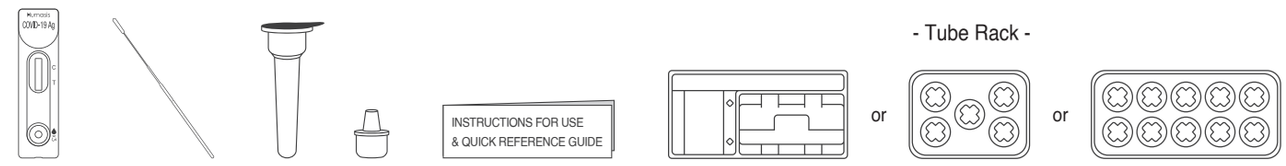
Humasis

Self-test

COVID-19 Ag Home Test

REF ACOVGS-7002
REF ACOVGS-7005
REF ACOVGS-7025

Check Your Test Kit



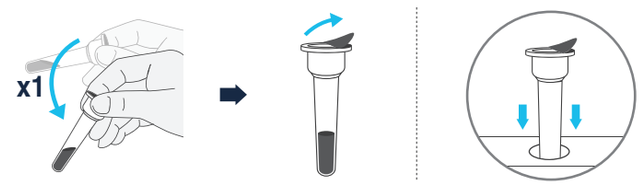
Components required but not provided: Timer or watch

Locate the kit components : It is recommended gloves (not provided) also be used during testing. Release the test tube and the test device from pouches and place those on a flat surface.
* In case the tests were refrigerated, keep them ambient for 30 minutes to let it reach the room temperature.
* Check the expiry date of test device.
* Do not use the test device if the pouch is damaged or expired.
* Testing should be completed within 30-60 minutes of opening the test pouch.

Wash Your Hands

Before you start testing, wash your hands or use hand sanitizer.
Make sure your hands are dry before starting.

Before You Start



Collect the buffer fluid at the bottom of the test tube by shaking it and then peel off the seal.

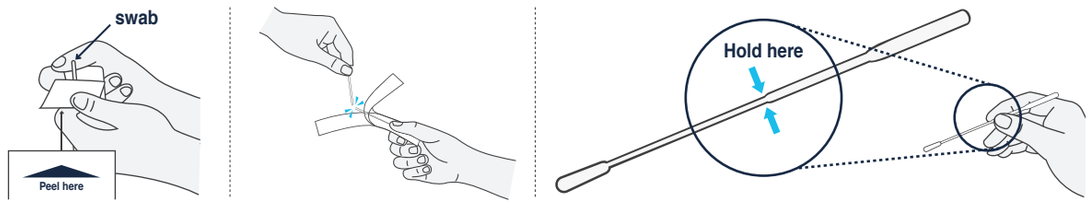
keep the pre-filled tube in the tube holder.

STEP-BY-STEP Instruction

* Only the swabs provided with the test kit (FA/FANAB01) should be used for specimen collection.

STEP 1

* Do not touch the soft tip or lay it down on any surfaces.



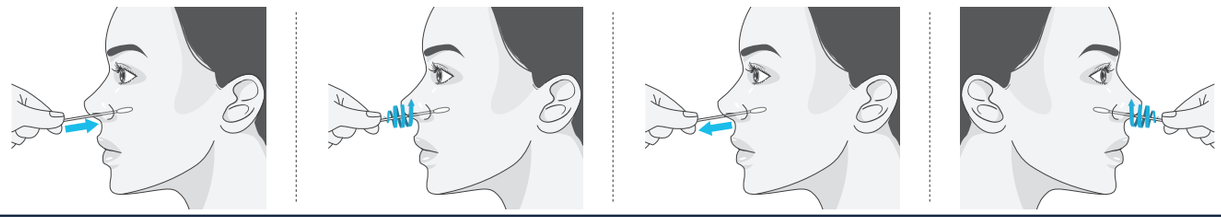
Look for the "PEEL HERE" sign to peel open the swab package halfway. Make sure the soft tip is still covered with the packaging.

Identify the breakpoint on the swab and break off the handle.

Remove the swab from the package. Do not touch the soft tip or lay it down on any surfaces. You will see two notches on the handle. Make sure to hold the swab at the second notch, as pictured.

STEP 2

Collecting Your Nasal Swab Sample: ***Incorrect swabbing may result in an inaccurate test result. This is especially important if you do not have symptoms.***



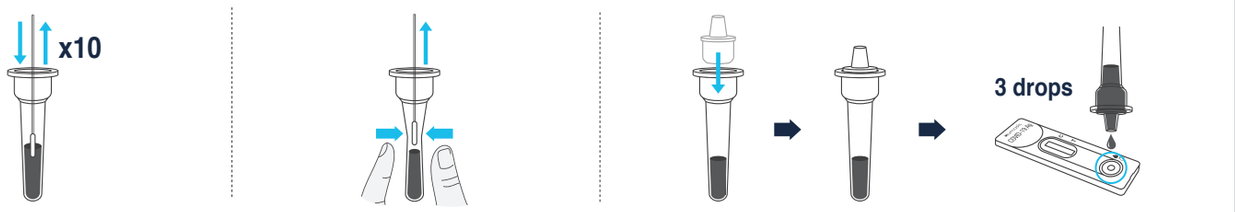
Insert the entire soft end of the swab straight back into your nostril less than one inch (about 2cm) or until resistance is felt.

