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

COVID-19 IgG/IgM Lateral Flow Assay Kit

Catalog No: E-HD-C060

20T/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.

Toll-free: 1-888-852-8623 Tel: 1-832-243-6086 Fax: 1-832-243-6017

Email: techsupport@elabscience.com

Website: www.vetassay-elab.com

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

Test principle

COVID-19 IgG/IgM Rapid Test (Serum/Plasma/Whole Blood) is a qualitative membrane-based immunoassay for the detection of COVID-19 antibodies in serum, plasma, or whole blood. This test consists of two test lines, an IgG line and an IgM line, which is pre-coated with two mouse anti-human monoclonal antibodies separately.

During testing, the sample reacts with COVID-19 antigen-coated on conjugated pad. As the complex continues to travel up the strip, the anti-COVID-19 IgM antibodies are bound on the IgM line, and the anti-COVID-19 IgG antibodies are bound on the IgG line. The control (C) line appears when sample has flowed through the strip. The presence of anti-COVID-19 IgM and/or IgG will be indicated by a visible test line in the IgM and IgG region.

To serve as a procedural control, the control line should always appear if the test procedure is performed properly and the reagents are working as intended.

Kit components

Item	Specification
Detection card	20/40 T
Sample Diluent	1 vial
Dropper	20/40
Manual	1 copy

Note: All reagent bottle caps must be tightened to prevent evaporation and microbial pollution.

Notes

1. Please read the manual carefully before use, changes of operation may result in unreliable results.
2. Do not use product out of date or in a broken aluminum foil, it is disposable and cannot be used repeatedly.
3. Please do not use but not limited to the following liquids for negative control: Water, PBS.
4. The tested sample should be fresh and clear. Avoid of using samples of turbidity, polluted, high hemolysis or abnormal viscous.
5. Avoid of touching the chromatography membrane of the sample well and test well.
6. The waste of experiment should be considered as contaminant, and must be properly handled according to the local regulations.
7. The test environment should be kept at a fixed temperature to avoid testing at high temperatures.
8. Each reagent is optimized for use in the **E-HD-C060**. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other **E-HD-C060** with different lot numbers.

Storage and expiry date

Storage: Store at 4-30℃. With cool and dry environment, avoid freeze.

Expiry date: expiration date is on the packing box.

Sample preparation

1. To collect finger prick whole blood samples.

Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.

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.

Rub the hand gently from wrist to palm to finger to form a rounded drop of blood over the puncture site.

Transfer the finger blood sample to the cassette by using the micropipette/ dropper immediately.

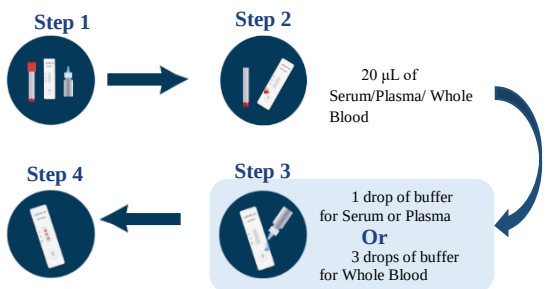
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed samples.
3. Test should be performed immediately after sample collection.
4. Serum and plasma samples may be stored at 2-8℃ for up to 3 days. For long-term storage, samples should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2-8℃ if the test is to be run within 2 days of collection. Do not freeze whole blood samples. Whole blood collected by fingertip should be tested immediately.
5. 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.

Assay procedure

Allow all kit components and sample to reach room temperature (25℃) prior to testing.

1. Bring the pouch to room temperature before opening. Take the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and flat surface.
3. **For Serum or Plasma samples:** add 20 μL of sample into sample well, then add 1 drop of buffer and start the timer. Avoid trapping air bubbles into the sample well.
4. **For Whole Blood samples:** add 20 μL of sample into sample well, then add 3 drops of buffer as soon as possible and start the timer. Avoid trapping air bubbles into the sample well. Note: It's recommended to add 1 more drop of buffer if the liquid flows too slowly.
5. Wait for the colored line(s) to appear. The result shall be read at 10 minutes. The result is valid within 20 minutes.

Note: It is recommended to use serum or plasma as the priority sample types for testing, and whole blood samples can be used in urgent or special cases.



Judgment of result

IgM POSITIVE: Two lines appear.

Colored lines should be in the control line region (C) and IgM test line region. No line appears in IgG test line region.

IgG and IgM POSITIVE: Three lines appear.

Colored lines should be in the control line region(C), IgG line test region and IgM test line region. The color intensities of the lines do not have to match.

IgG POSITIVE: Two lines appear.

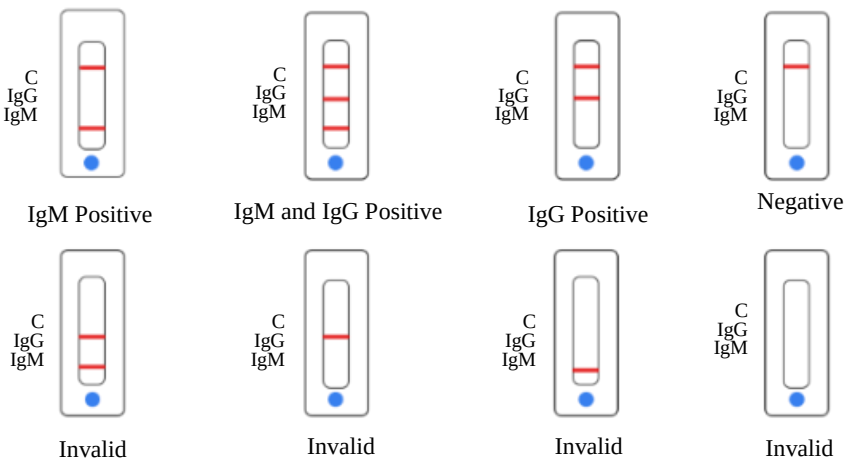
Colored lines should be in the control line region(C) and IgG test line region. No line appears in IgM test line region.

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 colored line should be in the control line region (C). No line appears in IgG and 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 cassette. If the problem persists, discontinue using the test kit and contact your local distributor.



NOTE: This figure is only used as a reference for judging results.

Limitations of this test method

1. COVID-19 Rapid Test is for in vitro diagnostic use only. The test should be performed using 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. COVID-19 Rapid Test 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. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
5. Results from immunosuppressed patients should be interpreted with caution.
6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
7. 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.