COVID-19
IgM-IgG Rapid Test

Instructions For Use

For Research Use Only. Not for Use in Diagnostic Procedures.

Contents of the Kit |
One test kit contains:
20 Test Cassettes | 1 Buffer Solution Bottle | 1 Package Insert
One test cassette contains:
• Dried reagents with stabilizers
• Colloidal gold-labeled novel coronavirus antigen
• Colloidal gold-labeled rabbit IgG
• Goat anti-rabbit IgG polyclonal antibody
• Mouse anti-human IgG monoclonal antibody
• Mouse anti-human IgM monoclonal antibody

Materials not provided but required:
Capillary Sampler | Lancet | Alcohol wipes | Gloves | Timer

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

Storage Instructions |
The reagent should be stored in the dark at room temperature (18° to 26°C) and has a shelf-life of 12 months. The container should be protected from light after being opened. Do not freeze.

Sample Requirements |
• Suitable for human serum, plasma, or whole blood samples including samples prepared by commonly-used anticoagulants (EDTA, heparin, sodium citrate).
• Fresh samples should be collected and tested immediately.
• 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.
• Anticoagulated whole blood samples can be stored at 2-8°C for 7 days.
• 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.

Test Procedure |
Do not open pouch until ready to use. Prep necessary materials: Test cassette | Buffer solution | Capillary Sampler Label Test cassette with patient ID.

1 | Obtain a specimen using standard laboratory protocols. Using capillary sampler, obtain 20µL of fingerstick or venous whole blood specimen or 10µL of serum or plasma.
2 | Obtain a specimen using standard laboratory protocols.
3 | Remove cap of the Buffer Solution bottle and dispense 2-3 drops into the Test Cassette sample well.
• Remove any air bubbles in the dropper.
• Test on a level surface at room temperature.
4 | Allow test to run for 15 minutes. Read the results by viewing the detection window.
• Test results that have run over 20 minutes are invalid.

Test Method Limitations |
• This product can only be used to detect the IgG and IgM antibodies of the novel coronavirus in human blood, serum, or plasma. It cannot be used with other body fluids or secretions.
• 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 novel coronavirus IgG/IgM antibody in the sample and therefore cannot completely rule out the possibility of infection.

• Test results can be affected by temperature and humidity.

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

1 | 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.

2 | Positive Result, M 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.

3 | Positive Result, G 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.

4 | Positive Result, G and M
• 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.

Internal Quality Control Procedure |
Each Test Cassette device has a built-in control. A red colored 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 BioMedomics.
References