Slowly rotate the swab, gently rubbing it along the insides of your nasal passage in circular motion 5 times.

Gently remove the swab.

Using the same swab, repeat this process in your other nostril with the same end of the swab.
Note: The swab included in the kit is designed for collection of samples from adults. Do not collect swabs from children under 14 years of age.

STEP 3



Put the tip of the swab into the test tube. Move the swab up and down at least 10 times to ensure sufficient sample extraction is extracted.

Remove the swab while pressing against the sides of the tube to ensure maximum amount of liquid has been squeezed from the swab.
Note: False negative results can occur if the specimen is not properly mixed or too vigorously mixed.

Put the filter cap on the opening of the test tube and immediately dispense three drops of sample extract into the sample well of device.
Note: Adding only one drop of solution or the entire vial may result in false negative results.

STEP 4

Read results at 15 minutes after applying the sample. Do not read results after 20 minutes.
Note: False negative or false positive results can occur if results are read before 15 minutes or after 20 minutes.

Disposal

All used test components should be disposed of in your household waste.

Wash Your Hands

After completing all steps, wash hands or use hand sanitizer.

How to Read the Results

NEGATIVE

If there is **ONE LINE**, next to the **"C"** and **NO LINE next to the "T", your test result is negative.**
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.

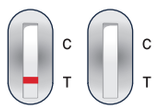
* Please refer to Frequently Asked Questions section - WHAT IF YOU TEST NEGATIVE? - for further information.

POSITIVE

If there is **TWO LINES,** next to the **"C"** and any line next to the **"T" even a faint one**, you may be infected with COVID-19.
You do not need to perform repeat testing if you have a positive result at any time.
A Positive Result indicates that viral antigens from COVID-19 were present in the specimen, and it is very likely that you have COVID-19 and should self-isolate. It is important to be under the care of your healthcare provider.

* Please refer to Frequently Asked Questions section - WHAT IF YOU TEST POSITIVE? - for further information.

INVALID



If there is NO LINE next to the "C" like above examples, your test is not working. Please contact the place of purchase.
If invalid results are obtained, repeat the test using a new device.

[INTENDED USE]

Humasis COVID-19 Ag Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein and receptor binding domain (RBD) of the SARS-CoV-2 spike proteins in mid-turbinate swabs from the SARS-CoV-2. This test is intended for home use with self-collected and adult-collected direct mid-turbinate swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first seven days of symptom onset. This test is also intended for home use with self-collected and adult collected mid-turbinate swab samples from individuals aged 14 years or older with or without symptoms or other epidemiological reasons to suspect COVID-19. *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.*
The Humasis COVID-19 Ag Home Test does not differentiate between SARS-CoV and SARS-CoV-2.
Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen and/or receptor binding domain (RBD). These antigens are generally detectable in mid-turbinate swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical 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. Individuals who test positive with the Humasis COVID-19 Ag Home Test should self-isolate and seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary.
Negative results are presumptive, 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 an individuals' 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. Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider. The Humasis COVID-19 Ag Home Test is intended for self-use or a lay user testing another person 14 years or older in a non-laboratory setting. Laboratories within Canada and its territories are required to report all results to the appropriate public health authorities.

[CONTENTS]

- Test devices packaged individually in aluminum pouch
- Disposable test tube with extraction buffer
- Filter cap
- Sterilized swabs for specimen collection
- Instructions for use & Quick reference guide
- Tube rack

[COMPONENTS REQUIRED BUT NOT INCLUDED]

- Timer or watch

[FREQUENTLY ASKED QUESTIONS]

WILL THE TEST HURT?

No, the swab included is not sharp, and it should not hurt. Swabbing in the nostril can sometimes feel slightly uncomfortable. If you feel pain during testing, stop the test and seek advice from your healthcare provider.

WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?

Potential risks include:
- Possible discomfort while you collect sample for testing.
- Possible incorrect test results (false positive or false negative). Please see WHAT IF YOU TEST POSITIVE and WHAT IF YOU TEST NEGATIVE.

Potential benefits include:
- Along with other clinical information, the test results can help you and your health provider to make informed decisions on medical treatments that may be needed.
- The test may help limit the spread of COVID-19 to your family and others.

WHAT IS SERIAL TESTING?

Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce the spread of infection. Serial testing is more likely to detect COVID-19, especially when you do not have any symptoms. Testing for symptomatic individuals should be performed 48 hours after the first negative test, for a total of at least two tests. Testing for asymptomatic individuals should be performed 48 hours after the first negative test, then 48 hours after the second negative test, for a total of at least three tests.

WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

Antigen tests, such as the Humasis COVID-19 Ag Home Test can detect proteins from the virus that causes COVID-19. Molecular tests are known as PCR tests and detect genetic material from the virus. As antigen tests may not be as sensitive as molecular tests, positive results are highly accurate while negative results do not rule out the possibility of infection. This means that there is a higher chance that this test may result negative when you have COVID-19.

HOW ACCURATE IS THE TEST?

The clinical evaluation of the Humasis COVID-19 Ag Home Test was evaluated by testing a total of 492, prospectively collected direct mid-turbinate nasal swab samples, consisted of 45 positive and 447 negative samples from suspected COVID-19 patients in United States that were within seven days of symptom onset or asymptomatic, aged 14 years and older. The Humasis COVID-19 Ag Home Test was compared to an FDA authorized molecular SARS-CoV-2 test. In this study, the Humasis COVID-19 Ag Home Test correctly identified 86.7% of positive samples and 99.8% of negative samples. *The study was based on testing only once.* ***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.***

HOW DO I INTERPRET THE RESULTS WHEN SERIAL TESTING?

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

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

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

WHAT IF YOU TEST POSITIVE?

A positive result indicates that antigens from COVID-19 were detected and it is very likely you currently have COVID-19 disease. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive you should self-isolate at home as per the health authority's recommendations to keep the virus from spreading to others. Please follow the health authority's recommendations regarding self-isolation. Seek advice with your healthcare provider immediately to determine how best to care for you depending on your result, symptoms and medical history. *You do not need to perform repeat testing if you have a positive result at any time.*

WHAT IF YOU TEST NEGATIVE?

A negative result means no antigens for COVID-19 were detected. There is a possibility for this test to give a negative result that is incorrect (false negative). Continue to follow all applicable rules regarding contact with others and protective measures. Negative results do not rule out COVID-19. Even if the test is negative, an infection may still be present. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. Negative results are presumptive and may need to be confirmed with a molecular test. This means that you could possibly still have COVID-19 even though the test is negative.
To increase the chance that the negative result for COVID-19 is accurate, you should:
- Test again in 48 hours if 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.

[PRECAUTIONS AND LIMITATIONS]

- For *in vitro* diagnostic use only
- Not to be taken internally. Avoid sample buffer contact with skin and eyes. If the buffer contacts with the skin, eyes, and mucous membranes, wash immediately under running water and seek medical attention.
- Do not use this test for individuals under 14 years of age. The swab included in the kit is designed for collection of samples from adults and additional safety measures are needed for safe collection in children under 14 years of age.
- Poor vision or poor lighting may affect your ability to interpret the test correctly.
- This test has been intended only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Do not use the test device beyond the expiration date.
- Keep sealed until usage, and once opened use immediately.
- Do not re-use the device.
- Handle all specimens safely as potentially infectious.
- This test is intended for initial screening of coronavirus infection by detecting COVID-19 antigen, but should not be used as a sole criterion for the determination of SARS-CoV-2 infection. Other methods and clinical information (signs and symptoms) should be used and considered for diagnosis.
- A negative test result may occur if the level of antigens in a sample is below the detection limit of the test or if the sample was collected improperly.
- Failure to follow the Test Procedure may adversely affect test performance 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 rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.
- Negative results should be treated as presumptive.
- 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 SARS-CoV-2 and their prevalence, which change over time.
- The user should not take any decision of medical relevance without first consulting his or her medical practitioner.
- The product is not intended to monitor disease status.
- Testing should be completed within 30-60 minutes of opening the test pouch.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.

The preservative sodium azide corresponds to H300, H310, H400, and H410 depending on GHS, but the manufacturer's sample extract contains a trace amount of less than 0.1% concentration. And therefore, does not exceed the HGS concentration of 1% concentration.

composition	concentration
Buffer	≥ 90%
Stabilizer	1.20%
Surfactants	1.20%
Preservative	< 0.1%

The extraction buffer solution in the extraction buffer tube contains a hazardous ingredient as shown in above table. If the extraction buffer solution contacts the skin or eye, immediately wash with plenty of running water.

Serial Testing (Repeat Testing) Information and 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 of 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.

