

**CATALOG NUMBER**

EGCV0092

EGCV0092L

**UDI DEVICE IDENTIFIER (UDI-DI)**

5060774580103

5060774580158

**INSTRUCTIONS FOR USE**

**GMDN DATES**

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

**USE**

This kit is used for the qualitative detection of IgG and IgM antibodies of the new COVID-19 coronavirus in human serum, plasma or whole blood in vitro.

**SUMMARY**

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

**PRINCIPLE OF THE TEST**

Edinburgh Genetics ActivXpress + COVID-19 IgG / IgM Immunoassay Complete Testing The kit is based on immunochromatography . The test card contains (1) colloidal gold-labeled recombinant new coronavirus antigen and colloidal gold-labeled quality control antibody, (2) two detection lines (lines G and M) and one quality control line (C) fixed on a nitrocellulose membrane. M is a fixed anti-human IgM monoclonal antibody to detect the IgM antibody of the new coronavirus . G is a fixed anti-human IgG monoclonal antibody to detect the IgG antibody of the new coronavirus . The quality control antibody is fixed on the C line. When an appropriate amount of test sample is added to the well of the test cassette, the sample will move forward along the test card by capillary action. If the sample contains an IgM antibody, the antibody will bind to the colloidal gold-labeled antigen of the new coronavirus . The antibody / antigen complex will be captured by the anti-human IgM antibody immobilized on the membrane, creating a red line M, indicating a positive result for the IgM antibody. If the sample contains an IgG antibody, the antibody will bind to the colloidal gold-labeled antigen of the new coronavirus and the antibody / antigen complex will be captured by anti-human IgG antibody immobilized on the membrane, forming a red line G, indicating a positive result for IgG antibody. If no antibody is present, a negative result is displayed. The card also contains a quality control line (C). Regardless of the antibodies present (or their absence), line C should be displayed, as this indicates that the sample has been properly transported across the membrane. If line C does not appear, it means that the test result is invalid and a new, unopened test cassette is required to repeat the test.

**STORAGE INSTRUCTIONS**

• The kit should be stored in the dark at room temperature (2 ° C to 25 ° C) and should have a shelf life of 18 months.

• Once opened, the container should be protected from light.

• Do not freeze.

**CONTENT**

EGCV0092: 10 x Edinburgh Genetics ActivXpress + COVID-19 IgG / IgM Immunoassay Complete Testing Kit

EGCV0092L: 1 x Edinburgh Genetics ActivXpress + COVID-19 IgG / IgM Immunoassay Complete Testing Kit

**Contains:** Edinburgh Genetics COVID-19 Colloidal Gold Immunoassay Testing Kit , IgG / IgM combined test cassette, 60μl buffer, sampling capillary, lancet, alcohol cleaning square, cotton swab, patch

**One test cassette contains:** dry reagents with stabilizers, colloidal gold-labeled new coronavirus antigen , mouse anti-human IgG monoclonal antibody, mouse anti-human IgM monoclonal antibody

**Materials not included but necessary:** Gloves, timer

**RESULTS**

A total of three detection lines are possible, with the control (C) line appearing when the sample has 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 new coronavirus antibody has been detected and the result is negative.

**•**

**Positive result, IgM only :** If the quality control line (C) and also the detection line M appear, then the IgM antibody of the new coronavirus has been detected and the result is positive for IgM antibody.

**•**

**Positive result, IgG only :** If the quality control line (C) as well as the detection line G appear, then the IgG antibody of the new coronavirus has been detected and the result is positive for IgG antibody.

**•**

**Positive result, IgG and IgM :** If the quality control line (C) as well as both detection lines G and M appear, then IgG and IgM antibodies of the new coronavirus were detected and the result is positive for both IgG and IgM antibodies.

**LIMITATION OF THE METHOD**

• This product can only be used to detect IgG and IgM antibodies of the new coronavirus in human whole blood, serum or plasma.

• This product is for qualitative testing only and the specific content of each indicator must be measured using other quantitative methods.

