Atomo

COVID-19 Antigen Test

Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen

ARTG No: 346587

REF ARCV003-01

For in vitro diagnostic use only
For professional use only

Package Insert
(Instructions for Use)

Intended Use

The *Atomo* COVID-19 Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal or anterior nasal swab specimens directly collected from individuals who are either suspected of COVID-19 by their healthcare provider within first five days of symptom onset. This test is intended for use at the Point of Care (POC).

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in nasopharyngeal or anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories are required to report all positive results to the appropriate public health authorities.

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 *Atomo* COVID-19 Antigen Test is intended for use by medical and healthcare professionals who are proficient in performing tests in point of care settings or trained clinical laboratory personnel.

Summary and Explanation of the Test

Since the first outbreak reported in December 2019, SARS-CoV-2 has spread rapidly worldwide, and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). Due to its highly contagious nature and global health crises, SARS-CoV-2 has been designated as a pandemic by the World Health Organization (WHO). SARS-CoV-2 continues to have devastating impacts on healthcare systems and the world economy.

To effectively end the SARS-CoV-2 pandemic, systematic screening and detection of both clinical and asymptomatic COVID-19 cases is critical. Particularly, the identification of subclinical or asymptomatic cases is important to reduce or stop the infection because these individuals may transmit the virus. As a point of care test with a 10 minute testing time, Atomo COVID-19 Antigen Test allows effective screening of COVID-19 infection on a large scale.

Principles of the Test

The *Atomo* COVID-19 Antigen Test is a lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein antigens specific to SARS-CoV-2 in nasopharyngeal or anterior nasal swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of symptom onset.

Nasopharyngeal and anterior nasal swabs require a sample preparation step in which the sample is eluted into the extraction buffer solution. Extracted swab sample is added to the sample well of the test device to initiate the test. When the swab sample migrates in the test strip, SARS-CoV-2 viral antigens bind to anti-SARS-CoV-2 nucleocapsid protein antibodies conjugated to indicator and capture particles in the test strip forming an immune complex. The immune complex is then captured by the test line on the nitrocellulose membrane as it migrates through the strip.

Test results are interpreted at 10 minutes. The presence of two coloured lines in the control line region "C" and test line region "T" indicates COVID-19 positive. The presence of one coloured line in the control line region "C" indicates COVID-19 negative. No appearance of a coloured line in the control region "C" indicates an invalid test

Reagents and Materials Provided

Contents Name	Quantity (in a kit)	Description
Test device	20 each	Foil pouched test device containing one test strip which is encased in plastic device cassette.
Extraction vial / cap	20 vials and caps	The extraction vial contains 400 µl extraction buffer solution.
Nasal swab*	20 each	Nasal swab for specimen collection.
Positive control swab	1 each	Recombinant SARS-CoV-2 nucleocapsid protein antigen is dried on the foam-tipped head.
Negative control swab	1 each	Blank swab
Package insert	1 each	Instructions for use
Quick Reference Instructions (QRI)	1 each	Quick reference instructions

**Only nasal swab provided in the test kit, nasopharyngeal swab to be sourced separately*

The following materials are needed but not provided:

▪ Pair of gloves ▪ Timer ▪ Biohazard or sharps container

Warnings and Precautions

- For professional *in vitro* diagnostic use only.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Immediately use after opening the test device in the pouch.
- In order to obtain accurate results, the user must follow this package insert..
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result. Avoid touching any bleeding areas when collecting specimens.
- Do not interpret the test result before 10 minutes and after 15 minutes of starting the test.
- Do not use if the test device package is damaged.
- Do not use the kit contents beyond the expiration date.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
- Nitrile or latex gloves should be worn when performing this test.
- If the extraction buffer contacts the skin or eye, flush with copious amounts of water.
- The SARS-CoV-2 positive control swabs have been prepared from recombinant viral proteins and do not contain infectious material.
- Handle all specimens as though they contain infectious agents.
- Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Reagents contain sodium azide, which is harmful if inhaled, swallowed, or exposed to skin. Contact with acids produces a very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.
- Do not interchange kit contents from different lots.
- Do not re-use any contents in the kit as they are single-use only.

Storage and Stability

- Store the test kit as packaged between 1 ~ 30°C.
- The reagents and materials in the *Atomo* COVID-19 Antigen are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date.
- The test device must remain in the sealed pouch until use.
- Do not freeze any contents of the kit.