: Manufacturer	: Do not reuse	: Consult instructions for use
REF : Catalogue number	LOT : Lot number	IVD : *In vitro* diagnostic medical device
: Temperature limit	: Use by	: Contains sufficient for <n> tests
: Keep away from sunlight	: Keep dry	: Do not use if package is damaged

Manufacturer
Humasis Co., Ltd.
Rm. 114, 502, 504, 604, 604-1, B03-01, B03-02, 88, Jeonpa-ro,
Dongan-gu, Anyang-si, Gyeonggi-do, 14042, Republic of Korea
TEL: +82-31-8085-6200, FAX: +82-31-8085-6249
Email: question@humasis.com
www.humasis.com

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SA /

Humasis

Self-test

COVID-19 Ag Home Test

[INTENDED USE]

Humasis COVID-19 Ag Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein and receptor binding domain (RBD) of the SARS-CoV-2 spike proteins in mid-turbinate swabs from the SARS-CoV-2. This test is intended for home use with self-collected and adult-collected direct mid-turbinate swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first seven days of symptom onset. This test is also intended for home use with self-collected and adult collected mid-turbinate swab samples from individuals aged 14 years or older with or without symptoms or other epidemiological reasons to suspect COVID-19. Humasis COVID-19 Ag Home 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 Humasis COVID-19 Ag Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen and/or receptor binding domain (RBD). These antigens are generally detectable in mid-turbinate swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical 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. Individuals who test positive with the Humasis COVID-19 Ag Home Test should self-isolate and seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary.

Negative results are presumptive, 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 an individuals' 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.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider. The Humasis COVID-19 Ag Home Test is intended for self-use or a lay user testing another person 14 years or older in a non-laboratory setting. Laboratories within Canada and its territories are required to report all results to the appropriate public health authorities.

[SUMMARY AND EXPLANATION]

Coronavirus is a group of viruses that belongs to the Family Coronaviridae; a type of RNA virus of 27~32kb commonly found in birds and mammals including human. Coronavirus is divided into four genera: alpha, beta, gamma and delta. The virus causes illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV).

Coronavirus disease 2019 (COVID-19) is a new strain caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The disease originated from Wuhan city of China in December 2019.The World Health Organization (WHO) publicly named this virus 'COVID-19' and declared it a pandemic and a Public Health Emergency of International Concern. The infection is typically spread from one person to another via direct contact or respiratory droplets from cough or sneeze. Latent period from exposure to onset of symptoms is between one to fourteen days (four to seven days on average). Common symptoms and signs of infection include fever, cough, shortness of breath and breathing difficulties. In severe cases, infections can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.

Because the symptoms of SARS-CoV-2 are similar to other viral respiratory infectious diseases such as influenza A or B, rapid detection test to distinguish SARS-CoV-2 from other respiratory infections at an early stage is highly important to break further transmissions.

The Humasis COVID-19 Ag Home Test is designed to detect COVID-19 antigens from suspected individuals within 15 minutes. This test is intended for self-use or an adult lay user testing another person (≥14 years of age) in non-laboratory settings including a home environment.

[PRINCIPLE OF THE TEST]

Humasis COVID-19 Ag Home Test uses monoclonal antibodies specific to COVID-19 antigens to detect COVID-19 specific antigens in human nasal swab specimens. A nitrocellulose membrane strip in the device contains one test line and one control line. The test line is pre-coated with anti-mouse monoclonal antibody to SARS-CoV-2 Nucleocapsid and RBD for detection of SARS-CoV-2 antigens, and the control line is coated with goat anti-mouse IgG. When the extracted swab specimen is added to the sample well, it will migrate to the conjugate pad, which contains conjugated antibodies conjugated with colloidal gold directed against the SARS-CoV-2 antigen. If the sample contains SARS-CoV-2 antigens, antigen-antibody-conjugate complex will be formed. The complex will continue to migrate across the membrane until it reaches the capture zone (test line) where the complex will bind to immobilized antibodies and form visible colored band in the test line. The sample will continue to move along the membrane until it reaches the control line where excess conjugate binds and produces a second visible line. This control line indicates that the sample has migrated across the membrane as intended and the test was performed properly.

[CONTENTS]

Product	2 Tests Kit	5 Tests Kit	25 Tests Kit
Kit components	- Test devices (2ea) - Test tube with extraction buffer (2ea) - Filter cap (2ea) - Swabs (2ea) - Instructions for use (1ea) - Quick reference guide (1ea) - Tube rack (1ea)	- Test devices (5ea) - Test tube with extraction buffer (5ea) - Filter cap (5ea) - Swabs (5ea) - Instructions for use (1ea) - Quick reference guide (1ea) - Tube rack (1ea)	- Test devices (25ea) - Test tube with extraction buffer (25ea) - Filter cap (25ea) - Swabs (25ea) - Instructions for use (1ea) - Quick reference guide (1ea) - Tube rack (1ea)

● Components required but not provided : Timer or watch

[STORAGE AND SHELF-LIFE]

