

ENG

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]

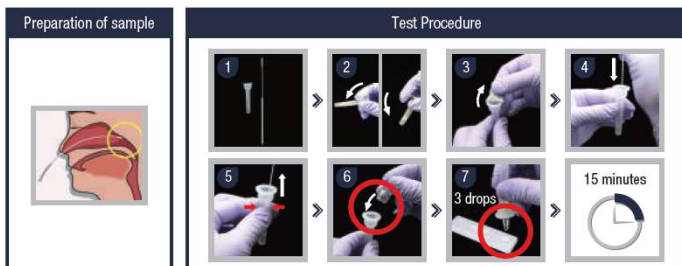
- Monoclonal antibody to SARS-CoV-2 Nucleocapsid
- Monoclonal antibody specific to RBD of SARS-CoV-2 Spike Protein
- Goat anti-mouse IgG

[STORAGE AND SHELF-LIFE]

- 18 months from manufacturing date at room temperature (2°C~30°C).

[TEST PROCEDURE]

- 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.
- 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.



Invalid

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



Positive

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



[PERFORMANCE CHARACTERISTICS]

• Limit of detection (LoD)

The limit of detection (LoD) of Humasis COVID-19 Ag Test is 5x10³ 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 ⁵ PFU/mL) | | | |
|------------------------------------|--------------------------------|----|---------------------------------|
| 1 | Human adenovirus 1 | 9 | Parainfluenza 3 |
| 2 | Coronavirus OC43 | 10 | Parainfluenza 4 |
| 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 ⁶ CFU/mL) | | | |
| 17 | <i>Mycoplasma pneumonia Ag</i> | 20 | <i>Streptococcus pneumoniae</i> |
| 18 | <i>Streptococcus pyogenes</i> | 21 | <i>Legionella pneumophila</i> |
| 19 | <i>Bordetella pertussis</i> | 22 | <i>Haemophilus influenzae</i> |

• 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 | Hani 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 umol/L | 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 303 clinical swab samples from individual patients, consisted of 112 positive and 191 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 | 107 | 0 | 107 |
| | 5 | 191 | 196 |
| Total | 112 | 191 | 303 |

- Clinical sensitivity: 95.5% (107/112) (95% CI: 90%-98.1%)

- Clinical specificity: 100.0% (191/191) (95% CI: 98%-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.
- [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/situation-reports/> (Accessed at 2 Feb, 2020).

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|--|-------------------------|-------------------------------|
| IVD : For in vitro diagnostic use | LOT : Lot number | REF : Catalogue number |
| : Consult instructions for use | : Store at 2~30°C | : Do not reuse |
| EC REP : Authorized Representative | : Manufactured by | : 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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