ACE
COVID-19 IgG / IgM Dual Detection Kit

Cat. No.: COV1001

Instruction for Use

For Prescription Use Only

For In Vitro Diagnostic Use Only

For Emergency Use Authorization (EUA) Only

Content

INTENDED USE

The ACE COVID-19 IgG / IgM Dual Detection Kit is a lateral flow immunoassay intended for qualitative detection and differentiation of IgG and IgM antibodies to SARS-CoV-2 human serum, plasma (heparin, dipotassium EDTA, and sodium citrate), and venous whole blood (heparin, dipotassium EDTA, and sodium citrate) from individuals with current or prior SARS-CoV-2 infection. The ACE COVID-19 IgG / IgM Dual Detection Kit is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The ACE COVID-19 IgG / IgM Dual Detection Kit should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to certified laboratories.

Results are for the detection of SARS CoV-2 antibodies. IgG and/or IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

The sensitivity of ACE COVID-19 IgG / IgM Dual Detection Kit early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for ACE COVID-19 IgG / IgM Dual Detection Kit may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay.

The ACE COVID-19 IgG / IgM Dual Detection Kit is only for use under the Food and Drug Administration's Emergency Use Authorization.

Special Conditions for Use Statements

For prescription use only
For *in vitro* diagnostic use only
For Emergency Use Authorization only

TEST PRINCIPLE

The ACE COVID-19 IgG / IgM Dual Detection Kit is a lateral flow chromatographic immunoassay which can detect antibodies against the SARS-CoV-2 virus. The test card consists of:

1) Binding pad: colloidal gold-labeled recombinant SARS-CoV-2 (2019-nCoV) antigens and quality control antibody;

2) NC membrane: coated with two detection lines (G and M lines) and a quality control line (C line). M-line coated with mouse anti-human IgM monoclonal antibody for detection of SARS-CoV-2 IgM antibodies; G-line coated with mouse anti-human IgG monoclonal antibody for detection of SARS-CoV-2 IgG antibodies; C-line coating with quality control antibody.

When an appropriate amount of test specimen is added to the sample hole of the test card, the specimen will move forward along the test card. If the specimen contains an IgM antibody, the antibody will bind to the colloidal gold-labeled SARS-CoV-2 antigen, and the immune complex will be on the M line. It forms a sandwich complex with the coated anti-human IgM monoclonal antibody, showing a purple-red M line, suggesting that the SARS-CoV-2 IgM antibody is positive.

If the specimen contains an IgG antibody, the antibody will bind to the colloidal gold-labeled SARS-CoV-2 antigen, and the immune complex will form a sandwich complex with the coated mouse anti-human IgG monoclonal antibody at the G line, showing a purple-red G line , suggesting that the SARS-CoV-2 IgG antibody is positive.

If the test lines G and M are not colored, a negative result is displayed.

The test card also contains a quality control line C. The C-line should appear purple-red regardless of whether a test line appears. If the C-line does not appear, the test result is invalid, and the specimen needs to be tested again.

KIT COMPONENTS

Reagents and Consumables Included in the Kit

- Disposable Detection Card – 50 packages
- Sample Diluent Buffer (3 ml/vial) – 3 vials
- Instruction for Use – 1 copy

OPTIONAL MATREIALS

- External Positive controls and negative controls
  - Positive control (PC) :

Cat. No.	Product Name	Size
A150124	Human Anti-S (SARS-COV-2) IgG antibody (standard for immunoassay)	100 µg/100µl
A150125	Human Anti-S (SARS-COV-2) IgM antibody (standard for immunoassay)	10 µg/1000 µl

  - Negative control (NC) solution includes one vial of SARS-CoV-2 negative pooled serum. The vial contains a volume of 100 µL and is enough for a single use.

MATREIALS REQUIRED BUT NOT PROVIDED

- External Positive controls and negative controls
- Serum blood collection tubes
- Plasma blood collection tubes
- Vortex mixer
- Sample storage tubes
- Desktop Centrifuge (for blood collection tubes and small storage tubes)
- Adjustable pipettes (10-100 µL)
- Sterile pipette tips with filters
- Powder free latex gloves
- Timer

STORAGE CONDITION AND VALIDITY

The ACE COVID-19 IgG / IgM Dual Detection Kit shall be stored at 2°C -30°C in a dry place away from light and shall not be frozen.

