SARS-CoV-2 Antigen Rapid Test

Package Insert

REF L031-125W5	English

A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal and nasopharyngeal swab specimens.
For professional in vitro diagnostic use only.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection the nucleocapsid protein antigen from SARS-CoV-2 in nasal and nasopharyngeal swab specimens. The SARS-CoV-2 Antigen Rapid 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. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.
Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory 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, from patients with symptom beyond seven days, should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control 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.
The SARS-CoV-2 Antigen Rapid Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings.

SUMMARY

The novel coronaviruses belong to the β genus.[1] COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test is a qualitative membrane based chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal and nasopharyngeal swab specimens.
When specimens are processed and added to the test cassette, SARS-CoV-2 antigens, if present in the specimen, will react with the anti-SARS-CoV-2 antibody-coated particles, which have been pre-coated on the test strip. The mixture then migrates upward on the membrane by capillary action. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibody bound on the membrane. Test results are interpreted visually at 15-30 minutes based on the presence or absence of visually colored lines.
To serve as a procedure control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test cassette contains anti-SARS-CoV-2 antibodies.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink, or smoke in the area where the specimens or kits are handled.
- Do not use the test if the pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against biological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves, mask and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations. The used test should be considered potentially infectious and be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
- The test line for a high viral load sample may become visible within 15 minutes, or as soon as the sample passes the test line region.
- The test line for a low viral load sample may become visible within 30 minutes.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube. The reagent solution in the tube contains hazardous ingredients (see table below). If the solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice.

Chemical Name/ Concentration	Harms (GHS) code for each ingredient	Concentration
Sodium Azide	Acute Tox. 2 * (H300); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410)	0.02%

STORAGE AND STABILITY

- The kit can be stored at temperatures between 2 - 30 °C.
- The test is stable until the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- DO NOT FREEZE.
- Do not use after the expiration date.

MATERIALS

Materials Provided

- Test Cassettes
- Disposable Swabs (Nasal Swabs)*
- Extraction Buffer Tubes
- Package Insert

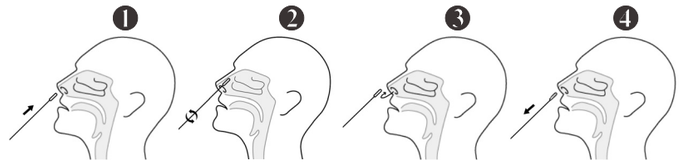
* *The Disposable Swabs are produced by another manufacturer.*

Materials Required But Not Provided

- Personal Protective Equipment
- Timer

SPECIMEN COLLECTION AND PREPARATION

- Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored at room temperature (15-30°C).
- **How to collect an anterior nasal swab sample:**

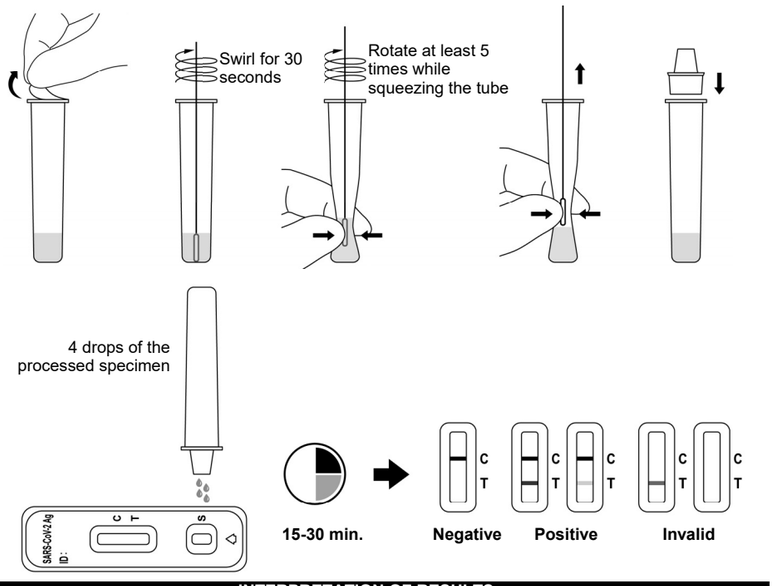


1. Carefully insert one of the Disposable Nasal Swabs, provided with your kit, into one nostril. Using gentle rotation, push the swab less than 2.5 cm (1 inch) from the edge of the nostril.
2. Rotate the swab 5 times against the mucosa inside the nostril to ensure sufficient specimen collection.
3. Using the same swab, repeat the process in the other nostril to ensure that an adequate amount of sample is collected from both nasal cavities.
4. Withdraw the swab from the nasal cavity. The specimen is now ready for preparation using the extraction buffer tubes.

