STEP-BY-STEP Instruction

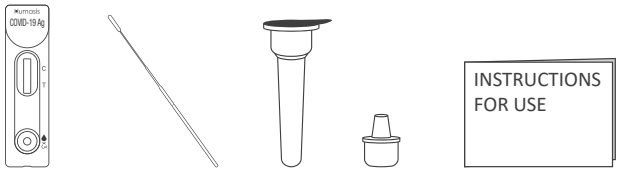
Humasis

COVID-19 Ag
Home Test

Wash Your Hands

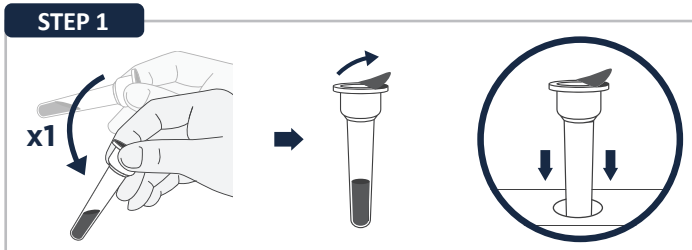
Before you start testing, wash your hands or use hand sanitizer.
Make sure your hands are dry before starting.

Check Your Test Kit



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.

STEP 1

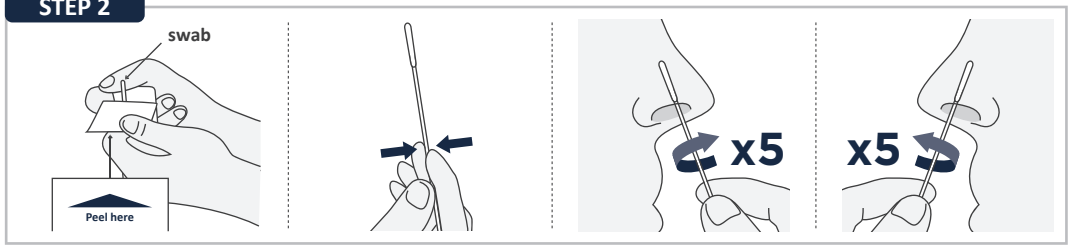


Collect the buffer fluid at the bottom of the test tube by shaking it and then peel off the seal.

keep the pre-filled tube in the tube holder.

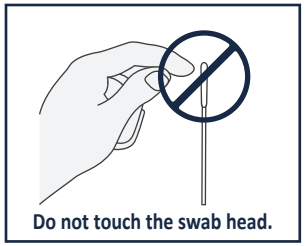
STEP 2

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

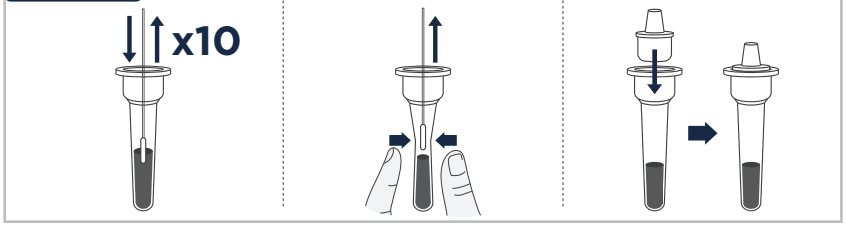


Look for the "PEEL HERE" sign to peel open the swab package halfway. And hold the swab towards the end of 1/3 point.

Insert the swab 1-2cm into one of the anterior nares. Rotate the swabagainst the nasal wall more than 5 times and withdraw. Repeat the other anterior nare using the same swab.



STEP 3



Put the tip of the swab into the test tube and move the swab up and down more than10 times.

Remove the swab while pressing against the sides the tube to squeeze the liquid from the swab.

Close the cap tightly.

STEP 4

Dispense three drops into the well next to "● x 3"

STEP 5

Start to read at 15~20 minutes.
(Do not read after 15->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.

Check Your Results

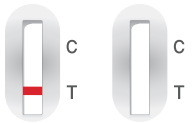
NEGATIVE

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

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.

INVALID



If there is **NO LINE** next to the "C" like above examples, your test is not working. Please contact the place of purchase.

