FAQ: Frequently Asked Questions

Device: COVID-19 IgG/IgM Rapid Test (REF 1507, 1507A, 1507B)

Sample Type

What type of sample can be used?
Serum, EDTA Plasma and whole blood can be used on the BIOMERICA COVID-19 IgG/IgM Rapid Test.

How long can samples be stored before testing?
Serum and plasma can be stored at 2 -8°C for 7 days for short term or at -20°C for long term storage before use. Whole blood should be used immediately.

Can Capillary Fingerstick whole blood be stored prior to testing?
Testing of capillary whole blood must be performed immediately after specimen collection. Do not store capillary fingerstick whole blood.

What should I do if the test sample is hemolyzed or lipemic?
Grossly hemolyzed, lipemic, and icteric samples as well as samples containing particulate matter or showing obvious microbial contamination should not be tested.

What is the minimum volume of sample required for testing?
20 µL of whole blood. 10 µL of serum or plasma.

Can I test non-Human samples?
At this time, Biomerica has not validated the BIOMERICA COVID-19 IgG/IgM Rapid Test kit with the use of non-Human whole blood, serum or plasma.

What happens if I cannot collect a sufficient volume of whole blood?
Please repeat the whole blood collection process to ensure the 20 µL capillary tube is filled to the line.

Reagents

Can I interchange lot numbers?
No. The BIOMERICA COVID-19 IgG/IgM Rapid Test kit components are lot specific. Do not interchange lot numbers from previous kits.

Can I use an alternative sample collection device?
No. The BIOMERICA COVID-19 IgG/IgM Rapid Test has been validated with the 20 µL capillary tube.

Can I reuse the capillary tube?
No. The capillary tube is for single use. Discard after use.

Can I reuse the test device?
No. The test device is for single use only. Discard after use.

What should I do if the test device pouch is punctured or not sealed?
Do not use the test device if the outer pouch is punctured or not sealed. Please contact your supplier.

What should I do if the test buffer is leaking or damaged?
Do not use the test buffer if leakage or damage is observed. Please contact your supplier.

Can I freeze the kit reagents?
No. Do not freeze the test kit components (Test Device and Test Buffer).

What is the storage temperature of the BIOMERICA COVID-19 IgG/IgM Rapid Test?
Store the tests at room temperature or refrigerated (2-30°C).

What is the shelf-life of the test cassette?
The shelf-life is 24 months from the date of manufacture. The product expiry is printed onto the packaging for reference. Do not use after the expiry date.

Testing Procedure

How does the BIOMERICA COVID-19 IgG/IgM Rapid Test work?
Recombinant SARS-CoV-2 nucleocapsid antigen conjugated to colloidal gold is immobilized onto a conjugate pad. Anti-human IgM and anti-human IgG are coated in the test line region. The specimen reacts with SARS-CoV-2 antigen-gold conjugate and then migrates upward on the membrane chromatographically to react with anti-human IgM and anti-human IgG. A pink/red colored band will appear next to the "IgM" in the test window if the sample contains IgM antibodies to SARS-CoV-2 and a second pink/red colored band will appear next to the "IgG" in the test window if contains IgG antibodies to SARS-CoV-2. If the specimen does not contain antibodies to SARS-CoV-2, no pink/red colored line(s) will appear in next to the "IgM" or "IgG" in the test window which indicates a negative result. A built-in control band will always show next to the "C" in the test window indicating that the proper volume of sample and test buffer has been added to the test device.

To which viral protein(s) does the test detect antibodies (spike protein, as well as nucleocapsid, etc.)?
Nucleocapsid.

What precautions should I take when running this kit?
All specimens, biological reagents and materials used in the assay must be considered potentially able to transmit infectious agents. Common precautions in handling should be exercised, as applied to any untested patient sample. The package insert must be read completely before performing the test. Failure to follow directions may yield inaccurate test results

What units are expressed in the test result?
The Biomerica COVID-19 IgG/IgM Rapid Test is qualitative. Valid tests are reported as positive or negative.