- An unopened test device should be stored at 2- 30°C (36 - 86°F). It is stable until the expiration date marked on the label.
- An opened test device is stable up to 1 hour after release from the aluminum pouch.
- Nasal swab sample eluted in extraction buffer is stable up to 4 hours at 30°C and up to 48 hours at 4°C

[TEST PROCEDURE]

Precautions Before the test

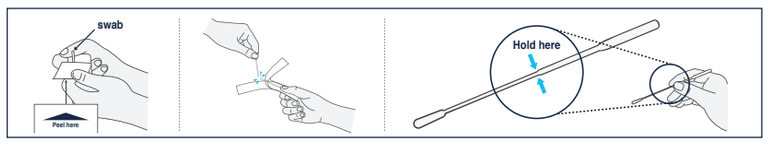
- Please carefully read and follow the STEP-BY-STEP instruction on the next page.
- Wash or sanitize your hands and dry them thoroughly before starting the test.
- In case the tests were refrigerated, keep them ambient for 30 minutes to let it reach the room temperature.

1. Specimen collection

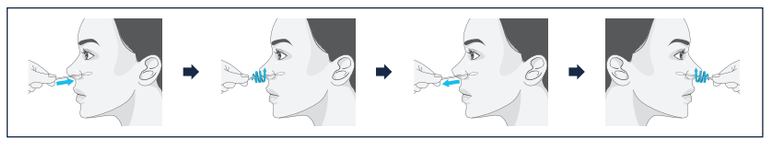
*Only the swabs provided with the test kit (FA/FANAB01) should be used for specimen collection.

1) Use the swab included in the package to collect nasal specimen.

2) Look for the "PEEL HERE" sign to peel open the swab package halfway. Make sure the soft tip is still covered with the packaging. Identify the breakpoint on the swab and break off the handle. Remove the swab from the package. Do not touch the soft tip or lay it down on any surfaces. You will see two notches on the handle. Make sure to hold the swab at the second notch.



3) Insert the entire soft end of the swab straight back into your nostril less than one inch (about 2cm) or until resistance is felt. Slowly rotate the swab, gently rubbing it along the insides of your nasal passage in circular motion 5 times.
*It is highly recommended to test the specimen immediately after collection for best results.

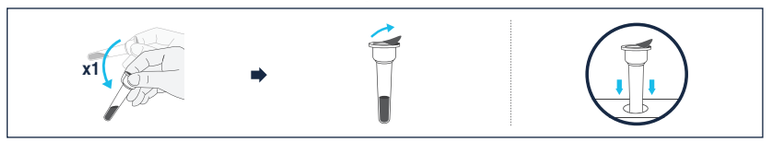


2. Test method

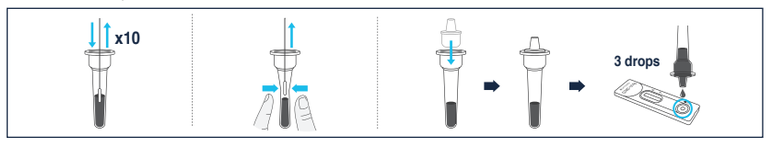
1) Prepare aluminum pouch containing the test device and place it on the testing surface along with test tube and filter cap.

2) Release the test device from aluminum pouch and place it on a level surface just prior to starting test.
*Do not use the test device if the pouch is damaged or the device is seriously broken.

3) Shake the test tube downwards so the buffer fluid can gather on the bottom of the tube before peeling off the sealed cap.



4) Insert the tip of the swab into the test tube and shake the tip up and down inside the tube more than 10 times to make sufficient sample extraction.



5) Remove the swab while squeezing the test tube.

6) Equip the filter cap on the test tube and dispense 3 drops of sample extracts (90~100uL) into the sample well of the device.

7) Read result at 15 minutes after applying sample. Do not read result after 20 minutes.

[INTERPRETATION OF RESULTS]

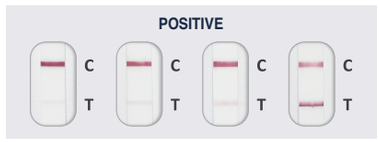
Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

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

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

Positive: If colored line is visible in the test line (T) and control line (C), the result is positive These are photos of actual positive results. Please note that the test line can show up faintly. This faint line still indicates a positive result.

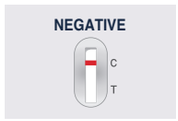
In case of a positive test result:
- *There is currently a suspicion of COVID-19 infection.*
- *immediately contact a doctor/family physician or the ocal public health department.*
- *follow local guidelines for self-isolation.*
- *You do not need to perform repeat testing if you have a positive result at any time.*



Negative: If no colored line appears in the test line (T) and a colored line is present on the control region (C), then the result is negative.

If the test result is negative:
- *Continue to follow all applicable rules regarding contact with others and protective measures.*

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: If there is no colored line in the control region (C), the result is invalid.

