For professional use

Humasis

# COVID-19 IgG/IgM Test

One Step COVID-19 IgG/IgM Test

Please read the instructions carefully before use!

## [ INTENDED USE ]

Humasis COVID-19 IgG/IgM test is one step in vitro diagnostic test based on an immunochromatographic assay. It is designed for qualitative detection of Immunoglobulin G and Immunoglobulin M antibody of Novel Coronavirus (COVID-19) in human whole blood, plasma or serum.

## [ 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 typically spreads 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. Therefore the need for point-of-care rapid test kit which requires less time and cost is rising.

## [ PRINCIPLE OF THE TEST ]

"Humasis COVID-19 IgG/IgM Test" is a rapid immunochromatographic assay test which detects IgG and IgM antibody to COVID-19 in human blood. A nitrocellulose membrane strip in the device contains two test lines (G and M line) and a control line (C). G line is pre-coated with mouse anti-human IgG for detection of IgG anti-COVID-19, and M line is pre-coated with mouse anti-human IgM for detection of IgM anti-COVID-19. C(Control line) is coated with goat anti-mouse IgG.
When sample is added to sample pad, it moves through the conjugate pad, where recombinant antigen-colloidal gold particle will react with the IgG and IgM antibodies specific to COVID-19 in the sample, forming an immunocomplex. The complex moves along the membrane by capillary action and makes contact with the immobilized antibody coated in the test region. Colored line in the test region indicates a positive result for coronavirus. The absence of colored line in the test region suggests a negative result. The complex continues to move to the control region and will react with immobilized reagents that capture colored conjugate regardless of test specimen composition. The resulting visible colored line in the control region confirms that the assay is functioning correctly and its result is valid.

## [ CONTENTS ]

- Humasis COVID-19 IgG/IgM Test device
- Assay diluent (5mL)
- Instruction for use

* Optional: Capillary tube (10uL)

## [ MATERIAL COMPOSITION ]

1 test device contains :

- Mouse anti-human IgM monoclonal antibody ..... 0.44±0.11 μg
- Mouse anti-human IgG monoclonal antibody ..... 0.44±0.11 μg
- 2019-nCOV n recombinant protein ..... 0.08±0.02 μg
- Goat anti-mouse IgG ..... 0.08±0.02 μg

## [ STORAGE AND SHELF-LIFE ]

- Store the test device packaged in a sealed foil pouch at 2 to 30℃ (36~86℉).
- Shelf-life is 6 months from manufacturing date.

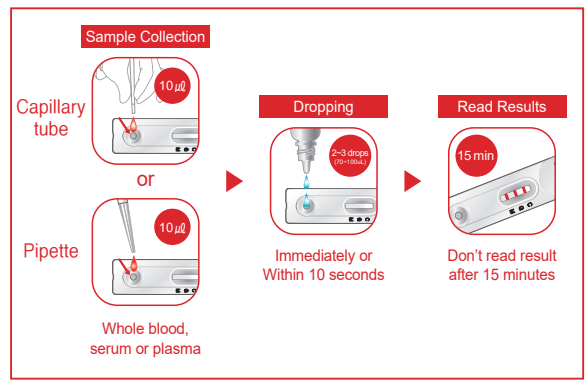
## [ SPECIMEN COLLECTION AND PREPARATION ]

The device can be performed using whole blood, plasma or serum.

- Whole blood : Collect specimen in collection tube with anticoagulant such as EDTA, heparin or sodium citrate. Perform test immediately after collection, or can be stored at 2~8℃ up to 24 hours before the test.
- Plasma : Collect specimen in collection tube with anticoagulant such as EDTA, heparin or sodium citrate and centrifuge the sample. The sample can be stored at 2~8℃ up to 3 days, and freeze the sample for longer storage.
- Serum : Collect specimen in collection tube without anticoagulant and place it in room temperature for 30 minutes before the centrifuge. Serum sample can be stored at 2~8℃ up to 3 days, and freeze the sample for longer storage.

## [ TEST PROCEDURE ]

1. If the collected specimens were stored in refrigerated condition, leave the samples in room temperature for 15 to 30 minutes before the test.
   Avoid unsealing the device if the device temperature is lower than the room temperature.
2. Open the sealed pouch and place the device on a clean, dry and level surface.
3. Release 10uL of whole blood, plasma or serum into the sample well.
   Then add 2 drops (70~100uL) of sample diluent immediately.
4. Read the result at 15 minutes. Do not read result after 15 minutes.




## [ INTERPRETATION OF RESULT ]

### Negative

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


### Positive

In addition to the presence of colored line in control region(C)


IgG and IgM positive : if there is colored line in both test region (G, M), then the result is positive.


IgG positive : if there is colored line in G but no development in M, then the result is IgG positive.


IgM positive : if there is no colored line in G but visible colored line in M, then the result is IgM positive.

### Invalid

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


## [ PERFORMANCE CHARACTERISTICS ]

- **Analytical sensitivity**

  Humasis COVID-19 IgG/IgM Test limit of detection (LoD), defined as the concentration of SARS-CoV-2 that produces positive results approximately 95% of the time, was identified by evaluating different dilution levels (1:1, 1:25, 1:50, 1:75, 1:100) of the virus in triplicates using 5 positive plasma samples. According to the result, analytical sensitivity of Humasis COVID-19 IgG/IgM Test was confirmed to be 1:50 dilution ratio from strong positive sample.