Humasis Co., Ltd.
Rm. 114, 502, 504, 604, 604-1, B03-1, B03-2,
88, Jeonpa-ro, Dongan-gu, Anyang-si,
Gyeonggi-do, 14042, Republic of Korea
TEL:+82-31-478-8597, FAX:+82-31-478-8586
Email:question@humasis.com
www.humasis.com

EC REP **MT Promedt Consulting GmbH**
Altenhofstr. 80
D-66386 St. Ingbert / Germany
TEL: +49 6894 - 58 10 20
FAX: +49 6894 - 58 10 21
Email: info@mt-procons.com
www.mt-procons.com

[INTENDED USE]

Humasis COVID-19 Ag Home Test is one step in vitro diagnostic test based on an immunochromatographic assay and designed for self-use (≥14 years of age) or a lay user testing another person (≥3 years of age) in non-laboratory site including a home environment to detect of SARS-CoV-2 antigens in nasal swab specimen of suspected patients.

[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.
Due to the wide variety of symptoms, it is difficult to differentiate COVID-19 from other existing respiratory viruses or bacteria. Diagnosing COVID-19 through isolating the virus or detecting specific genes from the collected respiratory droplet specimens is a challenge in terms of time and accessibility as it requires long hours, well-equipped laboratory and advanced technology which are often not available to many public. The test is designed to detect antigen to SARS-CoV-2, and it will help assess if an individual has COVID-19 antigen within 15 minutes in cost-effective and timely manner.

[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 nasall 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]

- Test devices packaged individually in aluminum pouch
- Disposable test tube with extraction buffer
- Filter cap
- Sterilized swabs for specimen collection
- Instruction for use

[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 released from the aluminum pouch.

[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.
- 3-14 years of age, the test should be carried out by legal guardian

1. Specimen collection

1) Use the swab included in the package to collect nasal specimen.
2) Insert the swab into left nostril up to 3/4 of an inch (about 2cm) and firmly brush against the nasal wall in circular motion 5 times or at least 15 seconds. Proceed to do the same for right nostril with same swab.
*It is highly recommended to test the specimen immediately after collection for best results.

2. Test method

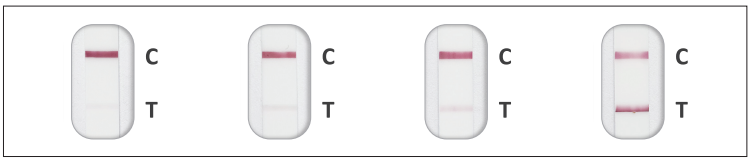
1) Prepare aluminum pouch containing the test device and place it on the testing surface along with test tube and filter cap.
2) Release the test device from aluminum pouch and place it on a level surface just prior to starting test.
3) Shake the test tube downwards so the buffer fluid can gather on the bottom of the tube before peeling off the sealed cap. 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.
4) Remove the swab while squeezing the test tube.
5) Equip the filter cap on the test tube and dispense 3 drops of sample extracts (90~100uL) into the sample well of the device.
6) Read result at 15 minutes after applying sample. Do not read result after 20 minutes.

[INTERPRETATION OF RESULTS]

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 local public health department.
- follow local guidelines for self-isolation.
- have a PCR confirmatory test performed.



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.
- Even if the test is negative, an infection may still be present.
- In case of suspicion, repeat the test after 1 - 2 days, as the coronavirus cannot be detected accurately in all phases of an infection.

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.
- If the test result is still invalid, contact your doctor or a COVID 19 test centre

[PERFORMANCE CHARACTERISTICS]

- Limit of detection (LoD)

The limit of detection (LoD) of Humasis COVID-19 Ag Test is $5x10^{0.8}TCID_{50}$/mL.

- Precision

4 individual studies were performed: repeatability (within-laboratory precision), between-operator precision, between-lot precision and between-place precision of the Humasis COVID-19 Ag Test. The test results confirmed that the Humasis COVID-19 Ag Test shows consistent performance within laboratory, between operators, between lots and between places, and all the results showed 100% agreement with the expected results.

- Reactivity / Inclusivity

Reactivity to the following recombinant antigens in which each important amino acid of Spike RBD was mutated were confirmed: SARS-CoV-2 Spike RBD(S477N), SARS-CoV-2 Spike RBD(N501Y), SARS-CoV-2 Spike RBD(L452R), SARS-CoV-2 Spike RBD(E484K) and SARS-CoV-2 Spike RBD (K417N, E484K, N501Y) showed reactivity to 100pg/mL.

