For professional use

Humasis

COVID-19 Ag Test

One Step COVID-19 Ag Test

Please read the instructions carefully before use!

[INTENDED USE]

Humasis COVID-19 Ag Test is one step in vitro diagnostic test based on an immunochromatographic assay. It is designed for qualitative detection of SARS-CoV-2 antigens in nasopharyngeal 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 Test uses monoclonal antibodies specific to COVID-19 antigens to detect COVID-19 specific antigens in human nasopharyngeal 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 (25test/box)
- Disposable test tube with extraction buffer (25ea/box)
- Filter cap (25ea/box)
- Sterilized swabs for specimen collection (25ea/box)
- Instruction for use (1ea)

[MATERIAL COMPOSITION]

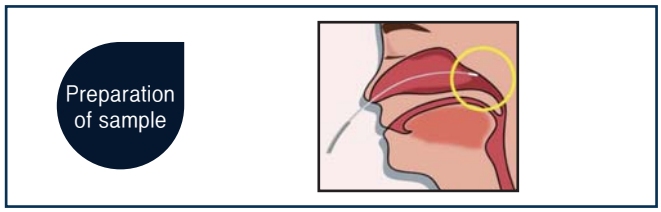
- Monoclonal antibody to SARS-CoV-2 Nucleocapsid
- Monoclonal antibody specific to RBD of SARS-CoV-2 Spike Protein
- Goat anti-mouse IgG

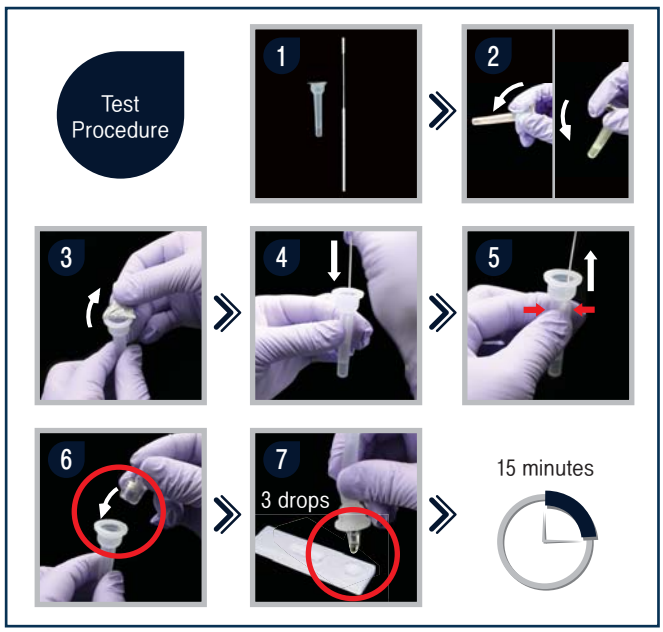
[STORAGE AND SHELF-LIFE]

- 18 months from manufacturing date at room temperature (2℃-30℃).

[TEST PROCEDURE]

1. Specimen collection:
   1) Use the swab included in the package to collect nasopharyngeal specimen.
   2) Collected specimen should be tested immediately after collection for best result
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.
   3) Peel off the cap of the test tube and insert the tip of the swab with patient specimen and swirl the tip more than 10 times to make sufficient sample extraction.
   4) After swirling, remove the swab by pressing the tip against the wall of test tube to squeeze out the extracted liquid.
   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 results at 15 minutes after applying sample. Do not read result after 15 minutes.





** Avoid swabbing and inserting excessive amount of nasopharyngeal specimen into the test tube, as it may block the filter cap when dispensing sample extracts.

[INTERPRETATION OF RESULT]

Negative

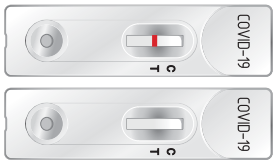
If no colored line appears in the test line (T) and a colored line is present on the control region (C), then the result is negative.

Positive

If colored line is visible in the test line (T) and control line (C), the result is positive.

