FAQ: Frequently Asked Questions

Device: COVID-19 Antigen Rapid Test – Nasopharyngeal Swab (REF 1509A-I)

Sample Type

What type of sample can be used?
Nasopharyngeal swab specimens can be used on the BIOMERICA COVID-19 Antigen Rapid Test.

Can extracted specimens for PCR tests or Viral Transport Media (VTM) be tested?
No. The BIOMERICA COVID-19 Antigen Rapid Test has only been validated with Biomerica's specimen collection tubes with extraction buffer. It has not been validated for use on extracted specimens for PCR test or Viral Transport Media (VTM) specimens.

Can non-human samples be tested?
No. At this time, BIOMERICA has not validated the BIOMERICA COVID-19 Antigen Rapid Test kit with the use of non-Human nasopharyngeal specimens.

Components

Are positive and negative controls supplied with the test kit?
No, positive and negative controls are not supplied with this kit. However, internal procedural controls are included in the test.

Can I interchange lot numbers?
No. The BIOMERICA COVID-19 Antigen Rapid Test 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 Antigen Rapid Test has been validated with the sterilized nasopharyngeal swab, extraction buffer, and specimen collection tubes provided in the kit.

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 specimen collection tube with extraction buffer is leaking or damaged?
Do not use the specimen collection tube with extraction buffer if leakage or damage is observed. Please contact your supplier.

In some of the extraction tubes, the buffer does not seem to be at the bottom of the tube. Is this an issue?
After extraction of the swab, the tube will be recapped and inverted 2-3 times, which will mix the extracted sample with all of the buffer in the tube. However, the tube can be gently tapped on a solid surface 3-5 times to bring the buffer down to the bottom of the tube.

What happens if there appears to be variation in the volume in the specimen collection tube with extraction buffer?
The performance of the test is consistent regardless of any variation in the extraction buffer fill volume, provided that three drops of extracted specimen can be dispensed to the test.

Specimen Preparation and Storage

How far should the swab be inserted into the nostril?
The sterile swab should be inserted into the patient's nostril reaching the surface of the posterior nasopharynx

How many times should you swab?
The posterior nasopharynx should be swabbed at least two times.

How long can freshly collected specimens and extracted specimens be stored?

- **Freshly collected specimens** should be processed as soon as possible, but can be stored for up to one hour at room temperature (15°C - 30°C), prior to extraction.

- **Extracted specimens** should be run immediately, but the extracted specimen is stable for up to 2 hours at room temperature (15°C - 30°C), or 24 hours refrigerated (2°C - 8°C). **DO NOT FREEZE** extracted specimens.

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

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

Do I have to allow the kit reagent to come to room temperature before testing?
If tests have been stored between 2°C - 14°C, allow test device and extraction buffer to reach room temperature (15°C - 30°C) for 30 minutes prior to testing.

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

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

Test Procedure

How does the BIOMERICA COVID-19 Antigen Rapid Test work?
SARS-CoV-2 antibodies are conjugated to latex particles and immobilized on a label pad. The specimen reacts with SARS-CoV-2 antibodies-latex conjugate and then migrates through the membrane via capillary action to react with the antibodies to SARS-CoV-2 coated in the test line region. A pink/red colored band will appear in the test line region, indicating a positive. If the specimen does not contain antigens to SARS-CoV-2, no pink/red colored line will appear at the test line region, indicating 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.)?
The BIOMERICA COVID-19 Antigen Rapid Test detects nucleocapsid protein antigen.

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 applies 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.

Is the BIOMERICA COVID-19 Antigen Rapid Test calibrated against an international standard?

There are currently no international reference standards available for SARS-CoV-2 antigens; however, the test has been evaluated by the German Paul-Ehrlich Institut with standardized antigen panels.

What is the operating temperature of the BIOMERICA COVID-19 Antigen Rapid Test?
The test must be run at 15°C - 30°C. Running the test under 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?
Use the test device within one hour after removing from sealed pouch.

