Edinburgh Genetics COVID-19 Colloidal Gold Immunoassay Testing Kit, IgG/IgM Combined

Instructions for Use

CATALOG NUMBER
EGCV0055

UDI DEVICE IDENTIFIER (UDI-DI)
5060774580004

GMDN TERM
SARS-CoV-2 immunoglobulin G (IgG)/IgM antibody IVD, kit, immunochromatographic test (ICT), rapid

INTENDED USE
This kit is used to qualitatively detect IgG and IgM antibodies of the COVID-19 novel coronavirus in human serum, plasma or whole blood in vitro.

SUMMARY
Coronavirus (CoV) belongs to the Coronaviridae family and is divided into three types: α, β and γ. Alpha and beta are only pathogenic to mammals and gamma mainly causes bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route. The COVID-19 novel coronavirus was discovered in 2019 in Wuhan, China with viral pneumonia cases and clinical manifestations were fever, fatigue, cough, and other symptoms. These can rapidly develop into severed pneumonia, respiratory failure, septic shock, multiple organ failure and severe acid-base metabolism disorders, etc.

TEST PRINCIPLE
Edinburgh Genetics Colloidal Gold Immunoassay Testing Kit, IgG/IgM Combined is immunochromatography based. The test card contains (1) colloidal gold-labeled recombinant novel coronavirus antigen and quality control antibody colloidal gold marker, (2) two detection lines (G and M lines) and one quality control line (C) fixed on a nitrocellulose membrane. M is fixed with monoclonal anti-human IgM antibody for detecting the novel coronavirus IgM antibody. G is fixed with monoclonal antihuman IgG antibody for detecting the novel coronavirus IgG antibody. The quality control antibody is fixed on the C line. When an appropriate amount of test sample is added to the sample well of the test cassette, the sample will move forward along the test card via capillary action. If the sample contains IgM antibody, the antibody will bind to the colloidal gold labeled novel coronavirus antigen. The antibody/antigen complex will be captured by the anti-human IgM antibody immobilised on the membrane, forming a red M line and indicating a positive result for the IgM antibody. If the sample contains IgG antibodies, the antibody will bind to the colloidal gold-labeled novel coronavirus antigen and the antibody/antigen complex will be captured by the antibody immobilised on the membrane, forming a red G line and indicating a positive result for the IgG antibody. If neither antibody is present, a negative result is displayed. The card also contains a quality control line (C). Regardless of the antibodies present (or not) the C line should appear to indicate that the sample has been transported properly through the membrane. If the C line does not appear it indicates that the test result is invalid and a new, unopened test cassette is required to retest the sample.

STORAGE INSTRUCTIONS
- The reagent should be stored in the dark at room temperature (2° to 25°C) and has a shelf-life of 18 months.
- The container should be protected from light after being opened.
- Do not freeze.

CONTENTS OF THE KIT

One test kit contains: 20 Test Cassettes, 1 Package Insert
One test cassette contains: Dried reagents with stabilisers, Colloidal gold-labeled novel coronavirus antigen, Mouse anti-human IgG monoclonal antibody, Mouse anti-human IgM monoclonal antibody
Materials not included but required: Buffer Solution, Capillary Samplers, Lancet, Alcohol Wipes, Gloves, Timer

RESULTS

A total of three detection lines are possible, with the control (C) line appearing when sample has been flowed through the cassette.

- **Negative Result:** If only the quality control line (C) appears and the detection lines G and M are not visible, then no novel coronavirus antibody has been detected and the result is negative.
- **Positive Result IgM only:** If both the quality control line (C) and the detection line M appears, then the novel coronavirus IgM antibody has been detected and the result is positive for the IgM antibody.
- **Positive Result, IgG only:** If both the quality control line (C) and the detection line G appears, then the novel coronavirus IgG antibody has been detected and the result is positive for the IgG antibody.
- **Positive Result, IgG & IgM:** If the quality control line (C) and both detection lines G and M appear, then the novel coronavirus IgG and IgM antibodies have been detected and the result is positive for both the IgG and IgM antibodies.