DIRECTIONS FOR USE

Allow the test and extraction buffer to reach room temperature (15-30 °C) prior to testing.

1. Use an extraction buffer tube for each specimen to be tested and label each tube appropriately.
2. Remove the aluminum foil from the top of extraction buffer tube.
3. Insert the swab into the tube and swirl it for 30 seconds. Then rotate the swab at least 5 times while squeezing the sides of the tube. Take care to avoid splashing contents out of the tube.
4. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
5. Attach the dropper tip firmly onto the extraction buffer tube containing the sample. Mix thoroughly by swirling or flicking the bottom of the tube.
6. Remove the test cassette from the foil pouch and use it as soon as possible.
7. Place the test cassette on a flat and clean surface.
8. Add the processed specimen to the sample well of the test cassette.
   a. Invert the extraction buffer tube with the dropper tip pointing downwards and hold it vertically.
   b. Gently squeeze the tube, dispensing 4 drops of the processed specimen into the sample well.
9. Wait for the colored line(s) to appear. The result should be read at 15-30 minutes. **Do not read the result after 30 minutes.**



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on First Day of Testing	First Result Day 1 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.

NEGATIVE: Only one colored control line appears in the control region (C). No apparent colored line appears in the test line region (T). This means that no SARS-CoV-2 antigen was detected.
To increase the chance that the negative result for COVID-19 is accurate, you should:
- Test again in 48 hours if the individual has symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.
All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.
POSITIVE:* Two distinct colored lines appear. One line in the control line region (C) and the other line in the test line region (T). This means that the presence of SARS-CoV-2 antigen was detected. Repeat testing does not need to be performed if the patient has a positive result at any time. A PCR confirmation test should be carried out.
***NOTE:** The intensity of the color in the test line (T) may vary depending on the level of the SARS-CoV-2 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect operation are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control swabs are not supplied with this kit; however, it is recommended that positive and negative controls should be tested as a good laboratory practice to ensure that the test cassette and that the test procedure performed correctly. Please contact with the local distributor to purchase the Flow*flex* SARS-CoV-2 Antigen Rapid Test control from *ACON*.

LIMITATIONS

1. The SARS-CoV-2 Antigen Rapid Test is for *in vitro* diagnostic use only. The test should be used for the detection of SARS-CoV-2 antigens in nasal and nasopharyngeal swab specimens only. The intensity of the test line does not necessarily correlate to SARS-CoV-2 viral titer in the specimen.
2. Specimens should be tested as quickly as possible after specimen collection and at most within the hour following collection.
3. Use of viral transport media may result in decreased test sensitivity.
4. A false-negative test may result if the level of antigen in a sample is below the detection limit of the test or if the sample was collected incorrectly.
5. Test results should be correlated with other clinical data available to the physician.
6. A positive test result does not rule out co-infections with other pathogens.
7. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
8. A negative test result is not intended to rule out other viral or bacterial infections.
9. The performance of the SARS-CoV-2 Antigen Rapid Test has not been assessed in a population vaccinated against COVID-19.
10. Laboratories may be required to report all positive results in accordance with any country-specific or public health authority requirements.
11. Use in conjunction with the testing strategy outlined by public health authorities in your area.
12. This test is not intended for home testing (or self-testing).
13. The performance has not been established with 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.
14. The SARS-CoV-2 Antigen Rapid Test can detect both viable and non-viable SARS-CoV-2 material.
15. Serial Testing (Repeat Testing) Information and Limitations:
    a) 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.
    b) A negative result should be followed up with repeat, or serial testing at least twice over three days with at least 48 hours between tests for symptomatic individuals and/or at least three times over five days with at least 48 hours between tests for asymptomatic individuals. A self-test may be used for this additional testing.
    c) The performance of this test was not clinically validated for serial testing. Serial testing recommendations are supported by the study conducted by the National Institutes of Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.
    d) 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.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

This clinical performance data reflects the accuracy of the test when testing once. This test was not clinically validated for serial testing. The serial testing recommendations are supported by the study conducted by the National Institutes of Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.

Nasal Swab Specimens

The performance of SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swabs collected from individual patients who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:

Method		RT-PCR (Nasopharyngeal Swab Specimens)		Total Results
SARS-CoV-2 Antigen Rapid Test (Nasal Swab Specimens)	**Results**	Negative	Positive	
	Negative	433	5	438
	Positive	2	165	167
Total Results		435	170	605

Relative Sensitivity: 97.1% (93.1%-98.9%)* Relative Specificity: 99.5% (98.2%-99.9%)*
Accuracy: 98.8% (97.6%-99.5%)* *95% Confidence Intervals

Stratification of the prospective positive samples post onset of symptoms between 0-3 days has a positive percent agreement (PPA) of 98.3% (n=60) and 4-7 days has a PPA of 96.0% (n=25).