In case of an invalid test result:
- *possibly caused by incorrect test performance.*
- *Repeat the test with a new test device.*

[PERFORMANCE CHARACTERISTICS]

● Limit of detection (LoD)

The limit of detection (LoD) of Humasis COVID-19 Ag Home Test is $3.2x10^1$ $TCID_{50}$/mL.

● Cross-reactivity

1) Wet testing

Potential cross-reactive organisms listed in the below table were prepared at the concentration of 10^5 PFU/mL or higher for viruses and 10^6 CFU/mL or higher for bacteria. They were spiked into the negative and low positive samples and were tested in 3 replicates. A total of 32 pathogens listed in the below table showed no cross-reactivity with the Humasis COVID-19 Ag Home Test.

	Virus				
1	Coronavirus OC43	4.4×10^7 PFU/mL	11	Parainfluenza 1	2.8×10^5 PFU/mL
2	Coronavirus 229E	3×10^6 PFU/mL	12	Parainfluenza 2	2×10^7 PFU/mL
3	Coronavirus NL63	1×10^5 $TCID_{50}$/mL	13	Parainfluenza 3	8×10^5 PFU/mL
4	MERS-coronavirus	$1.183 \times 10^5$$TCID_{50}$/mL	14	Parainfluenza 4a	1.3×10^8 PFU/mL
5	Human adenovirus 1	7×10^7 PFU/mL	15	Rhinovirus 1	1.4×10^5 PFU/mL
6	Human adenovirus 3	2.4×10^6 PFU/mL	16	Metapneumovirus	6×10^5 PFU/mL
7	Human adenovirus 5	4.0×10^7 PFU/mL	17	Human Enterovirus	1×10^6 PFU/mL
8	Human adenovirus 7	2.0×10^8 PFU/mL	18	Influenza A H1N1	2×10^5 PFU/mL
9	Respiratory syncytial virus A	8.0×10^5 PFU/mL	19	Influenza A H3N2	4.9×10^6 PFU/mL
10	Respiratory syncytial virus B	2.4×10^6 PFU/mL	20	Influenza B	1×10^6 PFU/mL
	Bacteria & Fungi				
21	*Mycoplasma pneumonia Ag*	1×10^7 CFU/mL	27	*Candida albicans*	1×10^6 CFU/mL
22	*Streptococcus pyogenes*	1×10^6 CFU/mL	28	*Chlamydia pnuemoniae*	2.0×10^7 $TCID_{50}$/mL
23	*Bordetella pertussis*	1×10^6 CFU/mL	29	*Staphylococcus epidermidis*	1×10^6 CFU/mL
24	*Streptococcus pneumoniae*	1×10^6 CFU/mL	30	*Staphylococcus aureus*	1×10^6 CFU/mL
25	*Legionella pneumophila*	1×10^6 CFU/mL	31	*Enterococcus casseliflavus*	1×10^6 CFU/mL
26	*Haemophilus influenzae*	1×10^6 CFU/mL		-	-
	Others (100%)				
32	Pooled human nasal wash – to represent diverse microbial flora in the human respiratory tract				

2) In-silico

To estimate the likelihood of cross-reactivity with SARS-CoV-2 virus in the presence 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.

- **Human coronavirus HKU1:** 12% homology was found between SARS-CoV-2 Receptor Binding Domain spike proteins and HKU1 spike protein, and 32% homology was found between SARS-CoV-2 Nucleocapsid protein and HKU1 Nucleocapsid protein. Therefore, cross-reactivity is highly unlikely but cannot be ruled out.
- ***Pneumocystis jirovecii:*** No sequence homology was found between SARS-CoV-2 RBD spike protein/nucleocapsid protein and P. jirovecii. Therefore, there is no cross-reactivity.
- ***Mycobacterium tuberculosis:*** There was 45.6% homology across 9% of the whole sequence between M. tuberculosis and SARS-CoV-2 RBD spike protein. No similarity was found between M. tuberculosis and SARS-CoV-2 NP. Therefore, cross-reactivity is highly unlikely but cannot be ruled out.
- **SARS-CoV:** 72% homology was found between SARS-CoV-2 receptor binding domain spike proteins and SARS-CoV spike protein, and 96% homology was found between SARS-CoV-2 nucleocapsid protein and SARS-CoV nucleocapsid protein. Therefore, cross-reactivity is highly likely.

● Interference

Below potential interfering substances did not affect performance of the Humasis COVID-19 Ag Home Test.