• Negative results may be due to low concentrations of IgG / IgM antibodies in the sample, and therefore the possibility of infection cannot be completely ruled out. It is recommended that the test be used at least 7 days after a clinical diagnosis made by other means.

• The results of this test are for clinical information only and should not be used as the sole basis for diagnosis. The results should be used in combination with clinical observations and other testing methods.

• Test results may be affected by temperature and humidity.

**INTERNAL QUALITY CONTROL**

Each test cartridge has an integrated control. The red bar in the detection window on the control line can be considered as an internal positive test control. If the test procedure was performed correctly, a control line will appear. If the control line does not appear, the test is invalid and a new test must be performed. If the problem persists, contact your local reseller or Edinburgh Genetics for technical support.

**PERFORMANCE CHARACTERISTICS**

To test the sensitivity of detection and the specificity of this test, blood samples were taken from clinically diagnosed COVID-19 patients in Wuhan . A total of 272 cases were tested: 127 (positive) clinically confirmed patients and 145 uninfected patients (negative). 127 positive patients were tested 7 days after being clinically diagnosed by PCR and CT. Among 127 clinically confirmed samples, 125 were detected using test reagents, with a positive detection rate (sensitivity) of 98.43%. Of the 145 clinically negative samples, 144 were detected using test reagents and the negativity agreement (specificity) was 99.31%.

**SAMPLE REQUIREMENTS**

• Suitable for human serum, plasma or whole blood samples (capillary or venous), including samples prepared with commonly used 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.

• Samples stored refrigerated or frozen should be slowly brought to room temperature and mixed before testing. If particles are clearly visible in the sample, the precipitate should be removed by centrifugation before testing.

• Fresh samples should be taken and tested immediately.

• Anticoagulated whole blood samples can be stored at 2-8 ° C for 7 days.

**TEST PROCEDURE**

• Do not open the bag until it is ready for use.

• Label the test cassette with the patient ID.

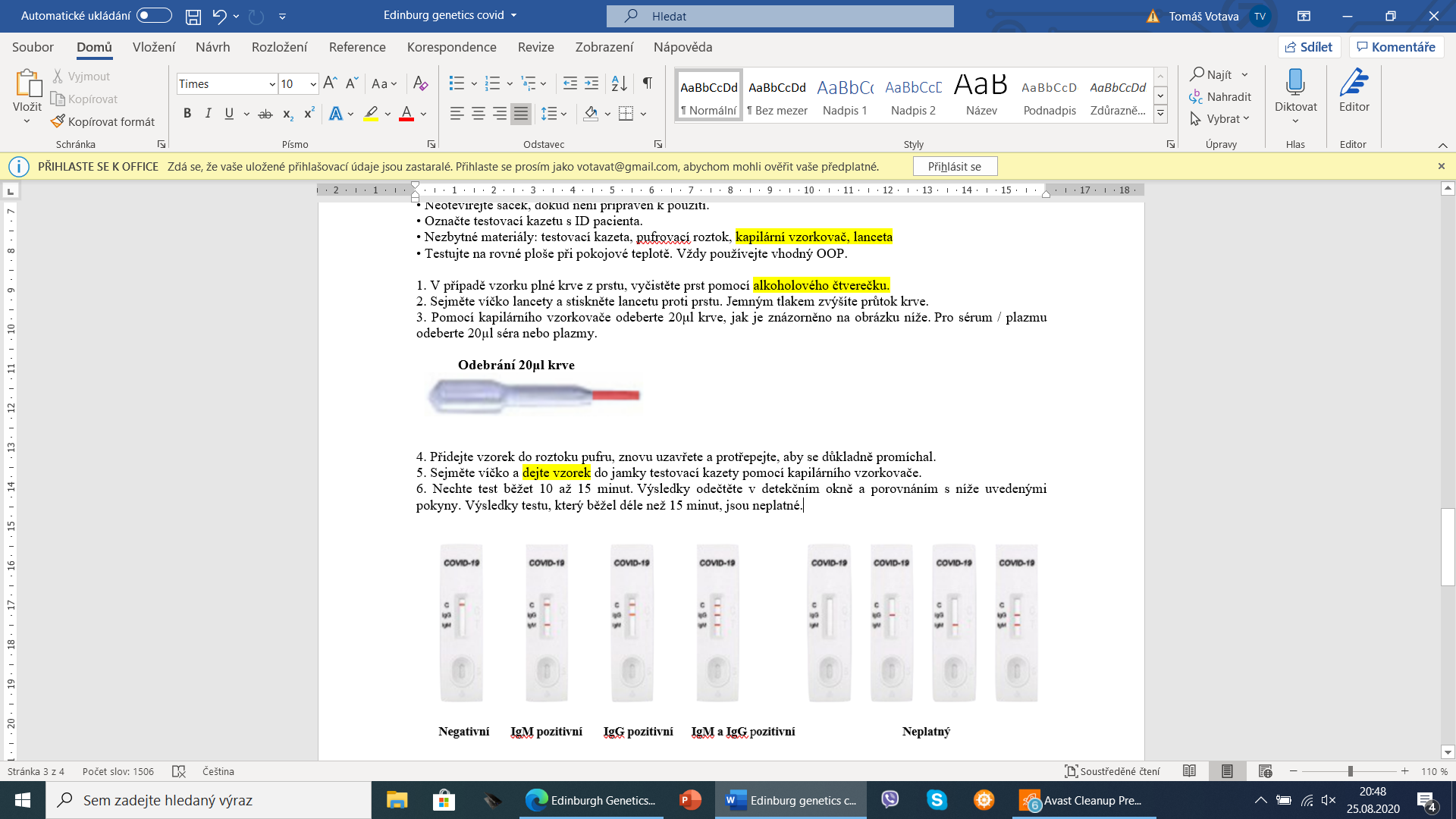
• Necessary materials: test cassette, buffer, sampling capillary, lancet