The test card will be invalided due to moisture absorption after opening the inner package, please use in it within one hour.

Do not use after expiration date printed on the label.

WARNING AND PRECAUTIONS

- For In vitro diagnostics use only.
- For use under an Emergency Use Authorization only.
- For prescription use.
- For professional in vitro diagnostic use only.
- Use of this product is limited to certified laboratories.
- This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
- This product should only be used by trained professional.
- Hemolytic samples cannot be used for testing.
- Do not use turbid contaminated samples for testing.
- Do not dilute the specimen for testing, or you may get inaccurate results.
- After the specimen and the Sample Diluent Buffer have been added to the sample well, wait 15 minutes for the completion of the reaction. Results must be read visually within 5 minutes after the completion of the reaction.
- Do not open the sealed pouch until you are ready to conduct the assay. Once opened, the test card should be used within 1 hour.
- Do not use expired devices.
- Bring all reagents to room temperature (15-30°C) before use.
- Do not use the components of any other type of test kit as a substitute for the components in this kit.
- Samples for human serum, plasma or whole blood should be considered as potentially infectious. Wear protective clothing and disposable gloves while handling the kit reagents and clinical samples. Wash hands thoroughly after performing the test.
- Use a new clean disposable sample dispensing plastic dropper or tip for every sample to avoid cross contamination.
- Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and materials used to perform the test as biohazardous waste.
- Prepare the negative and positive controls as instructed and treat them in the same manner as patient specimens for operator protection.
- Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.
- The test card cannot be reused.

SAMPLE REQUIREMENT

Preparation of serum:

1. **Blood collection**: the blood is collected into the non-anticoagulant vacuum blood collection vessels by professionals through venous blood collection.
2. **Coagulation**: the vessels stand still at room temperature for 30 minutes.
3. **Centrifugation**: then the vessels are centrifuged at 3000 r/min for 10 min.
4. **Separation**: the supernatant (serum) can be absorbed by pipette and sub-packed in tubes.
5. **Storage**: if the test cannot be performed immediately, the serum sample can be stored at 4°C for 3 days and returned to room temperature before the test.

Preparation of plasma:

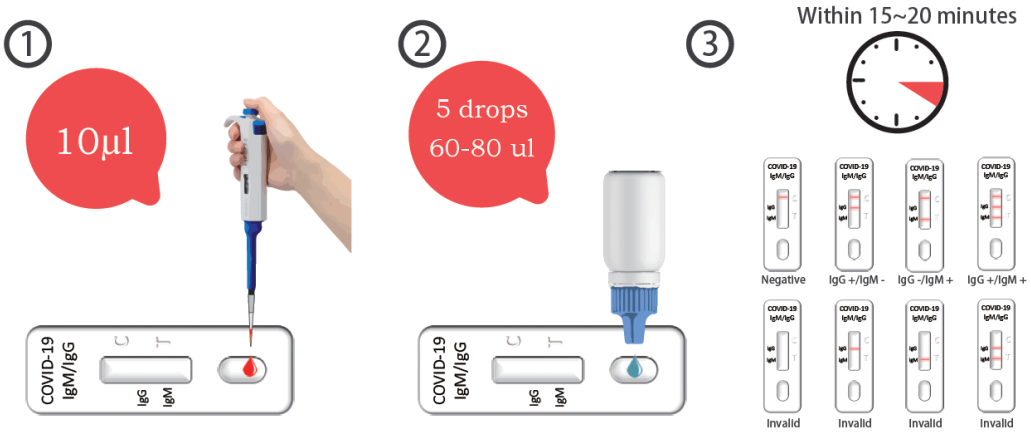
1. **Blood collection**: the blood is collected into the anticoagulant vacuum blood collection vessels by professionals through venous blood collection.
2. **Blend**: the vessels should be turned upside-down 5~8 times after blood collection.
3. **Centrifugation**: then the vessels are centrifuged at 3000 r/min for 10 min.
4. **Separation**: the supernatant (plasma) can be absorbed by pipette and sub-packed in tubes.
5. **Storage**: if the test cannot be performed immediately, the plasma sample can be stored at 4°C for 3 days and returned to room temperature before the test.