No.	Interfering substances	Testing conc.	No.	Interfering substances	Testing conc.
1	Whole blood	4%	28	Ibuprofen	2.425 mmol/L
2	Mucin	0.5%	29	Olopatadine hydrochloride	5 mg/mL
3	Chloraseptic	1.5 mg/mL	30	Hanmi Ko-and-Cool Nasal Spray (Chlorpheniramine Maleate 250 mg/ 100 mL, Xylometazoline Hydrochloride 0.1 g/100 mL)	10%(v/v)
4	NeilMed NasoGel	5% v/v			
5	CVS Nasal drops	15% v/v			
6	Afrin (Oxymetazoline)	15% v/v	31	Samchundang Narista-S Nasal Spray (Chlorpheniramine Maleate 2.5 mg/mL, Dipotassium Glycyrrhizinate 3 mg/mL, Naphazoline Hydrochloride 0.5 mg/mL)	10%(v/v)
7	Sodium cromoglycate (CVS nasal spray, Cromolyn)	15% v/v			
8	Zicam	15% v/v			
9	Homeopathic (Alkalol)	1:10 dilution	32	Sodium chloride	20 mg/mL
10	Sore throat Phenol Spray	15% v/v	33	Zanamivir	5 mg/mL
11	Tobramycin	5 µg/mL	34	Oseltamivir	10 mg/mL
12	Mupirocin	10 mg/mL	35	Artemether-lumefantrine	50 µmol/L
13	Fluticas one Propionate	5% v/v	36	Doxycycline hyclate	70 µmol/L
14	Tamiflu (Oseltamivir Phosphate)	5 mg/mL	37	Quinine	150 µmol/L
15	Albumin, human	3000 mg/dL	38	Lamivudine	1 mg/mL
16	Bilirubin	500 µmol/L	39	Erythromycin	81.6 µmol/L
17	Hemoglobin	500 mg/dL	40	Ciprofloxacin	30.2 µmol/L
18	Cholesterol	20 µmol/L	41	Rheumatoid factor positive plasma	10%(v/v)
19	Triglycerid	1000 mg/dL	42	Neutrogena lotion (glycerin)	1% v/v
20	Biotin	0.75 mg/mL	43	Hand sanitizer (ethyl alcohol)	1% v/v
21	Sodium citrate	25 mg/mL	44	Hand soap (benzalkonium chloride)	1% v/v
22	Heparin	100 U/mL	45	Laundry detergent (C12-15 pareth-7 and sodium laureth-12 sulfate)	1% v/v
23	EDTA	5 µmol/L			
24	K3-EDTA	20 mg/mL	46	Bleach (sodium hypochlorite)	1% v/v
25	Diphenhydramine hydrochloride	5 mg/mL	47	Surface sanitizer (citric acid)	1% v/v
26	Acetaminophen	199 µmol/L	48	Dish-washing liquid (sodium lauryl sulfate)	1% v/v
27	Acetylsalicylic acid	3.62 mmol/L			

[HIGH-DOSE HOOK EFFECT]

Pooled nasopharyngeal specimens were used as clinical matrix, and SARS-CoV-2 virus inactivated by beta-Propiolactone (BPL) was spiked to make various high concentration levels of SARS-CoV-2 antigens.

Prepared samples of each concentration levels were tested using Humasis COVID-19 Ag Home Test in 3 replicates following instructions. No high-dose hook effect was observed up to 6.3×10^5 $TCID_{50}$/mL, approx. 20,000xLoD.

[CLINICAL EVALUATION]

The clinical evaluation of the Humasis COVID-19 Ag Home Test was evaluated by testing a total of 492 prospectively collected direct mid-turbinate nasal swab samples, consisted of 45 positive and 447 negative samples from suspected COVID-19 patients in United States that were within seven days of symptom onset or asymptomatic, aged 14 years and older. The Humasis COVID-19 Ag Home Test was compared to an FDA authorized molecular SARS-CoV-2 test. In this study, the Humasis COVID-19 Ag Home Test correctly identified 86.7% of positive samples and 99.8% of negative samples. The study was based on testing only once. **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.**

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.

Table 1. Demographic and Clinical Characteristics

Characteristic		Total number	Total Positive by RT-PCR	% Positive
Age Range	14-24	88	12	12/88 (13.6%)
	25-64	381	31	31/381 (8.1%)
	≥65	23	2	2/23 (8.7%)
Sex	Female	266	18	18/266 (6.8%)
	Male	226	27	27/226 (11.9%)
Total		492	45	45/492 (9.1%)

Table 2. Observations of All subjects

Characteristic		Reference PCR Results		
		Positive	Negative	% Positive
Humasis COVID-19 Ag Home Test	Positive	39	1	40
	Negative	6	446	452
	Total	45	447	492

PPA:86.7 % (95% CI: 73.8%-93.7%)
NPA: 99.8 % (95% CI: 98.7%-100.0%)

Table 3. Observations of Symptomatic subjects

Symptomatic Data		Reference PCR Results		
		Positive	Negative	% Positive
Humasis COVID-19 Ag Home Test	Positive	31	1	32
	Negative	5	174	179
	Total	36	175	211

