（FOR RESEARCH USE ONLY. DO NOT USE IT IN CLINICAL DIAGNOSTICS !）

Human Corona Virus Disease 2019 (COVID-19) IgG/IgM Lateral Flow Assay Kit (Whole Blood/ Serum/ Plasma)

Catalog No: E-HD-C044
Size: 40T

This manual must be read attentively and completely before using this product.

If you have any problems, please contact our Technical Service Center for help (info in the header of each page).

Phone: 240-252-7368(USA) 240-252-7376(USA)
Email: techsupport@elabscience.com
Website: www.elabscience.com

Please refer to specific expiry date from label on the side of box.

Please kindly provide us with the lot number (on the outside of the box) of the kit for more efficient service.

Intended use

This kit is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies specific to COVID-19 in human whole blood, serum or plasma as an aid in the scientific research of primary and secondary COVID-19 infections.

Background

COVID-19(Corona Virus Disease 2019) is an infectious disease caused by the most recently discovered coronavirus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019.

The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but don't develop any symptoms and don't feel unwell. Most people (about 80%) recover from the disease without needing special treatment.

Around 1 out of every 6 people who gets COVID-19 becomes ill seriously and has difficult breathing among senior people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness. About 2% of people with the disease have died. People with fever, cough and difficulty breathing should seek medical attention.

People can catch COVID-19 from others who carry the virus. The disease can spread from person to person through small droplets from the nose or mouth when a person with COVID-19 coughs or exhales. These droplets land on objects or surfaces around the patients, like soap or towel that patients have used. Other people then may catch COVID-19 by touching those objects or surfaces, then touching their eyes, nose or mouth. People can also catch COVID-19 if they massage the hand without touching the puncture site by rubbing breathe in droplets from a person with COVID-19 who coughs out or exhales droplets. The incubation period for COVID-19 generally ranges from 1-14 days.

Test principle

This kit applies the GICA(Gold Immunochromatography) method for the detection of IgG and IgM specific to COVID-19 in human whole blood, serum, or plasma. It consists of two test lines, an IgG line and an IgM line, and a control line. The anti-human IgG mouse monoclonal is pre-coated in IgG test line region while the anti-human IgM mouse monoclonal is pre-coated in IgM test line region. And the anti-mouse IgG goat polyclonal is pre-coated in the control line region.

During testing, the sample reacts with COVID-19 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the sample contains IgG antibodies to COVID-19, a colored line will appear in IgG test line region. In the same way, if the sample contains IgM antibodies to COVID-19, a colored line will appear in IgM test line region. And if the tested sample does not contain antibodies specific to COVID-19, no colored line will appear in either of the two test line regions, which indicates a negative result.

To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of sample has been added and membrane wicking has occurred.

Kit components & Storage

The kit can be stored at room temperature or refrigerated (2-30℃). DO NOT FREEZE.

The test cassette is stable before the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use.

Item	**Specifications**	**Storage**
Test Cassette	40 tests(with desiccant)	2-30℃, 18 months
Buffer	1 vial, 5 mL	
Dropper	1 bag, 40 pieces	
Product Description	1 copy	

Note: It is suggested to use the buffer within 6 months after opening the vial.

Other supplies required

Sample collection container

Centrifuge

Micropipette

Timer

Sample collection and preparation

This kit can be performed with human whole blood, serum, or plasma.

Whole blood: Collect whole blood by using anticoagulant tube.

Serum: Use a serum separator tube (SST) and allow samples to clot for 30 minutes at room temperature before centrifugation for 15 minutes at 1000×g at 2-8℃. Collect the supernatant to carry out the assay.

Plasma: Collect plasma by using an anticoagulant tube. Centrifuge samples for 15 min at 1000×g at 2-8℃ within 30 min of collection. Collect the supernatant to carry out the assay.

Fingerstick whole blood: Collect it in a common way. The following steps can be the reference.

1) Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
2) Then massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger. Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
3) Rub the hand gently from wrist to palm to finger to form a rounded drop of blood over the puncture site.
4) Add the fingerstick whole blood to the test by using a capillary tube.

Note for sample

1. Don't use hemolysis, turbidity, hyperlipidemic or polluted samples.
2. Serum and plasma samples should be assayed within 4 hours or 3 days when stored at room temperature or 2-8℃, otherwise samples must be stored at -20℃ for a long-term storage. Whole blood collected by venipuncture should be stored at 2-8℃ if the test is to be run within 2 days of collection. Whole blood collected by fingertip should be tested immediately. **Do not freeze whole blood samples.** Avoid repeated freeze-thaw cycles.
3. Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.
4. If samples are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.
5. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for sample collection.
6. Heat treated samples may interfere the detection result.

Assay procedure

1. Bring the test cassette, sample, buffer, and/or controls to room temperature (15-30℃) prior to testing.
2. Take the test cassette from the sealed pouch and use it within one hour. It is recommended to run the test immediately after opening the foil pouch.
3. Place the test cassette on a clean and level surface.

   For Serum or Plasma Samples.

   a) To use a dropper: Hold the dropper vertically, draw the sample and transfer the sample to the sample well of the test cassette (one drop approximately 20 μL), then add 1 drop of buffer (approximately 40 μL) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

   b) To use a micropipette: Pipette and dispense 20 μL of sample to the sample well of the test cassette, then add 1 drop of buffer (approximately 40 μL) to the sample well and start the timer.

   For Whole Blood Samples.

   a) To use a dropper: Hold the dropper vertically, draw the sample and transfer the sample to the sample well of the test cassette (two drops approximately 40 μL), then add 3 drops of buffer (approximately 100 μL) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

   b) To use a micropipette: Pipette and dispense 40 μL of sample to the sample well of the test cassette, then add 3 drops of buffer (approximately 100 μL) to the sample well and start the timer.
4. Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 20 minutes.

Interpretation of results

IgG and IgM Positive: Three lines appear

One colored line should always appear in the control line region(C), and two-colored lines should appear in IgG test line region and IgM test line region respectively. This result is positive for IgG & IgM antibodies specific to COVID-19 virus and is probably indicative of secondary COVID-19 infection.

IgG Positive: Two lines appear

One colored line should appear in the control line region(C), and a colored line appears in IgG test line region. The result is positive for COVID-19 virus specific-IgG and is probably indicative of secondary COVID-19 infection.

IgM Positive: Two lines appear

One colored line should appear in the control line region (C), and a colored line appears in IgM test line region. The result is positive for COVID-19 virus specific-IgM and is probably indicative of primary COVID-19 infection.

NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the

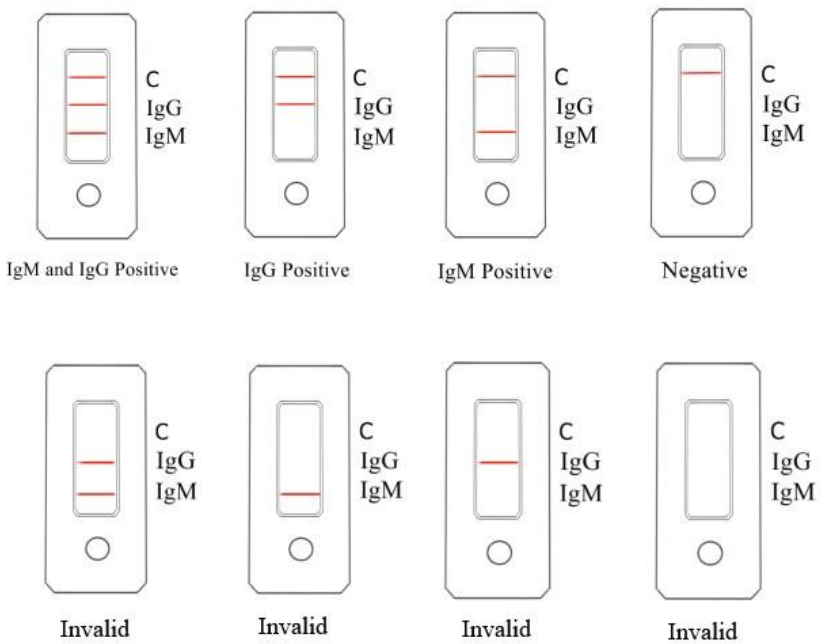
concentration of COVID-19 antibodies in the sample. Therefore, any shade of color in the IgG and/or IgM test line region(s)should be considered positive.