TEST METHOD LIMITATIONS

- This product can only be used to detect the IgG and IgM antibodies of the novel coronavirus in human whole blood, serum, or plasma.
- This product is only for qualitative testing and the specific content of each indicator must be measured using other quantitative methodologies.
- Negative results may be caused by low concentrations of the IgG/IgM antibody in the sample and therefore cannot completely rule out the possibility of infection. It is recommended to use the test at least 7 days after clinical diagnosis by other means.
- The results of this test are for clinical reference only and should not be the only basis for diagnosis. Results should be used in combination with clinical observations and other testing methods.
- Test results can be affected by temperature and humidity.

INTERNAL QUALITY CONTROL PROCEDURE

Each Test Cassette device has a built-in control. A red coloured line in the detection window at the Control line can be considered an internal positive procedural control. The Control line will appear if the test procedure has been correctly performed. If the Control line does not appear, the test is invalid and a new test must be performed. If the problem persists, please contact your local vendor or Edinburgh Genetics for technical support.

PERFORMANCE CHARACTERISTICS

In order to test the detection sensitivity and specificity of this test, blood samples were collected from clinically diagnosed COVID-19 patients in Wuhan. A total of 272 cases were tested: 127 (positive) clinically confirmed patients and 145 non-infected patients (negative). The 127 positive patients were tested 7 days after being clinically diagnosed by PCR and CT. Among the 127 clinically confirmed samples, 125 were detected by the test reagents, with a positive detection rate of 98.43% (125/127). Of the 145 clinically negative samples, 144 were detected by the test reagent, and the negative coincidence rate was 99.31% (144/145).

SAMPLE REQUIREMENTS

- Suitable for human serum, plasma, or whole blood samples (capillary or venous) including samples prepared by commonlyused anticoagulants (EDTA, heparin, sodium citrate).
- Serum and plasma samples can be stored at 2-8°C for 5 days.
- If long-term storage of serum or plasma samples is required, store at -20°C and avoid repeated freeze/thaw cycles.
- Before testing, samples stored in refrigerated or frozen storage should be slowly returned to room temperature (15-30° C) and stirred. When particulates are clearly visible in the sample the precipitate should be removed by centrifugation before testing.
- Fresh samples should be collected and tested immediately.
- Anticoagulated whole blood samples can be stored at 2-8°C for 7 days.

TEST PROCEDURE

- Do not open pouch until ready to use.
- Label Test cassette with patient ID.
- Necessary materials: Test cassette, Buffer solution, Capillary Sampler, Lancet
- Test on a level surface at room temperature. Always use appropriate PPE.

1. For fingerpick whole blood sample, use capillary sampler to obtain 20μL of blood. For serum/plasma sample, take 20μL serum or plasma sample respectively,
2. Add the sample into 2ml of buffer solution, recap and shake sample to mix thoroughly.
3. Remove cap of the buffer solution and dispense 2-3 drops into the Test Cassette sample well using the capillary sampler.
4. Allow test to run for 10 minutes. Read the results by viewing the detection window and comparing to the guidance below. Test results that have run over 15 minutes are invalid.

Negative **IgM Positive** **IgG Positive** **IgM & IgG Positive** **Invalid**

For Use in the United States

Laboratories and healthcare providers must include this information in their patient test report as specified in FDA guidance:

- This test has not been reviewed by the FDA.
- Negative results do not rule out SARS-CoV-2 infection, 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 SARS-CoV-2 infection or to inform infection status.
- 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.
- Not for the screening of donated blood.

WARNINGS AND PRECAUTIONS

- Only for human in vitro clinical diagnostics only.
- After opening the sealed cassette pouch the test should be used within one hour.
- Do not freeze test cassette or buffer solution.
- Wear protective gloves, clothing, and eyewear.
- Do not use test cassette, buffer solution, or any kit component beyond the indicated expiration date.
- Do not use test cassette, buffer solution, or any other kit components if the pouch is damaged or the seal is broken.
- The product should only be used by trained clinical professionals.
- Handle specimens in accordance to the OSHA Standard on Blood borne Pathogens.
- Do not immerse test cassette in water.
- Wash hands thoroughly after handling specimens.
- Dispose of all used or damaged test cassettes, capillary samplers, or other kit component as biohazardous materials.
- Do not use samples containing lipids, hemolysis, or turbidity which can affect results.

MANUFACTURER

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CE

Catalog Number


Manufacturer

Lot Number


Storage Temperature Range


Do Not Reuse


Consult Instructions

In Vitro Diagnostic Medical Device