Prospective positive samples with Ct value ⩽30 has a positive percent agreement (PPA) of 100% (n=73) and Ct value >30 has a positive percent agreement (PPA) of 81.0% (n=21).

Nasopharyngeal Swab Specimens

The performance of SARS-CoV-2 Antigen Rapid Test was established with 299 nasopharyngeal swabs collected from individual patients who were suspected of COVID-19. The results show that the relative

sensitivity and the relative specificity are as follows:

Method		RT-PCR (Nasopharyngeal Swab Specimens)		Total Results
SARS-CoV-2 Antigen Rapid Test (Nasopharyngeal Swab Specimens)	**Results**	Negative	Positive	
	Negative	175	3	178
	Positive	1	120	121
Total Results		176	123	299

Relative Sensitivity: 97.6% (92.8% - 99.5%)* Relative Specificity: 99.4% (96.5% - 99.9%)*
Accuracy: 98.7% (96.5% - 99.6%)* *95% Confidence Intervals

Stratification of the prospective positive samples post onset of symptoms between 0-3 days has a positive percent agreement (PPA) of 100% (n=20) and 4-7 days has a PPA of 100% (n=24).

Prospective positive samples with Ct value ⩽30 has a positive percent agreement (PPA) of 100% (n=39) and Ct value >30 has a positive percent agreement (PPA) of 88.9% (n=9).

Serial-testing clinical performance

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 below table:

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

Days after First PCR Positive Test Result	Asymptomatic on First Day of Testing			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%)	N/A	4/9 (44.4%)	3/7 (42.9%)	N/A

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.

Limit of Detection (LOD)

The LOD of SARS-CoV-2 Antigen Rapid Test was established using limiting dilutions of an inactivated viral sample. The viral sample was spiked with negative human nasal and nasopharyngeal sample pool into a series of concentrations. Each level was tested for 30 replicates. The results show that the LOD is $1.6*10^2$ $TCID_{50}$/mL.*

* Base on the concentration of virus in extraction buffer

Cross-Reactivity (Analytical Specificity) and Microbial Interference

Cross-reactivity was evaluated by testing a panel of related pathogens and microorganisms that are likely to be present in the nasal cavity. Each organism and virus were tested in the absence or presence of heat-inactivated SARS-CoV-2 virus at low positive level. Both nasal swab specimens and nasopharyngeal swab specimens were tested.

No cross-reactivity or interference was observed with the following microorganisms when tested at the concentration presented in the table below. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

Potential Cross-Reactant		Test Concentration	Cross-Reactivity (in the absence of SARS-CoV-2 virus)	Interference (in the presence of SARS-CoV-2 virus)
Virus	Adenovirus	1.14×10^6 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Enterovirus	9.50×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Human coronavirus 229E	1.04×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Human coronavirus OC43	2.63×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Human Metapneumovirus	1.25×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	MERS-coronavirus	7.90×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Influenza A	1.04×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Influenza B	1.04×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 1	1.25×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 2	3.78×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 3	1.0×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 4	2.88×10^6 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Respiratory syncytial virus	3.15×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Rhinovirus	3.15×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
Bacteria	Bordetella pertussis	2.83×10^9 CFU/mL	No 3/3 negative	No 3/3 positive
	Chlamydia trachomatis	3.13×10^8 CFU/mL	No 3/3 negative	No 3/3 positive
	Haemophilus influenza	1.36×10^8 CFU/mL	No 3/3 negative	No 3/3 positive
	Legionella pneumophila	4.08×10^9 CFU/mL	No 3/3 negative	No 3/3 positive
	Mycobacterium tuberculosis	1.72×10^7 CFU/mL	No 3/3 negative	No 3/3 positive
	Mycoplasma pneumoniae	7.90×10^7 CFU/mL	No 3/3 negative	No 3/3 positive
	Staphylococcus aureus	1.38×10^7 CFU/mL	No 3/3 negative	No 3/3 positive
	Staphylococcus epidermidis	2.32×10^9 CFU/mL	No 3/3 negative	No 3/3 positive
	Streptococcus pneumoniae	1.04×10^8 CFU/mL	No 3/3 negative	No 3/3 positive
	Streptococcus pyogenes	4.10×10^6 CFU/mL	No 3/3 negative	No 3/3 positive
	Pneumocystis jirovecii-S. cerevisiae	8.63×10^7 CFU/mL	No 3/3 negative	No 3/3 positive
	Pseudomonas aeruginosa	1.87×10^8 CFU/mL	No 3/3 negative	No 3/3 positive
	Chlamydia pneumoniae	1×10^6 IFU/ml	No 3/3 negative	No 3/3 positive
Yeast	Candida albicans	1.57×10^8 CFU/mL	No 3/3 negative	No 3/3 positive
Pooled human nasal wash			No 3/3 negative	No 3/3 positive

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, in-silico analysis was used to assess the degree of protein sequence homology. The comparison between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 revealed a low homology of 36.7% across 82.8% of the SARS-CoV-2 nucleocapsid sequence. The result suggests that cross-reactivity with human coronavirus HKU1 cannot be completely ruled out.