Negative: One line appears

One colored line should appear in the control line region (C). No line appears in either IgG or IgM test line region(s).

Invalid: Control line fails to appear

Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Product Performance Index

1. **Positive reference of product compliance rate:** The positive reference of product compliance rate is 5/5.
2. **Negative reference of product compliance rate:** The negative reference of product compliance rate is 10/10.
3. **Precision reference:** Detect 10 precision references, the results are consistent.
4. **Specificity analysis:**

   4.1 Cross-reaction:

   This product does not have cross reaction with positive samples of parainfluenza virus antibody, influenza A virus antibody, influenza B virus antibody, chlamydia pneumoniae antibody,

mycoplasma pneumoniae antibody, adenovirus antibody, respiratory syncytial virus antibody, hepatitis B surface antibody, type C Hepatitis virus antibody, treponema pallidum antibody, human immunodeficiency virus antibody, EB virus antibody, measles virus antibody, cytomegalovirus antibody, enterovirus 71 antibody, mumps virus antibody, chicken pox-zoster virus.

4.2 Interfering substances:

1) When the bilirubin concentration is ≤ 250 μmol/L, the hemoglobin content is ≤ 9 g/L, the triglyceride content is ≤ 15 mmol/L, the rheumatoid factor content is ≤ 80 IU/mL, and the antinuclear antibody (ANA) titer is ≤ 1: 240, anti-mitochondrial antibody (AMA) ≤ 80 U/mL, mouse IgG content ≤ 1000 μg/mL, will not interfere with the detection results of this product.
2) Histamine hydrochloride, alpha-interferon, zanamivir, ribavirin, oseltamivir, peramivir, lopinavir, ritonavir, abidol, levofloxacin, azithromycin, Ceftriaxone, meropenem, and tobramycin have been validated to have no effect on the test results of this product.

5. **Hook effect:** Within the titer range of positive samples of the new coronavirus antibody, the test result of this product does not show a hook effect.
6. The test results of this product are not affected by the disrupted new coronavirus-specific IgM antibodies.
7. 403 copies of 2019-nCoV novel coronavirus clinical positive serum samples were studied, and the test results of this kit indicate:
   Relative sensitivity: 98.511%(95%CI*: 96.788%-99.452%)
   Relative specificity: 88.208%(95%CI*: 83.086%-92.221%）

Quality Control

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations

1. This kit should be used for the detection of COVID-19 antibodies in human serum, plasma or whole blood samples only. Neither the quantitative value nor the rate of increase in COVID-19 antibody concentration can be determined by this qualitative test.
2. This kit will only indicate the presence of COVID-19 antibodies in the sample and should not be used as the sole criteria for the diagnosis of COVID-19 infection.
3. In the early onset of fever, anti-COVID-19 IgM concentrations may be below detectable levels.
4. Results from immunosuppressed patients should be interpreted with caution.
5. If the test result is negative and clinical symptoms persist additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of COVID-19 infection.

Note

1. This product is for scientific research only.
2. Please read the manual carefully before use. All kinds of reagents provided in this kit are only for this experiment.
3. Do not use expired products or products with a broken aluminum foil.
4. Handle all samples cautiously as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of samples.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
6. Do not eat, drink or smoke in the area where samples or kits are handled.
7. The used tests, samples and potentially contaminated should be discarded according to the local regulation.
8. Humidity and temperature could adversely affect results.
9. Do not use components from different batches of kits.