- Cross-reactivity

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

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

- Interference

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

No.	Interfering substances	Concentration	No.	Interfering substances	Concentration
1	Whole blood	4%	24	K3-EDTA	20 mg/mL
2	Mucin	0.5%	25	Diphenhydramine hydrochloride	5 mg/mL
3	Chloraseptic	1.5 mg/mL	26	Acetaminophen	199 µmol/L
4	NeilMed NasoGel	5% v/v	27	Acetylsalicylic acid	3.62 mmol/L
5	CVS Nasal drops	15% v/v	28	Ibuprofen	2.425 mmol/L
6	Afrin (Oxymetazoline)	15% v/v	29	Olopatadine hydrochloride	5 mg/mL
7	Sodium cromoglycate (CVS nasal spray, Cromolyn)	15% v/v	30	Hanmi Ko-and-Cool Nasal Spray (Chlorpheniramine Maleate 250 mg/ 100 mL, Xylometazoline Hydrochloride 0.1 g/100 mL)	10%(v/v)
8	Zicam	15% v/v			
9	Homeopathic (Alkalol)	1:10 dilution	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)
10	Sore throat Phenol Spray	15% v/v			
11	Tobramycin	5 µg/mL			
12	Mupirocin	10 mg/mL			
13	Fluticasone Propionate	5% v/v	32	Sodium chloride	20 mg/mL
14	Tamiflu (Oseltamivir Phosphate)	5 mg/mL	33	Zanamivir	5 mg/mL
15	Albumin, human	3000 mg/dL	34	Oseltamivir	10 mg/mL
16	Bilirubin	500 µmol/L	35	Artemether-lumefantrine	50 µmol/L
17	Hemoglobin	500 mg/dL	36	Doxycycline hyclate	70 µmol/L
18	Cholesterol	20 µmol/L	37	Quinine	150 µmol/L
19	Triglycerid	1000 mg/dL	38	Lamivudine	1 mg/mL
20	Biotin	0.75 mg/mL	39	Erythromycin	81.6 µmol/L
21	Sodium citrate	25 mg/mL	40	Ciprofloxacin	30.2 µmol/L
22	Heparin	100 U/mL	41	Rheumatoid factor positive plasma	10%(v/v)
23	EDTA	5 µmol/L	-		

[CLINICAL EVALUATION]

A combined study of usability and clinical evaluation was conducted by testing a total of 664 samples prospectively collected from individual patients suspected of COVID-19 infection at multiple sites : 1. Self-collection usability arm; 2. Sample-collection usability arm; and 3. Clinical evaluation arm. All participants were tested for COVID-19 using FDA EUA RT-PCR for result comparison.

Test result		RT-PCR		Total
		Positive	Negative	
Humasis COVID-19 Ag Test	Positive	102	2	104
	Negative	9	551	560
Total		111	553	664

Parameter	Proportion (%)	95% Confidence Interval
Sensitivity	91.9% (102/111)	85.3 – 95.7%
Specificity	99.6% (551/553)	98.7 – 99.9%
Positive predictive value	98.1% (102/104)	93.3 – 99.5%
Negative predictive value	98.4% (551/560)	97.0– 99.2%

[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 touches the skin, eyes, and mucous membranes, wash immediately under running water and seek medical attention.
- Keep out of the reach of children. Any child under age 18 shouldn't perform the test without parental guidance, or professional aid.
- Poor vision or poor lighting may affect your ability to interpret the test correctly .
- This test has been authorized 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 use the test device if the pouch is damaged or the device is seriously broken.
- 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 or transported 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 clinical performance has not been established in all circulating variants, and that performance may vary depending on the variants, and their prevalence, circulating at the time of patient testing.

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 GHS concentration of 1% concentration.

composition	concentration
Buffer	≥ 90%
stabilizer	1.20%
Surfactants	1.20%
preservative	< 0.1%

[REFERENCES]

[1] Zhu N, Zhang D, Wang W, et al. A Novel Coronavirus from Patients with Pneumonia in China, 2019. N Engl J Med 2020.
[2] Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet 2020.
[3] Kang CK, Song KH, Choe PG, et al. Clinical and Epidemiologic Characteristics of Spreaders of Middle East Respiratory Syndrome Coronavirus during the 2015 Outbreak in Korea. J Korean Med Sci 2017; 32:744-9.
[4] WHO, Novel Coronavirus (2019-nCoV) situation reports. Available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situationreports/ (Accessed at 2 Feb, 2020).