Quality Control

Internal Quality Control:

The *Atomo* COVID-19 Antigen Test contains a built-in internal procedural control that is included in the test device. A red-coloured line appearing in the control region "C" is designed as an internal procedural control. The appearance of the procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. If the procedural control line does not develop in 10 minutes, the test result is considered invalid and retesting with a new device is recommended. If the internal procedural control line is still absent in the retest, please contact covidfeedback@atomodiagnostics.com

External Control:

External control is used to demonstrate that the test device and test procedure perform properly. It is recommended that positive and negative external control swabs are run once with every new lot, shipment, and each new user. External positive and negative control swabs are provided in the kit. The external control should be tested using the swab test procedure provided in this package insert or the quick reference instruction card. If the external control results are invalid, please contact covidfeedback@atomodiagnostics.com before testing patient specimens.

Specimen Type

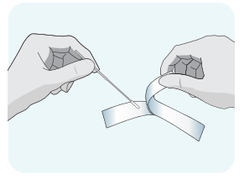
Acceptable specimen type for testing with the *Atomo* COVID-19 Antigen Test is a direct nasal swab or nasopharyngeal swab specimen. It is essential that correct specimen collection and preparation methods be followed. Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, specimen collection requires specific training and guidance due to the importance of specimen quality to obtain accurate test results.

Swab Sample Collection Procedure

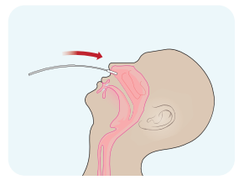
Procedural Notes

- Process the test sample immediately after collection.
- Use only recommended swab for specimen collection.
- Collect the specimen wearing safety gloves to avoid contamination.
- Do not touch the tip (specimen collection area) of the swab.
- Collect samples as soon as possible within the first 5 days of symptom onset.

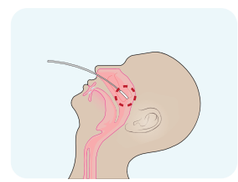
Nasopharyngeal Swab Collection



1
Remove a nasopharyngeal swab from the pouch.

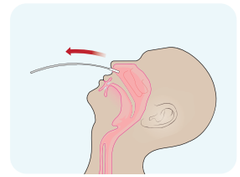


2
Place the swab into one of the patient's nostrils until it reaches the posterior nasopharynx.

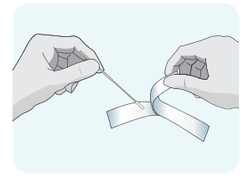


3
Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.

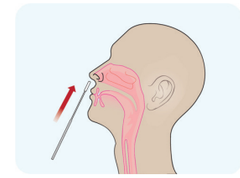
Anterior Nasal Swab Collection



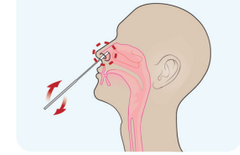
4
Remove the swab from the nostril.



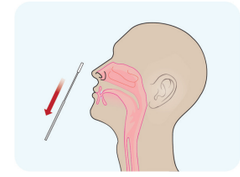
1
Remove a nasal swab from the pouch.



2
Insert the swab into one of patient's nostrils up to 2-3 cm from the edge of the nostril.



3
Slowly roll the swab 5 times over the surface of the nostril. Using the same swab, repeat this collection process in the other nostril.
Take approximately 15 seconds to collect the specimen.



4
Slowly remove the swab from the nostril while rotating it.

Following specimen application (steps 1-4) using your preferred swab (Nasal or Nasopharyngeal) the swab needs to be applied to the test. See steps 5-11 on the reverse side of this IFU for swab sample application procedures.

Description of Symbols

IVD ***In vitro* diagnostic medical device**
Indicates a medical device that is intended to be used as an *in vitro* diagnostic medical device.

Consult instructions for use
Indicates the need for the user to consult the instructions for use.

Manufacturer
Indicates the medical device manufacturer.

LOT Batch code
Indicates the manufacturer's batch code so that the batch or lot can be identified.

Do not re-use
Indicates a medical device that is intended for one use, or uses on a single patient during a single procedure.

Use by date
Indicates the date after which the medical device is not to be used.

CONTROL + Positive control
Indicates a control material that is intended to verify the results in the expected positive range.

CONTROL − Negative control
Indicates a control material that is intended to verify the results in the expected negative range.

REF Catalog number
Indicates the manufacturer's catalog number so that the medical device can be identified.

Caution
Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

Date of manufacture
Indicates the date when the medical device was manufactured.

Temperature limit
Indicates the temperature limits to which the medical device can be safely exposed.