PPA: 86.1% (95% CI: 71.3% - 93.9%)
NPA: 99.4% (95% CI: 96.8% - 99.9%)

Table 4. Observations of Asymptomatic subjects

Asymptomatic Data		Reference PCR Results		
		Positive	Negative	% Positive
Humasis COVID-19 Ag Home Test	Positive	8	0	8
	Negative	1	272	273
	Total	9	272	281

PPA: 88.9 % (95% CI: 56.8%-98.0%)
NPA: 100.0% (95% CI: 98.6%-100.0%)

Table 5. PPA and NPA by days since onset of symptoms

Days since symptom onset	PPA (95% CI)	NPA (95% CI)
Asymptomatic	88.9% (8/9) (95% CI: 56.5% - 98.0%)	100% (272/272) (95% CI: 98.6% - 100.0%)
1	75.0% (3/4) (95% CI: 30.1% - 95.4%)	95.8% (23/24) (95% CI: 79.8% - 99.3%)
2	100.0% (8/8) (95% CI: 67.6% - 100.0%)	100.0% (40/40) (95% CI: 91.2% - 100.0%)
3	100.0% (9/9) (95% CI: 70.1% - 100.0%)	100.0% (38/38) (95% CI: 90.8% - 100.0%)
4	85.7% (6/7) (95% CI: 48.7% - 97.4%)	100.0% (30/30) (95% CI: 88.6% - 100.0%)
5	66.7% (2/3) (95% CI: 20.8% - 93.9%)	100.0% (24/24) (95% CI: 86.2% - 100.0%)
6	100.0% (2/2) (95% CI: 34.2% - 100.0%)	100.0% (12/12) (95% CI: 75.8%-100.0%)
7	33.3% (1/3) (95% CI: 6.1%-79.2%)	100.0% (7/7) (95% CI: 64.6%-100.0%)

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 Table 6.

Table 6: 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 Test	3 Test	1 Test	2 Test	3 Test
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

[PRECAUTIONS AND LIMITATIONS]

- For *in vitro* diagnostic use only
- Not to be taken internally. Avoid sample buffer contact with skin and eyes. If the buffer contacts with the skin, eyes, and mucous membranes, wash immediately under running water and seek medical attention.
- Do not use this test for individuals under 14 years of age. The swab included in the kit is designed for collection of samples from adults and additional safety measures are needed for safe collection in children under 14 years of age.
- Poor vision or poor lighting may affect your ability to interpret the test correctly.
- This test has been intended only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Do not use the test device beyond the expiration date.
- Keep sealed until usage, and once opened use immediately.
- Do not re-use the device.
- Handle all specimens safely as potentially infectious.
- This test is intended for initial screening of coronavirus infection by detecting COVID-19 antigen, but should not be used as a sole criterion for the determination of SARS-CoV-2 infection. Other methods and clinical information (signs and symptoms) should be used and considered for diagnosis.
- A negative test result may occur if the level of antigens in a sample is below the detection limit of the test or if the sample was collected improperly.
- Failure to follow the Test Procedure may adversely affect test performance 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 rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.
- Negative results should be treated as presumptive and confirmed with a 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 SARS-CoV-2 and their prevalence, which change over time.
- The user should not take any decision of medical relevance without first consulting his or her medical practitioner.
- The product is not intended to monitor disease status.
- Testing should be completed within 30-60 minutes of opening the test pouch.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.
- The Humasis COVID-19 Ag Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

The preservative sodium azide corresponds to H300, H310, H400, and H410 depending on GHS, but the manufacturer's sample extract contains a trace amount of less than 0.1% concentration. And therefore, does not exceed the HGS concentration of 1% concentration.

composition	concentration
Buffer	≥ 90%
Stabilizer	1.20%
Surfactants	1.20%
Preservative	< 0.1%

The extraction buffer solution in the extraction buffer tube contains a hazardous ingredient as shown in the above table. If the extraction buffer solution contacts the skin or eye, immediately wash with plenty of running water and seek medical attention

Serial Testing (Repeat Testing) Information and 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 of 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.

[ASSISTANCE]

If you have any questions regarding the use of this product or if you want to report a test system problem, please contact Humasis Co., Ltd. (via email: question@humasis.com)

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: Manufacturer | : Do not reuse | : Consult instructions for use
REF : Catalogue number | LOT : Lot number | IVD : *In vitro* diagnostic medical device
: Temperature limit | : Use by | : Contains sufficient for <n> tests
: Keep away from sunlight | : Keep dry | : Do not use if package is damaged

Manufacturer
Humasis Co., Ltd.
Rm. 114, 502, 504, 604, 604-1, B03-01, B03-02, 88, Jeonpa-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14042, Republic of Korea
TEL: +82-31-8085-6200, FAX: +82-31-8085-6249
Email: question@humasis.com
www.humasis.com

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