• Test on a flat surface at room temperature. Always use suitable PPE.

1. For a whole blood sample from a finger, clean the finger with an alcohol swab.

2. Remove the lancet cap and press the lancet against your finger. Apply gentle pressure to increase blood flow.

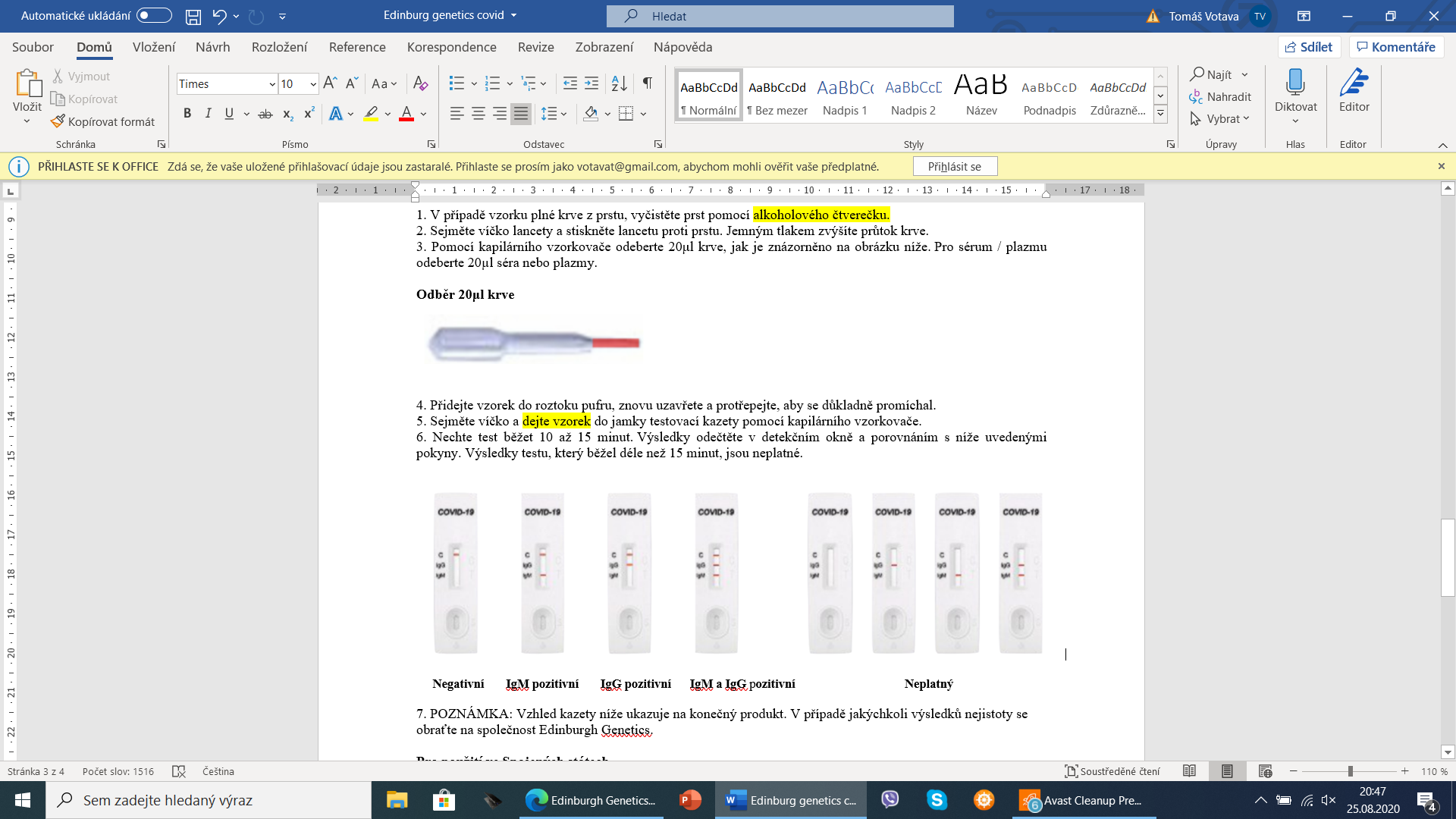
3. Using a sampling capillary, collect 20μl of blood as shown in the figure below. Collect 20µl of serum or plasma for serum / plasma.



4. Add sample to buffer, reseal, and shake to mix thoroughly.

5. Remove the cap and place the sample in the well of the test cassette using a capillary.

6. Let the test run for 10 to 15 minutes. Read the results in the detection window and compare with the instructions below. Test results that run for more than 15 minutes are invalid.



7. NOTE: The appearance of the cartridge indicates the final product. Contact Edinburgh Genetics for any uncertain results .

**For use in the United States**

Laboratories and healthcare providers must include this information in the patient's test report, as stated in the FDA guidelines:

• This test has not been reviewed by the FDA.

• Negative results do not rule out SARS-CoV-2 infection, especially in people who have been in contact with the virus. Subsequent molecular diagnostic testing should be considered to rule out infection in these individuals.

• Antibody testing results should not be used as the sole basis for diagnosing or excluding SARS-CoV-2 infection or for informing the status of the infection.

• Positive results may be due to past or current infection with coronavirus strains other than SARS-CoV-2, such as coronavirus HKU1, NL63, OC43 or 229E.

• Not intended for screening donated blood.

**WARNINGS AND PRECAUTIONS**

• For in vitro human clinical diagnosis only.

• After opening the sealed cartridge, the test should be performed in one hour.

• Do not freeze the test cassette or buffer solution.

• Wear protective gloves, clothing and goggles.

• Do not use the test cassette, buffer solution, or any kit components after the date expiration .

• The product should only be used by a trained clinician.

• Handle samples in accordance with the standard OSHA Standard on Blood borne Pathogens .

• Do not immerse the test cartridge in water.

• Wash your hands thoroughly after handling specimens.

• Dispose of all used or damaged test cartridges, sampling capillaries, or other kit components as biohazardous materials.

• Do not use the test cartridge, buffer solution, or any other components of the kit if the package is damaged or the seal is broken.

• Do not use samples that contain lipids, hemolysis, or turbidity that may affect the result.

**PRODUCER**

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