Do not use if the package is damaged
Indicates a medical device that should not be used if the package has been damaged or opened.

Contains sufficient for <n> tests
Indicates the total number of IVD tests that can be performed with the IVD.

Manufactured by:
Access Bio, Inc.
65 Clyde Road, Suite A.
Somerset, NJ 08873, USA
Tel: 732-873-4040
Fax: 732-873-4043
Email: info@accessbio.net
Website: www.accessbio.net

Distributed by:
Atomo Diagnostics Ltd.
Level 2, 701-703 Parramatta Road,
Leichhardt, NSW 2040, Australia
covidfeedback@atomodiagnostics.com

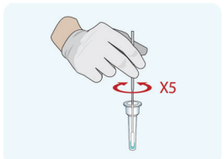
AccessBio

Swab Sample Application Test Procedures

Procedural Notes

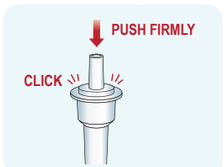
- Allow test devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30°C) prior to testing.
- Remove the *Atomo* COVID-19 Antigen test device and extraction vial from its foil pouch immediately before testing.
- The *Atomo* COVID-19 Antigen kit IS INTENDED to be used only with a nasopharyngeal or anterior nasal swab specimen.
- The *Atomo* COVID-19 Antigen kit IS NOT INTENDED for testing other liquid samples such as nasal wash aspirate samples or samples in viral transport media as results can be compromised by over dilution.

5 Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer

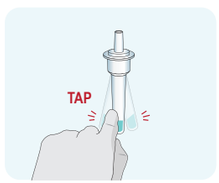


6 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.

7 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.

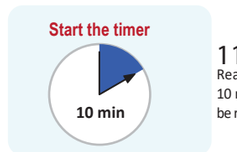


8 Close the vial with the provided cap and push firmly onto the vial.



9 Mix thoroughly by flicking the bottom of the tube.

10 Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow three (3) drops of sample to fall into the sample



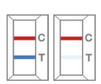
11 Read and interpret the test result at 10 minutes. The test result should not be read and interpreted after 15 minutes.

Interpretation of Results

NOTE: The test results should be read and interpreted at 10 minutes after the sample application and the reading and interpretation of the results should not exceed 15 minutes. The test results should not be interpreted using any instruments.

Positive: two distinct coloured lines appear.

One red-coloured line next to "C" and one blue-coloured line next to "T" indicate COVID-19 positive result.



NOTE: The colour intensity in the test region will vary depending on the amount of SARS-CoV-2 nucleocapsid protein antigen present in the sample. Any faint colored line(s) in the test region(s) should be considered as positive.

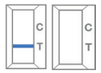
Negative:

One red-coloured line only next to "C" indicates a negative result.

NOTE: Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.

Invalid:

If the red-coloured line in the control region "C" is not visible, the result is invalid. Re-run the test one time using a new device with the remaining specimen in the extraction vial if an invalid result is obtained during initial testing.



Limitations

1. 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 test should be considered to rule out infection in these individuals.
2. Results from antigen testing should not be used as the sole basis to diagnose or, exclude SARS-CoV-2 infection or to determine infection status.
3. This test may compliment the diagnostic accuracy of quantitative polymerase chain reaction (qPCR) tests, but it is not meant to compare this test's clinical sensitivity and specificity with those of a molecular test since the performance of these tests is affected by virus titers and patient's immunity against SARS-Cov-2.
4. This test will indicate the presence of SARS-CoV-2 nucleocapsid protein antigen in the specimen from both viable and non-viable SARS-CoV-2 virus. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
5. The detection of SARS-CoV-2 nucleocapsid antigen is dependent upon proper specimen collection, handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
6. Results from the device should be correlated with the clinical history, epidemiological data and other data available to the clinician evaluating the patient.
7. This device has been evaluated for use with human specimen material only.
8. False-negative results may occur if the concentration of the target antigen in the clinical specimen is below the detection limits of the device.
9. This device is a qualitative test and does not provide information on the viral concentration present in the specimen.
10. This test cannot rule out diseases caused by other bacterial or viral pathogens.
11. The prevalence of infection will affect the test's predictive values.
12. Positive and negative predictive values are highly dependent on prevalence. False-negative test results are more likely during peak activity when the prevalence of the disease is high. False-positive test results are more likely during the periods of low SARS-CoV-2 activity when prevalence is moderate to low.
13. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
14. 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 SARS-CoV-2 and their prevalence, which change over time.
15. Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
16. False negative results may occur in patients who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin (>10mg per day). Biotin levels of 2.5 µg/mL have been demonstrated to result in false negative test results.