What happens if too little or too much sample is added?
Too little sample (less than 3 drops) can lead to invalid results from an absence of a control line. Too much sample could lead to flooding of the test strip and possibly lead to inaccurate results.

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

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 at 15 minutes after extracted specimen is applied to the test device. Do not interpret results after 20 minutes as it may give erroneous results.

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

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

Interpretation of Results

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

Who can interpret test results?
The test result should be interpreted by a physician or qualified medical professional along with clinical findings and other laboratory test results.

Color-blind operators should not read or interpret 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 with a new test.

What is considered a valid test?
The appearance of a colored band next to the "C" when results are read at 15 minutes should be considered a valid test.

What happens if the test or control line is broken?
If the Control line is visible and the Test line is very light or faint pink, it is considered a positive result.

What is considered an invalid test?
An absence of a colored band next to the "C" regardless of the appearance of a colored band next to the test region should be considered an invalid test.

Can I read the test when lines appear?
The BIOMERICA COVID-19 Antigen Rapid Test should be read after 15 minutes and before 20 minutes. The test result is not valid if read outside this timeframe.

Performance Characteristics

Which cross-reactants have been tested against SARS-CoV-2?
The following potentially cross-reactive microorganisms were tested with the BIOMERICA COVID-19 Antigen Rapid Test without any effect on the expected results:

- Arcanobacterium
- Candida albicans
- Corynebacterium
- Escherichia coli
- Moraxella catarrhalis
- Neisseria lactamica
- Nesseria subllava
- Pseudomonas aeruginosa
- Staphylococcus aureus subspaureus
- Staphylococcus epidermidis
- Streptococcus pneumoniae
- Streptococcus pygenes
- Streptococcus salivarius
- Streptococcus sp group F

The following potentially cross-reactive viral strains were tested with the BIOMERICA COVID-19 Antigen Rapid Test without any effect on the expected results:

Description	Test Level	Description	Test Level
Adenovirus type 3	3.16×10^4 $TCID_{50}$/ml	Influenza A H1N1	3.16×10^5 $TCID_{50}$/ml
Adenovirus type 7	1.58×10^5 $TCID_{50}$/ml	Influenza A H3N2	1×10^5 $TCID_{50}$/ml
Human coronavirus 229E	5×10^5 $TCID_{50}$/ml	Influenza B	3.16×10^6 $TCID_{50}$/ml
Human coronavirus HKU1	1×10^6 $TCID_{50}$/ml	Measles	1.58×10^4 $TCID_{50}$/ml
Human coronavirus NL63	1×10^6 $TCID_{50}$/ml	Mumps	1.58×10^4 $TCID_{50}$/ml
Human coronavirus OC43	1×10^6 $TCID_{50}$/ml	Parainfluenza virus 2	1.58×10^7 $TCID_{50}$/ml
Human rhinovirus 14	1.58×10^6 $TCID_{50}$/ml	Parainfluenza virus 3	1.58×10^8 $TCID_{50}$/ml
Human rhinovirus 16	8.89×10^6 $TCID_{50}$/ml	Respiratory syncytial virus	8.89×10^4 $TCID_{50}$/ml
Human rhinovirus 2	2.81×10^4 $TCID_{50}$/ml		

Limitation of Procedure

What are some of the limitations of the BIOMERICA COVID-19 Antigen Rapid Test?
Please see the Package Insert for limitations of the BIOMERICA COVID-19 Antigen Rapid Test.

Supplemental Information

Does Biomerica provide a quality control?
A procedural control is included in the test. A 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 Antigen Rapid Test be used as a self-test?
No. The BIOMERICA COVID-19 Antigen Rapid Test is for professional use only.

Regulatory Status
On January 12, 2021 Biomerica received CE Mark for its COVID-19 Antigen Rapid Test.

On January 18, 2021 Biomerica fulfilled the criteria to be included on the Bundesinstitut für Arzneimittel und Medizinprodukte, (BfArM) list.

On March 24, 2021 Biomerica fulfilled the criteria to be included on the Paul-Ehrlich Institut list.