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated. Each substance was tested in the absence or presence of SARS-CoV-2 virus at low positive level. The final concentration of the substances tested are listed below and were found not to affect test performance.

Interfering Substance	Active Ingredient	Concentration	Results (in the absence of SARS-CoV-2 virus)	Results (in the presence of SARS-CoV-2 virus)
Endogenous	Biotin	2.4 mg/mL	3/3 negative	3/3 positive
	Mucin	0.5% w/v	3/3 negative	3/3 positive
	Whole Blood	4% v/v	3/3 negative	3/3 positive
Afrin Original Nasal Spray	Oxymetazoline	15% v/v	3/3 negative	3/3 positive
ALKALOL Allergy Relief Nasal Spray	Homeopathic	1:10 Dilution	3/3 negative	3/3 positive
Chloraseptic Max Sore Throat Lozenges	Menthol, Benzocaine	1.5 mg/mL	3/3 negative	3/3 positive
CVS Health Fluticasone Propionate Nasal Spray	Fluticasone propionate	5% v/v	3/3 negative	3/3 positive
Equate Fast-Acting Nasal Spray	Phenylephrine	15% v/v	3/3 negative	3/3 positive
Equate Sore Throat Phenol Oral Anesthetic Spray	Phenol	15% v/v	3/3 negative	3/3 positive
Original Extra Strong Menthol Cough Lozenges	Menthol	1.5 mg/mL	3/3 negative	3/3 positive
NasalCrom Nasal Spray	Cromolyn	15% v/v	3/3 negative	3/3 positive
NeilMed NasoGel for Dry Noses	Sodium Hyaluronate	5% v/v	3/3 negative	3/3 positive
Throat Lozenge	Dyclonine Hydrochloride	1.5mg/mL	3/3 negative	3/3 positive
Zicam Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	5% v/v	3/3 negative	3/3 positive
Antibiotic	Mupirocin	10 mg/mL	3/3 negative	3/3 positive
Tamiflu	Oseltamivir Phosphate	5 mg/mL	3/3 negative	3/3 positive
Antibiotic	Tobramycin	4 µg/mL	3/3 negative	3/3 positive
Mometasone Furoate Nasal Spray	Mometasone Furoate	5%v/v	3/3 negative	3/3 positive
Physiological Seawater Nasal Cleaner	NaCl	15%v/v	3/3 negative	3/3 positive

PRECISION

Intra-Assay

Within-run precision was determined using 60 replicates of specimens: negative control and SARS-CoV-2 antigen positive controls. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision was determined using 60 independent assays on the same specimen: negative specimen and SARS-CoV-2 antigen positive specimen. Three different lots of the SARS-CoV-2 Antigen Rapid Test were tested using these specimens. The specimens were correctly identified >99% of the time.

High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 1.43×10^5 $TCID_{50}$/mL of heat-inactivated SARS-CoV-2 virus with the SARS-CoV-2 Antigen Rapid Test.

POC STUDY

A total of 9 operators from 3 sites performed the SARS-CoV-2 Antigen Rapid Test on 60 blinded labeled specimens by following the instructions of the package insert and recorded the results on data sheet. Based on the results of this POC clinical evaluation, untrained operators with various background and experience levels can perform the SARS-COV-2 Antigen Rapid Test correctly after read the product package insert without other training. The untrained operators found that the test procedure described in the package insert is simple to follow.

BIBLIOGRAPHY

1. Shuo Su, Gary Wong, Weifeng Shi, et al. Epidemiology, Genetic recombination, and pathogenesis of coronaviruses. Trends in Microbiology, June 2016, vol. 24, No. 6: 490-502
2. Susan R. Weiss, Julian L. Leibowitz, Coronavirus Pathogenesis, Advances in Virus Research, Volume 81: 85-164

Index of Symbols

	Manufacturer	Σ	Contains sufficient for <*n*> tests		Temperature limit
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
	Consult instructions for use	LOT	Batch code	REF	Catalogue number
	Date of manufacture				

***ACON* Biotech (Hangzhou) Co., Ltd.**
No.210 Zhenzhong Road, West Lake District
Hangzhou, P.R. China, 310030

Number: 1151429802
Revision Date: 2022-11-30