Performance Characteristics

Clinical Performance – Nasopharyngeal Swab

A total of 126 blinded frozen swab samples were tested in one (1) CLIA waived investigational site by five (5) minimally trained operators in the U.S during the 2020 COVID-19 season.

A total of 126 frozen swab samples consisted of 43 positive, 63 negative nasopharyngeal (NP) swab specimens, and 20 contrived near the cut-off samples (10 positives and 10 negatives in total). All the NP swab specimens were confirmed as positive or negative and validated with Ct value by the FDA EUA RT-PCR as a comparator method prior to the study taking place.

To reflect the natural distribution of SARS-CoV-2 viral loads in the study population, five (5) (approximately 11.63%) out of 43 positive clinical populations were low positives (>30 Ct value for the RT-PCR). In addition to the clinical population, a total of 20 contrived near the cut-off samples, 10 low positives near the Limit of Detection (LoD) (2x LoD), and 10 negatives (zero analytes) samples, were prepared using the inactivated SARS-CoV-2 strain spiked into the simulated nasal swab matrix, UVT. The heat-inactivated SARS-CoV-2 isolate USA-WA1/2020 was used to prepare the positive samples. The contrived near the cut-off samples were added to the clinical population and tested at the same study site by the same operators.

A total of 126 frozen swab samples were considered evaluable in this study. The performance of the *Atomo* COVID-19 Antigen Test compared to the RT-PCR comparator method are presented below:

Atomo COVID-19 Antigen Test (retrospective samples) Performance Against the Comparator Method

Atomo COVID-19 Antigen Test	Comparator		
	Positive	Negative	Total
Positive	38	0	38
Negative	5	63	68
Total	43	63	106
Positive Percent Agreement (PPA)	88.37% (95% CI: 75.52% – 94.93%)		
Negative Percent Agreement (NPA)	100% (95% CI: 94.25% – 100%)		

Atomo COVID-19 Antigen Test (near the cut-off samples) Performance

Sample Category	Overall % Agreement (result count)
True negative (zero analytes)	100.0% (10/10)
Low positive (2x LoD)	100.0% (10/10)

The *Atomo* COVID-19 Antigen test was evaluated for clinical performance using nasopharyngeal swab specimen in an additional multi-site prospective study in the U.S. between September 2020 and November 2020 against an FDA EUA RT-PCR as a comparator method. A total of three (3) POC investigational sites throughout the U.S. participated in the study. To be enrolled in the study, patients had to be presenting at the participating study centers with COVID-19 like symptoms and meet inclusion/exclusion criteria. All patients presented with fever or at least two symptoms of COVID-19 infection. The patients presenting the COVID-19 like symptoms within five (5) days of symptom onset at the study sites were enrolled. The first collected nasopharyngeal swab was collected from one nostril from each subject using standard collection methods for the comparator method. The second collected nasopharyngeal swab from the same nostril was tested directly on the *Atomo* COVID-19 Antigen test to demonstrate the agreement with the comparator method.

Testing was performed by six (6) operators with no laboratory experience and who were representative of the intended users. Operators were only using the QRI for the test without any training provided.

A total of 180 nasopharyngeal swab specimens collected from individual symptomatic patients (within 5 days of onset) were considered evaluable. The performance of the *Atomo* COVID-19 Antigen test compared to the comparator method is presented in the tables below.

Atomo COVID-19 Antigen Test nasopharyngeal clinical performance within 5 days of symptom onset against the comparator method

Atomo COVID-19 Antigen Test	Comparator		
	Positive	Negative	Total
Positive	30	1	31
Negative	2	147	149
Total	32	148	180
Positive Percent Agreement (PPA)	93.75% (95% CI: 79.85% – 98.27%)		
Negative Percent Agreement (NPA)	99.32% (95% CI: 96.27% – 99.88%)		

Patient Demographics

Age Group	*Atomo* COVID-19 Antigen Test		
	Total #	Positive	Prevalence
≤5 Years of Age	0	0	0.00%
6-21 Years of Age	22	3	13.64%
22-59 Years of Age	134	27	20.15%
≥60 Years of Age	24	2	8.33%

Clinical Performance – Anterior Nasal Swab

The *Atomo* COVID-19 Antigen test was evaluated for clinical performance using anterior nasal swab specimen in an additional multi-site prospective study in the U.S. between September 2020 and November 2020 against an FDA EUA RT-PCR as a comparator method.

