes. If the test is read before 15 minutes or after 30 minutes, false-negative or false-positive results may occur, and the test should be repeated with a new test cassette.
- Do not ingest any kit components.
- Keep the test out of reach of children.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube.
- Avoid handling the results window area of the test strips.
- This product has been authorized only to detect proteins from SARS-CoV-2, not for any other viruses or pathogens.
- The chemicals in the reagent solution may be hazardous to the skin and eye. Please see the table below for safety recommendations for skin and eye irritation. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

Chemical Name/CAS	GHS Code for applicable Ingredient	Concentration (%)
Sodium Azide/ 26628-22-8	*Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310*	*0.02%*

5. LIMITATIONS

- This device is only used for testing direct human anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- The 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.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the sample was collected improperly.
- Failure to follow the test procedure correctly may results in false-negative or false-positives results and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not exclude co-infection with other pathogens.
- Negative test results are not indicative of the presence/absence of other viral or bacterial pathogens.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Negative results should be treated as presumptive and confirmed with an FDA-authorized molecular assay, if necessary, for clinical management.
- If the differentiation of specific coronaviruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after seven days are more likely to be negative compared to RT-PCR.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in 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 SARSCoV-2 and their prevalence, which change over time.

6. SERIAL TESTING (REPEAT TESTING) INFORMATION & LIMITATIONS

- Serial testing (i.e., testing every other day) is more likely to detect COVID-19, both when you do or do not have any symptoms.
- Symptomatic individuals that test negative should repeat testing at least twice over three days with at least 48 hours between tests and at least three times over five days with at least 48 hours between tests if they are asymptomatic.
- The performance of this test was not clinically validated for serial testing in patients with or without symptoms consistent with COVID-19. Serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.

7. STORAGE AND STABILITY

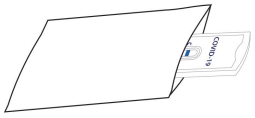
- Store the COVID-19 Antigen Home Test at 2~30℃ when not in use.
- **DO NOT FREEZE**.
- Kit contents are stable until the expiration dates marked on their outer packaging and containers.

8. TEST PROCEDURE

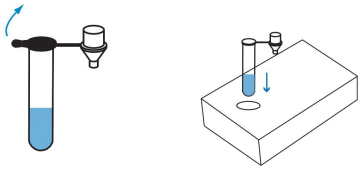
- For best results, the assay should be performed within one hour of sample collection
- For each specimen, open the foil pouch just before testing, remove the test device, and put it on a clean, level surface.
- Swab specimens should be tested as soon as possible after collection. Use freshly collected specimens for best test performance.

1) Wash your hands thoroughly.

2) Open the pouch.

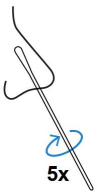


3) Peel off the aluminum foil cover of the extraction buffer and insert the extraction buffer into the tube holder.

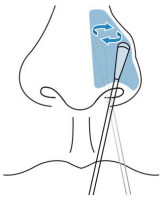


4) Remove the swab from its packing. Do not touch the padded tip of the swab.

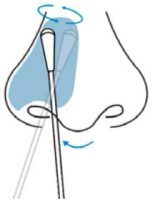
5) Insert the swab into the nostril (1/2-3/4 inch). Gently twist the swab 5 times against the nasal wall. The swab should remain in the nostril for 15 seconds. **Note: With children, the maximum depth of insertion into the nostril may be less than 3/4 of an inch, and you may need to have a second person hold the child's head while swabbing.**



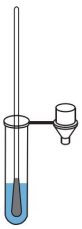
6) Pull the swab out of the nose while twisting it slightly.



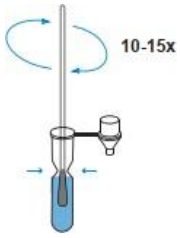
7) Repeat the process with the same swab in the other nostril for 15 seconds.



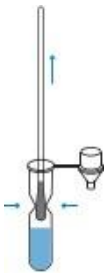
8) Place the swab into the tube.



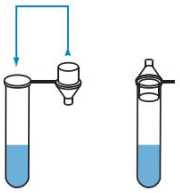
9) Rotate the swab while squeezing the lower part of the tube 10-15 times so that a slight pressure is exerted on the tip of the swab.



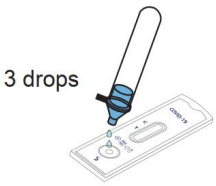
10) Remove the swab. Squeeze the tube to squeeze as much liquid out of the swab as possible.