Invalid

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



[PERFORMANCE CHARACTERISTICS]

- **Limit of detection (LoD)**
  The limit of detection (LoD) of Humasis COVID-19 Ag Test is 2 x $10^{3.1}$ TCID50/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.
- **Cross-reactivity**
  Below potential cross-reactive substances did not affect performance of the Humasis COVID-19 Ag Test.

Virus (≥ 10^5PFU/mL)			
1	Human adenovirus 1	9	Parainfluenza 3
2	Coronavirus OC43	10	Parainfluenza 4a
3	Coronavirus 229E	11	Rhinovirus 1
4	Coronavirus NL63	12	Metapneumovirus
5	Respiratory syncytial virus A	13	Human Enterovirus
6	Respiratory syncytial virus B	14	Influenza A H1N1
7	Parainfluenza 1	15	Influenza A H3N2
8	Parainfluenza 2	16	Influenza B
Bacteria (≥ 10^6CFU/mL)			
17	*Mycoplasma pneumonia Ag*	20	*Streptococcus pneumoniae*
18	*Streptococcus pyogenes*	21	*Legionella pneumophila*
19	*Bordetella pertussis*	22	*Haemophilus influenzae*

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

No.	Interfering substances	Con.	No.	Interfering substances	Con.
1	Albumin, human	3000 mg/dL	17	Olopatadine hydrochloride	5 mg/mL
2	Bilirubin	500 umol/L	18	Hami Pharm Ko-and-cool Nasal Spray	10%(v/v)
3	Hemoglobin	500 mg/dL	19	Samchundang Narista-S Nasal Spray	10%(v/v)
4	Cholesterol	20 mmol/L	20	Sodium chloride	20 mg/mL
5	Triglyceride	1000 mg/dL	21	Zanamivir	5 mg/mL
6	Biotin	0.75 mg/mL	22	Oseltamivir	10 mg/mL
7	Sodium citrate	25 mg/mL	23	Artemether-lumefantrine	50 umol/L
8	Heparin	100 U/mL	24	Doxycycline hyclate	70 umol/L
9	EDTA	5 umolL	25	quinine	150 umol/L
10	K3-EDTA	20 mg/mL	26	lamivudine	1 mg/mL
11	Mucin	100 ug/mL	27	Mupirocin	10 mg/mL
12	Diphenhydramine hydrochloride	5 mg/mL	28	Tobramycin	5 ug/mL
13	Acetaminophen	199 umol/L	29	Erythromycin	81.6 umol/L
14	Acetylsalicylic acid	3.62mmol/L	30	Ciprofloxacin	30.2 umol/L
15	Ibuprofen	2.425mmol/L	31	Rheumatoid factor positive plasma	10%(v/v)
16	Sodium cromoglycate	10 mg/mL	-		

- **Clinical evaluation**
  The clinical evaluation of the Humasis COVID-19 Ag Test was evaluated by testing a total of 45 clinical swab samples from individual patients, consisted of 25 positive and 20 negative samples.
  The statistical analysis for deriving clinical sensitivity and specificity was carried out as indicated in the CLSI EP12 A2 "User Protocol for Evaluation of Qualitative Test Performance."
  Study results showed that clinical sensitivity and specificity of the Humasis COVID-19 Ag Test was as follows:

Test result		RT-PCR		Total
		Positive	Negative	
Humasis COVID-19 Ag Test	Positive	23	0	23
	Negative	2	20	22
Total		25	20	45

- Clinical sensitivity: 92.00% (23/25) (95% CI: 75%-97.8%)
- Clinical specificity: 100.00% (20/20) (95% CI: 83.9%-100%)

[PRECAUTIONS AND LIMITATIONS]

- For in vitro diagnostic use only
- 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.

[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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[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).

IVD : For *in vitro* diagnostic use
LOT : Lot number
REF : Catalogue number
: Consult instructions for use
2°C~30°C : Store at 2~30℃
: Do not reuse
EC REP : Authorized Representative
: Manufactured by
EXP : Use by / Expiry date
CE : This product fulfills the requirements for Directive 98/79/EC on *in vitro* diagnostic medical devices

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