- **Precision**

  Reproducibility study of Humasis COVID-19 IgG/IgM Test was conducted by multiple operators at multiple sites, using blind coded specimens that are negative, low positive (1:50 dilution), medium positive (1:25 dilution) and high positive (1:1 dilution) SARS-CoV-2 viral samples. The test was conducted over 5 to 20 different days.
  There was no differences in the test results observed within run, between run, between sites or between operators; all negative samples showed negative results and all positive samples showed positive results.

- **Interference**

  The following substances which are naturally present in human or artificially introduced when collecting human blood specimen were evaluated with Humasis COVID-19 IgG/IgM Test at the concentrations listed below.
  According to test results, none of the substances showed interference with the performance of Humasis COVID-19 IgG/IgM Test.

| No. | Analytes | Con. | No. | Analytes | Con. |
|---|---|---|---|---|---|
| 1 | Acyclovir | 66.6 umol/L | 8 | Cyanocobalamin | 740 pmol/L |
| 2 | Albumin | 5 g/dL | 9 | Ethanol | 86.8 umol/L |
| 3 | Amoxicillin | 206 umol/L | 10 | Glucose | 6.7 mmol/L |
| 4 | Ampicillin | 152 umol/L | 11 | Hemoglobin | 20 g/dL |
| 5 | Ascorbic acid | 227 umol/L | 12 | Heparin | 5 IU/mL |
| 6 | Bilirubin | 86 umol/L | 13 | Sodium citrate | 2.5 mg/mL |
| 7 | Chloramphenicol | 155 umol/L | 14 | EDTA | 2 mg/mL |

- **Cross-reactivity**

  Cross-reactivity of the Humasis COVID-19 IgG/IgM Test was evaluated using samples containing antibodies to pathogens shown in below table.
  All of the samples containing cross-reactive substances below showed no cross-reactivity and showed negative results when tested with Humasis COVID-19 IgG/IgM Test.

| IgG Cross-reactants | IgM Cross-reactants |
|---|---|
| Anti-influenza A IgG | Anti-influenza A IgM |
| Anti-influenza B IgG | Anti-influenza B IgM |
| Anti-HCV IgG | Anti-HCV IgM |
| Anti-HBV IgG | Anti-HBV IgM |
| Anti-Haemophilus influenza IgG | Anti-Haemophilus influenza IgM |
| Anti-229E (alpha coronavirus) IgG | Anti-229E (alpha coronavirus) IgM |
| Anti-NL53 (alpha coronavirus) IgG | Anti-NL53 (alpha coronavirus) IgM |
| Anti-OC43 (beta coronavirus) IgG | Anti-OC43 (beta coronavirus) IgM |
| Anti-HKU1 (beta coronavirus) IgG | Anti-HKU1 (beta coronavirus) IgM |
| ANA IgG | ANA IgM |
| Anti-RSV IgG | Anti-RSV IgM |
| Anti-HIV IgG | Anti-HIV IgM |
| Anti-CMV IgG | Anti-CMV IgM |
| Anti-Mycoplasma IgG | Anti-Mycoplasma IgM |
| Anti-Dengue IgG | Anti-Dengue IgM |

- **Clinical evaluation**

  The clinical performance of the Humasis COVID-19 IgG/IgM Test was evaluated by testing a total of 125 clinical samples from individual patients: 50 positive and 75negative samples.

  The statistical analysis was carried out as indicated in the CLSI EP12 A2 "User Protocol for Evaluation of Qualitative Test Performance." Positive and negative performance agreement between the Humasis COVID-19 IgG/IgM Test and the RT-PCR assay were calculated as below with 95% confidence interval:

  a. Positive percent agreement (PPA)
  = True positives / (True positives + False negatives) x 100(%)
  b. Negative percent agreement (NPA)
  = True negatives / (True negatives + False positives) x 100(%)

  The result of clinical evaluation of the Humasis COVID-19 IgG/IgM Test was as follows:

| IgM Result | | RT-PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Humasis COVID-19 IgG/IgM Test | Positive | 48 | 1 | 49 |
| | Negative | 2 | 74 | 76 |
| Total | | 50 | 75 | 125 |

Positive percent agreement (PPA) for IgM = 96.00% (48/50), (95% CI: 86.5% – 98.9%)
Negative percent agreement (NPA) for IgM = 98.7% (74/75), (95% CI: 92.8% – 99.8%)

| IgG Result | | RT-PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| Humasis COVID-19 IgG/IgM Test | Positive | 46 | 0 | 46 |
| | Negative | 4 | 75 | 79 |
| Total | | 50 | 75 | 125 |

Positive percent agreement (PPA) for IgG = 92.00% (46/50), (95% CI: 81.2% – 96.8%)
Negative percent agreement (NPA) for IgG = 100.00% (75/75), (95% CI: 95.1% – 100%)

## [ PRECAUTIONS ]

- 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.

## [ LIMITATIONS ]

- This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- This test is not for screening of donated blood.
- **Negative results do NOT rule out COVID-19, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic SHOULD be considered to rule out infection in these individuals.**
- **Results from antibody testing should NOT be used as the sole basis to diagnose or exclude COVID-19 or to inform infection status.**

## [ REFERENCES ]


- Korean Centers for Disease Control http://ncov.mohw.go.kr/
- FIND https://www.finddx.org/covid-19/
- CDC https://www.cdc.gov/
- Development and Clinical Application of a Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 Infection Diagnosis. Z Li,. Journal of Medical Virology


IVD : For *in vitro* diagnostic use
LOT : Lot number
REF : Catalogue number
: Consult instructions for use
: 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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