A total of three (3) Point-of-Care investigational sites throughout the U.S. participated in the study. To be enrolled in the study, patients had to be presenting at the participating study centers with COVID-19 like symptoms and meet inclusion/exclusion criteria. All patients presented with fever or at least two symptoms of COVID-19 infection. The patients presenting the COVID-19 like symptoms within five (5) days of symptom onset at the study sites were enrolled. Clinical studies in asymptomatic patients undergoing serial testing are ongoing to establish the clinical performance.

Two (2) nasal swabs were collected using the provided swabs. One (1) swab was tested on the *Atomo* COVID-19 Antigen test and the second swab was processed in transport media for the comparator method. Collection order for the swab to be tested on the *Atomo* COVID-19 Antigen test and the swab for reference testing was randomized.

Testing was performed by eight (8) operators with no laboratory experience and who were representative of the intended users. Operators were only using the QRI for the test without any training provided.

A total of 92 nasal swab specimens collected from individual symptomatic patients (within 5 days of onset) were considered evaluable. The performance of the *Atomo* COVID-19 Antigen test compared to the comparator method is presented in the tables below.

Atomo COVID-19 Antigen anterior nasal clinical performance within 5 days of symptom onset against the comparator method

Atomo COVID-19 Antigen Test	Comparator		
	Positive	Negative	Total
Positive	34	0	34
Negative	5[b]	53	58
Total	39	53	92
Positive Percent Agreement (PPA)	87.18% (34/39) (95% CI: 73.29%-94.40%)		
Negative Percent Agreement (NPA)	100.00% (53/53) (95% CI: 93.24%-100.00%)		

[b]*COVID-19 was not detected in 0/5 False Negative specimens using an alternative FDA-EUA molecular Assay*

The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications, and performance may differ in these populations.

Patient Demographics

Age Group	*Atomo* COVID-19 Antigen Test		
	Total #	Positive	Prevalence
≤5 Years of Age	1	1	100.00%
6-21 Years of Age	38	13	34.21%
22-59 Years of Age	47	20	42.55%
≥60 Years of Age	6	0	0%

Positive results broken down by days since symptom onset:

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative *Atomo* COVID-19 Antigen Test Positive (+)	PPA	95% Confidence interval	
0	3	3	100.00%	43.85%	100.00%
1	11	10	90.91%	62.27%	98.38%
2	24	21	87.50%	69.00%	95.66%
3	33	29	87.88%	72.68%	95.19%
4	37	32	86.49%	72.02%	94.09%
5	39	34	87.18%	73.30%	94.40%

Analytical Sensitivity: Limit of Detection (LoD)

The LoD for direct swab was established using heat-inactivated SARS-CoV-2 isolate USA-WA1/2020 (NR-52286). The strain was spiked into the pooled human nasal swab matrix obtained from multiple healthy volunteers eluted in VTM and confirmed as SARS-CoV-2 negative by RT-PCR to prepare positive samples. The estimated LoD found from the initial two-fold serial dilution test was confirmed by testing 20 replicates. The confirmed LoD for direct swab was 8 x 10^2 TCID 50 /ml.

Analytical Specificity: Cross Reactivity (Exclusivity) and Microbial Interference

The potential cross-reactivity (exclusivity) of a panel of common organisms was evaluated with SARS-CoV-2 negative samples using the *Atomo* COVID-19 Antigen test. Potential microbial interference was evaluated with samples containing heat-inactivated SARS-CoV-2 isolate USA-WA1/2020 at approximately 3x LoD. A total of 8 bacteria were tested at a target concentration of approximately 10^7 cfu/ml with the exception of *Mycoplasma pneumoniae*, which was tested at a final concentration of 1.5 x 10^3 cfu/ml. The 18 viruses were tested at concentrations between 1.4 x 10^4 and $10^{7.9}$ TCID 50 /ml. All negative samples gave negative results at the concentrations of the potentially cross-reactive common organisms tested showing no cross-reactivity with *Atomo* COVID-19 Antigen assay.

All samples with SARS-CoV-2 strain tested positive showing no microbial interference at the concentrations of the potentially interfering common organisms tested.