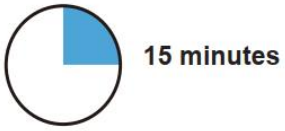
11) Insert the nozzle back into the buffer tube.



12) Invert the tube and add 3 drops of the solution to the sample well by gently squeezing the tube.



13) Look at the clock. You can read the result after 15 minutes. After more than 30 minutes, the result is no longer valid. After test is completed, dispose of used materials in trash.



Note:

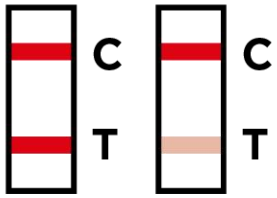
1. The COVID-19 Home Test is not intended for testing other samples such as nasopharyngeal secretions or aspirate samples.

9. RESULT INTERPRETATION

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another in the test region (T).

Notice：You do not need to perform repeat testing if you have a positive result at any time.

The intensity of the color in the test area (T) can vary. However, any shade in the test area should be considered positive. A positive test result means that the virus that causes COVID-19 was detected in your sample, and you are very likely to have COVID-19. Please seek care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your test results, medical history, and symptoms. You should also self-isolate at home and avoid contact with others to avoid spreading the virus. There is a very small chance that this test can give a positive result that is incorrect (a false-positive).



NEGATIVE: Only one colored band appears in the control region (C): No apparent colored band appears in the test region (T).

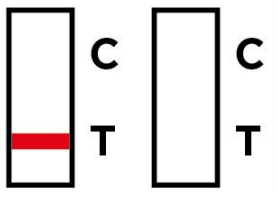
Notice：To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If all repeat tests are negative and you are concerned you have COVID-19, you may choose to test again using an antigen test or consult with your health care provider regarding molecular testing.

INVALID: Control band fails to appear. Any test that has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat it with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

An invalid result may have been caused by an incorrect test execution. An invalid result does not indicate if the individual did or did not have COVID-19.



NOTE:

1. The color intensity in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure, or expired tests are the most likely reasons for control band failure.
3. Repeat testing is needed to improve test accuracy. Please follow Table 3 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.

10. QUALITY CONTROL

Internal Procedural Controls

The COVID-19 Antigen Home Test has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. Before reading the result, the user should confirm that the colored band located at the "C" region is present.

11. PERFORMANCE CHARACTERISTICS

Clinical Performance:

COVID-19 Antigen Home Test for the detection of the SARS-CoV-2 in subject-collected anterior nasal (AN) swab samples. The study evaluated the investigational test's performance in symptomatic or asymptomatic individuals. A total of 361 symptomatic or asymptomatic subjects were enrolled, 110 positive specimens and 251 negative specimens were confirmed by RT-PCR. **The COVID-19 Antigen Home Test correctly identified 93.6% of positive specimens and 99.6% of negative specimens in that clinical study.** The table below shows the results. **However, clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results.**

Summary of the Performance of the COVID-19 Antigen Home Test Compared to RT-PCR

COVID-19 Antigen Home Test	RT-PCR		Total
	Positive	Negative	
Positive	103	1	104
Negative	7	250	257
Total	110	251	361
Positive Percent Agreement (PPA)	**93.6% (95%CI: 87.4%-96.9%)**		
Negative Percent Agreement (NPA)	**99.6% (95%CI: 97.8%-99.9%)**		
Overall Agreement	**97.8% (95%CI:95.7%-98.9%)**		

Importance of Serial (Repeat) Testing

A 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 Table 5.

Table 5 : 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			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive/PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
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 Sensitivity (Limit of Detection):

The limit of detection was $2\times10^{2.4}TCID_{50}$/mL and was determined using inactivated SARS-CoV-2 virus spiked onto swabs.

Cross-Reactivity and Microbial Interference:

Cross reactivity and microbial interference of COVID-19 Antigen Home Test was evaluated by testing 31 commensal and pathogenic microorganisms (bacteria, viruses, and pooled human nasal wash) that may be present in the nasal cavity. Each organism and virus were tested in the absence and presence of inactivated SARS-CoV-2. All testing samples were prepared in the negative nasal wash. No cross-reactivity was observed for any of the organisms expect SARS with the concentration 7.9×10^{1} $TCID_{50}$/mL concentrations.