Venipuncture for blood collection

1. Venous blood collection is dangerous and needs to be operated by professionals.
2. The whole blood should be test immediately after collection.
3. If need to separate serum or plasma from the whole blood, please refer to the "**Preparation of serum**" or "**Preparation of plasma**".
4. If the test cannot be carried out immediately, the whole blood can be stored at 2°C ~8°C for 3 days. Stored blood samples should be returned to room temperature before test.

TEST PROCEDURE

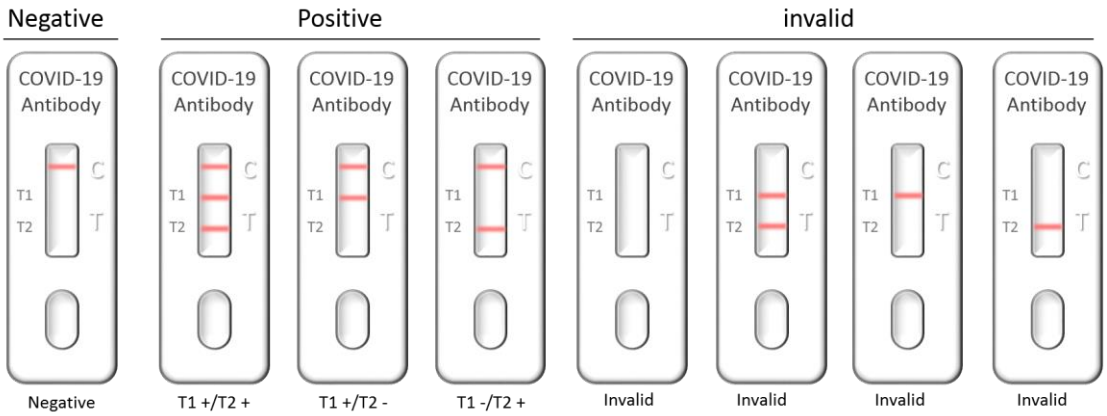
1. If the reagent is stored in a refrigerator at 2-8°C, remove the reagent card and equilibrate at room temperature for more than 30 minutes.
2. Open the test card aluminum foil bag. Remove the test card and place it horizontally on a table.
3. Use pipette to aspirate sample (serum, plasma or whole blood) and **add 10 µl to the sample hole** of the test card, and then add **5 droplets of sample dilution solution (60~80 µl)** immediately.
4. Read the result at 15min. Results after 20 minutes are invalid.



INTERPRETATION OF TEST RESULTS

Assessment of The ACE COVID-19 IgG / IgM Dual Detection Kit results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

1. **Negative results:** If only the quality control line C shows color and neither the G nor M test lines develop color, no SARS-CoV-2 IgG/IgM antibody is detected, and the result is negative.
2. **Positive results:**
   T1+/T2+, T1+/T2-, or T1-/T2+, : If the quality control line C and the detection lines T1 and/or T2 are colored, suggested that the SARS-CoV-2 antibodies are detected, and the results are positive for the SARS-CoV-2 antibodies.
3. **Invalid result:** If the quality control line C does not develop color, regardless of whether the test line G/M develops color, the result is invalid, and the test needs to be performed again.



QUALITY CONTROL

- Internal Procedural Controls

The internal control is built in within each test card at the C Line position and is coated with a goat anti-chicken IgY capture antibody. As the sample migrates from the conjugate pad, it will carry the pre-coated chick IgY conjugate towards the C Line that contains goat anti-chicken IgY capture antibody. The C Line will become purple-red regardless of the development status of the G and M Lines. If no C Line is observed, the test result is invalid, and the specimen must be retested with a new test card.

- External Positive and Negative Controls

  NOTE: Positive and negative controls are not included in The ACE COVID-19 IgG / IgM Dual Detection Kit but positive controls are manufactured by ACE Biolabs Co Ltd., and can be purchased separately using the following catalog number

  - Positive control (PC) :

Cat. No.	Product Name	Size
A150124	Human Anti-S (SARS-COV-2) IgG antibody (standard for immunoassay)	100 µg/100µl
A150125	Human Anti-S (SARS-COV-2) IgM antibody (standard for immunoassay)	10 µg/1000 µl

  - Negative control (NC) solution includes one vial of SARS-CoV-2 negative pooled serum. The vial contains a volume of 100 µL and is enough for a single use.