Potential Cross-Reactants		
Adenovirus 1	MERS-Coronavirus, Irradiated Lysate	*Bodetella pertussis*
Adenovirus 7	Parainfluenza virus type 1	*Candida albicans*
Enterovirus 71, Tainan/4643/1998	Parainfluenza virus type 2	*Chlamydophila pneumoniae*
Human coronavirus(OC43)	Parainfluenza virus type 3	*Haemophilus influenzae*
Human coronavirus(229E)	Parainfluenza virus type 4	*Legionella pneumophila*
Human coronavirus(NL63)	Respiratory syncytial virus Type B	*Mycoplasma pneumoniae*
Human metapneumovirus(hMPV)	Rhinovirus	*Streptococcus pneumoniae*
Influenza A/Michigan/45/2015	SARS-Coronavirus	*Streptococcus pyogenes, Group A*
Influenza B/Wisconsin/01/2010	Pooled human nasal wash	

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, *in silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

https://blast.ncbi.nlm.nih.gov/Blast.cgi?PAGE=Proteins&PROGRAM=blastp&BLAST_PROGRAMS=blastp&PAGE_TYPE=BlastSearch&BLAST_SPEC=blast2seq&DATABASE=n/a&QUERY=&SUBJECTS=

- The homology between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 nucleocapsid protein is relatively low, at 36.7% across 86.4% of sequences, but cross-reactivity cannot be ruled out.
- The homology between SARS-CoV-2 nucleocapsid protein and *Mycobacterium tuberculosis* total protein (3,991 proteins) is relatively low, homology-based cross-reactivity can be ruled out.
- The homology between SARS-CoV-2 nucleocapsid protein and *Pneumocystis jirovecii* total protein (3,745 proteins) is relatively low, homology-based cross-reactivity can be ruled out.
- The homology between SARS-CoV-2 nucleocapsid protein and human coronavirus 229E nucleocapsid protein is relatively low, at 28.8% across 72.1% of sequences, but cross-reactivity cannot be ruled out. However, a result of the cross-reactivity wet study showed that *Atomo* COVID-19 Antigen Test had no cross-reactivity against human coronavirus 229E.
- No homologous protein was detected as a result of *in silico* assay with all the proteins (686 proteins) of *Mycoplasma pneumoniae* and the nucleocapsid protein (NP) of SARS-CoV-2.

Endogenous Interfering Substances Effect

To assess substances with the potential to interfere with the performance of the *Atomo* COVID-19 Antigen Test, positive and negative samples were tested with the addition of potentially interfering substances. The SARS-CoV-2 target concentration in the positive samples was approximately 2x LoD. All samples tested produced expected results, demonstrating that the *Atomo* COVID-19 Antigen test performance was not affected by any of the 30 potentially interfering substances listed in the table below at the concentrations tested.

Potential Interfering Substances	Concentration	Potential Interfering Substances	Concentration
Acetaminophen	10 mg/ml	Mometasone	1 mg/ml
Acetyl salicylic acid	15 mg/ml	Mucin	2%
Beclomethasone	0.5 mg/ml	Mupirocin	1 mg/ml
Benzocaine	5 mg/ml	OTC Throat drop (Halls)	15%
Budesonide	2 mg/ml	OTC Throat drop (Ricola)	15%
Chlorpheniramine maleate	5 mg/ml	OTC Nasal spray (Afrin)	15%
Dexamethasone	1 mg/ml	OTC Nasal spray (VicksSinex)	15%
Dextromethorphan HBr	2 mg/ml	OTC Nasal spray (Zicam)	15%
Diphenhydramine HCl	5 mg/ml	Oxymetazoline HCl	10 mg/ml
Ephedrine HCl	10 mg/ml	Phenylephrine HCl	5 mg/ml
Flunisolide	5 mg/ml	Phenylpropanolamine	5 mg/ml
Fluticasone	1 mg/ml	Tobramycin	1 mg/ml
Guaiacol Glyceryl Ether	20 mg/ml	Triamcinolone	1 mg/ml
Histamine Dihydrochloride	10 mg/ml	Whole Blood	2%
Menthol	10 mg/ml	Zanamivir	1 mg/ml

The interfering effects of biotin concentrations ranging between 625 ng/mL and 10 µg/mL were tested in a separate study. Biotin concentrations up to 1.25 µg/ml did not lead to false results. Biotin concentrations ≥2.5 µg/ml can cause false-negative COVID-19 results with the *Atomo* COVID-19 Antigen Test.

High-dose Hook Effect

The *Atomo* COVID-19 Antigen was tested up to 10^5 TCID 50 /ml of heat-inactivated SARS-CoV-2 strain and no high-dose hook effect was observed.

Technical Support

For questions, or to report a problem, please contact:
covidfeedback@atomodiagnostics.com