[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.
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 authorized for non-prescription self-use or an adult lay user testing another person (≥3 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]

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

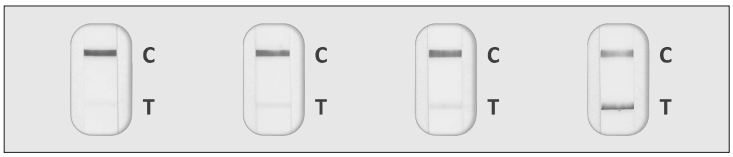
1) Prepare aluminum pouch containing the test device and place it on the testing surface along with test tube and filter cap.
2) Release the test device from aluminum pouch and place it on a level surface just prior to starting test.
   *Do not use the test device if the pouch is damaged or the device 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. 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.*
- *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 and 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. If you receive a negative result, you should test again in 24-48 hours. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider immediately. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 infection status after testing or think you may need follow up testing, please contact your healthcare provider.*
- *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 with a new test device.*

[PERFORMANCE CHARACTERISTICS]

- Limit of detection (LoD)
  The limit of detection (LoD) of Humasis COVID-19 Ag Home 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 Home Test. The test results confirmed that the Humasis COVID-19 Ag Home 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
  The Humasis COVID-19 Ag Home Test can detect Alpha, Beta, Gamma, Delta, and Omicron variants up to 25 $TCID_{50}$/mL. Reactivity to the following recombinant antigens in which each important amino acid of NP and RBD mutation observed in various SARS-CoV-2 variants including Alpha, Beta, Gamma, Delta, and Omicron was confirmed up to 100 ng/mL:
- Cross-reactivity
  Below potential cross-reactive substances did not affect performance of the Humasis COVID-19 Ag Home Test.

Virus							
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 & Fungi							
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 Home Test.

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

[CLINICAL EVALUATI ON]

The combined study of usability and clinical evaluation was conducted by testing a total of 874 samples prospectively collected from individual patients suspected of COVID-19 infection at multiple sites. All participants were tested for COVID-19 using FDA EUA RT-PCR for result comparison.
Humasis COVID-19 Ag Home Test correctly identified 92.3% (132 out of 143) of COVID-19 positive sample with a 95% confidence interval of 86.8-95.7% (sensitivity) and 99.6% (728 out of 731) of COVID-19 negative samples with a 95% confidence interval of 98.8-99.9% (specificity). The ratio of true positive (based on RT-PCR) to all those who had positive results from the Humasis COVID-19 Ag Home Test was 97.8% (132 out of 135) with a 95% confidence interval of 93.7-99.2% (positive predictive value). The ratio of true negative (Based on RT-PCR) to all those who had negative results from the Humasis COVID-19 Ag Home Test was 98.5% (728 out of 739) with a 95% confidence interval of 97.4-99.2% (negative predictive value)

[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.
- Keep out of the reach of children. Any child under age 14 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 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 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.

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%

[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: info@humasis.com)

[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.
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[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).