LIMITATION OF THE PROCEDURES

1. For use under an Emergency Use Authorization Only
2. Humidity and temperature can affect results adversely.
3. The instructions for the use of the test should be followed during testing procedures.
4. There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
5. Although the test demonstrates superior accuracy in detecting antibodies against 2019-nCoV virus, a low incidence of false results can occur.
6. The positive result may be due to previous or current infection with other coronavirus strains other than 2019-nCoV virus. In order to confirm the positive results, additional examination and clinical evaluation should be carried out under the guidance of doctors.
7. The negative results **DO NOT** exclude the infection of 2019-nCoV virus. If the test results are negative, but the clinical symptoms persist, additional tests need to be performed using other analytical methods.
8. The final clinical diagnosis should not be based only on the results of test of this product, but should only be issued by a doctor after evaluation of all clinical and laboratory findings.
9.

PERFORMANCE CHARACTERISTICS

1. Cross-Reactivity

Cross-reactivity of the Anti-SARS-CoV-2 Rapid Test was evaluated using serum samples containing antibodies against high-risk groups. 118 potential cross-reactant serum samples were tested, no IgM or IgG false positive results were observed with the following potential cross-reactants:

Table 1. Cross-reactivity results

Cross-reactivity		High-risk groups				Total
		Medical staff[1]		Suspect symptoms[2]		
		Serum	Plasma	Serum	Plasma	
ACE COVID-19 IgG / IgM Dual Detection Kit	POS	0	0	0	0	0
	NEG	69	0	57	6	132
Total		69		63		132

2. Clinical Studies

The clinical performance of ACE COVID-19 IgG / IgM Dual Detection Kit was evaluated through a clinical study conducted in Taipei Hospital, Ministry of Health and Welfare, in New Taipei City, Taiwan (R.O.C).

Retrospective serum/plasma samples were collected from 27 COVID-19 positive patients confirmed by an FDA authorized SARS-CoV-2 PCR test. Negative retrospective serum/plasma samples were collected from 51 COVID-19 PCR negative samples. Testing of serum samples using ACE COVID-19 IgG / IgM Dual Detection Kit was conducted at the Reach Reference Laboratory in New Taipei City, Taiwan.

Table 2. Overall clinical study results for all time periods from symptom onset

		PCR Comparator*		Total
		Pos	Neg	
ACE COVID-19 Antibody Detection Kit	Pos	26	0	26
	Neg	1	51	52
Total		27	51	78

**Note: Serum and plasma samples were collected from the same patients for serology testing between 1 day and > 45 days after PCR sample collection.*

Positive Percent Agreement (PPA)= (Antibody positive)/(PCR positive)

PPA: 96.80% (26/27)

Negative Percent Agreement: (NPA) = (Antibody negative)/(PCR negative)

NPA: 100.00% (51/51)

REFERENCES

- "Naming the coronavirus disease (COVID-19) and the virus that causes it". World Health Organization. Archived from the original on 28 February 2020. Retrieved 28 February 2020.
- "Coronavirus Disease 2019 (COVID-19) Symptoms". Centers for Disease Control and Prevention. United States. 10 February 2020. Archived from the original on 30 January 2020.
- " EUA Authorized Serology Test Performance ". FDA. United States. 16 July 2020.
- " In Vitro Diagnostics Detecting Antibodies to SARS-CoV-2 Virus ". World Health Organization. Archived from the original on 03 July 2020.
- Sethuraman N, Jeremiah SS, Ryo A: Interpreting Diagnostic Tests for SARS-CoV-2. JAMA 2020.

SYMBOL DESCRIPTION

	Caution, please read instruction
	Please read instruction before use
	For in vitro diagnosis use only
	For single use only; Do not reuse
	Store at 2°C -30°C
	Catalogue number
	Batch code
	Date of manufacture
	Manufacturer
	Expiry date

GENERAL INFORMATION

Applicant/ Manufacturer

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