Organism	Target Concentration	Cross-reactivity result	Microbial Interference result
Human coronavirus 229E	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Human coronavirus OC43	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Human coronavirus NL63	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
MERS-coronavirus	1.0×10^{6} $TCID_{50}$/mL	No Cross-reactivity	No Interference
SARS-coronavirus	7.9×10^{1} $TCID_{50}$/mL	Cross-reactivity	No Interference
Human coronavirus HKU1	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Adenovirus	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Human Metapneumovirus	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Parainfluenza virus 1	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Parainfluenza virus 2	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Parainfluenza virus 3	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Parainfluenza virus 4	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Influenza A (H1N1)	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Influenza A (H3N2)	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Influenza B Victoria lineage	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Influenza B Yamagata lineage	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Enterovirus	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Respiratory syncytial virus A	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Respiratory syncytial virus B	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Rhinovirus	1.0×10^{5} $TCID_{50}$/mL	No Cross-reactivity	No Interference
Haemophilus influenzae	1.0×10^{6} CFU/mL	No Cross-reactivity	No Interference
Streptococcus pneumoniae	1.0×10^{6} CFU/mL	No Cross-reactivity	No Interference

Streptococcus pyogenes	1.0×10^6 CFU/mL	No Cross-reactivity	No Interference
Candida albicans	1.0×10^6 CFU/mL	No Cross-reactivity	No Interference
Bordetella pertussis	1.0×10^6 CFU/mL	No Cross-reactivity	No Interference
Mycoplasma pneumoniae	1.0×10^6 CFU/mL	No Cross-reactivity	No Interference
Chlamydia pneumoniae	1.0×10^6 CFU/mL	No Cross-reactivity	No Interference
Legionella pneumophila	1.0×10^6 CFU/mL	No Cross-reactivity	No Interference
Staphylococcus aureus	1.0×10^6 CFU/mL	No Cross-reactivity	No Interference
Staphylococcus epidermidis	1.0×10^6 CFU/mL	No Cross-reactivity	No Interference
Pooled human nasal wash	/		

To estimate the likelihood of cross-reactivity with SARS-COV-2 of organisms, in silico analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to determine the degree of protein sequence homology.

For *Pneumocystis jirovecii (PJP)*, BLAST results showed no homology between the SRAS-COV-2 nucleocapsid protein and Pneumocystis jirovecii (PJP).

For *Mycobacterium tuberculosis*，BLAST results showed no homology between the SRAS-COV-2 nucleocapsid protein and Mycobacterium tuberculosis.

Interfering Substances

The following substances, naturally present in respiratory specimens or artificially introduced into the respiratory tract, were evaluated at the concentrations listed below. None of them were found to affect the test performance of The COVID-19 Antigen Home Test.

Substance	Concentration	Cross-reactivity result	Interference result
Whole Blood	4%	No Cross-reactivity	No Interference
Mucin	0.5%	No Cross-reactivity	No Interference
Cepacol® Sore Throat Lozenges (benzocaine/menthol)	1.5 mg/mL	No Cross-reactivity	No Interference
Naso GEL (NeilMed)	5% v/v	No Cross-reactivity	No Interference
Nasal Drops (Phenylephrine)	15% v/v	No Cross-reactivity	No Interference
Nasal Spray (Oxymetazoline)	15% v/v	No Cross-reactivity	No Interference
Nasal Spray (Cromolyn)	15% v/v	No Cross-reactivity	No Interference
Zicam	5% v/v	No Cross-reactivity	No Interference
Homeopathic (Alkalol)	1:10 dilution	No Cross-reactivity	No Interference
Sore Throat Phenol Spray	15% v/v	No Cross-reactivity	No Interference
Tobramycin	4μg/mL	No Cross-reactivity	No Interference
Mupirocin	10 mg/mL	No Cross-reactivity	No Interference
Fluticasone Propionate	5% v/v	No Cross-reactivity	No Interference
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No Cross-reactivity	No Interference
Body&Hand lotion(Cerave)	0.5%(w/v)	No Cross-reactivity	No Interference
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v	No Cross-reactivity	No Interference
Hand Lotion (Eucerin)	5% w/v	No Cross-reactivity	No Interference
Hand soap liquid gel(soft soap)	10%(w/v)	No Cross-reactivity	No Interference
Hand Sanitizer, 80% ethanol, fast drying	15% v/v	No Cross-reactivity	No Interference

High-Dose Hook Effect

The COVID-19 Antigen Home Test demonstrated no hook effect at $1\times10^{6.4}$ $TCID_{50}$/mL.

For the most up to date information on COVID-19, please visit:

https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/testing screening-contact-tracing/information-patients-guide-self-testing.html

12. LITERATURE REFERENCES

1. Forni, D., Cagliani, R., Clerici, M. & Sironi, M. Molecular evolution of human coronavirus genomes. Trends Microbiol. 25, 35–48 (2017).
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13. GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer	②	Do not reuse

TECHNICAL SUPPORT

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