Is the BIOMERICA COVID-19 IgG/IgM Rapid Test calibrated against an international standard?
There is currently no international reference standard available for SARS-CoV-2 antibody.

What is the operating temperature of the BIOMERICA COVID-19 IgG/IgM Rapid Test?
The test must be run at 15 -30°C. Using temperatures that differ from what is listed in the Package Insert may give erroneous results, and is therefore discouraged.

How long can I wait to run the test after removing the device from the pouch or canister?
Use the test device within one hour after removing from sealed pouch or from closed canister

Do I have to allow the kit reagent to come to room temperature before testing?
Yes, allow the test device, sample, and test buffer to reach room temperature ((15° - 30°C) for 30 minutes prior to testing.

Can I move the test device while it is running?
Do not move the test after buffer addition and before reading the results.

How long do I have to wait to read the results?
The test results should be read between 10 and 20 minutes after a specimen is applied to the test device. Results read after 20 minutes may give erroneous results.

What happens if buffer is added before the blood sample?
The BIOMERICA COVID-19 IgG/IgM Rapid Test results will be invalid.

What happens if too much or too little buffer is added?
The BIOMERICA COVID-19 IgG/IgM Rapid Test results will be invalid.

What happens if buffer is not added?
The BIOMERICA COVID-19 IgG/IgM Rapid Test results will be invalid.

What happens if too much or too little sample is added?
The BIOMERICA COVID-19 IgG/IgM Rapid Test results will be invalid.

What happens if the sample is not added?
The BIOMERICA COVID-19 IgG/IgM Rapid Test results will be invalid.

Can multiple patients be tested with the BIOMERICA COVID-19 IgG/IgM Rapid Test?
No. The BIOMERICA COVID-19 IgG/IgM Rapid Test has been developed to test one patient only.

How should I dispose of the BIOMERICA COVID-19 IgG/IgM Rapid Test and associated regents?
The BIOMERICA COVID-19 IgG/IgM Rapid Test should be disposed following local regulations for biohazardous waste disposal.

Can I use a test that has expired?
No. The BIOMERICA COVID-19 IgG/IgM Rapid Test should not be used after the expiration date provided.

Interpretation of Results

What is the purpose of the line in the control area "C"?
The line in the control area assures you that the test was run correctly. If no line appears in the control area then the test is invalid and should be repeated

What is considered a valid Test?
The appearance of a pink/red-colored band next to the "C" when results are read at 10 minutes should be considered a valid test.

What is considered an invalid Test?
An absence of a colored band next to the "C" regardless of the appearance of colored band(s) next to "IgM" and/or "IgG" should be considered an invalid test.

Can I read the test when lines appear?
The BIOMERICA COVID-19 IgG/IgM Rapid Test should be read after 10 minutes and before 20 minutes. The test will be invalid if read outside this timeframe.

What happens if the test or control line is broken?
If the lines can be read then the result can be reported as valid.

What happens if there is blood in the test area?

Performance Characteristics

Which cross-reactants have been tested against SARS-CoV-2?
Anti-influenza A virus
Anti-influenza B virus
Anti-RSV
Anti-Adenovirus
HBsAg
Anti-Syphilis
Anti-H. Pylori
Anti-HIV
Anti-HCV

Limitation of Procedure

What are some of the limitations of the Biomerica COVID-19 IgG/IgM Rapid Test?
Please see the Package Insert for limitations of the Biomerica COVID-19 IgG/IgM Rapid Test.

Supplemental Information

Does BIOMERICA provide a quality control?
A procedural control is included in the test. A pink/red colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique.

Can the BIOMERICA COVID-19 IgG/IgM Rapid Test be used as a self-test?
No. The BIOMERICA COVID-19 IgG/IgM Rapid Test is for professional use only.

Is the test CE Marked?
Yes.