SARS-CoV-2 IgG Antibody Detection Kit Instructions
Coronavirus (SARS-CoV-2) IgG Antibody Detection Kit for Finger Prick Samples
Read the instructions carefully before use.
The test should be used within 1 hour after opening. If the ambient temperature is higher than 30 °C, or the test environment is humid, the Detection Cassette should be used immediately.

SAMPLE PREPARATION AND TESTING

- Wash your hands with warm water.
- Select the finger you are going to prick and choose a puncture site off center of the fingertip.
  - Massage and/or shake to stimulate blood flow towards the collection area.
- Clean the collection area and the pipet provided with the alcohol swab (provided in the kit).
- Place the finger with the chosen collection area on a flat surface facing up.
- Twist the cap off the lancet (provided in the kit) and press firmly against the collection site to puncture the finger.

- Create a large drop of blood by applying pressure at the base of the finger and massaging upward
- Squeeze the pipet bulb to expel air
- Draw fingertip blood into the pipet by gently releasing the bulb
- The pipet should be filled just up to the indicated line (refer to the figure at left)
- Take care to avoid bubbles

- Transfer the blood drawn to the Sample Diluent vial
- Mix thoroughly by squeezing the pipet 3 times
• Use the pipet to add 2-3 drops to the release pad section (S) of the Detection Cassette
• The sample should be run as soon as possible after collection per the instruction above
• If there is no movement of the liquid after 30 seconds of beginning the test, 1 additional drop of sample solution should be added.

Step 4

• Set a timer. Wait 8-10 minutes and read the results. Take a clear and well-lit picture of the results. Assure you are as zoomed in and focused as possible with the picture so the photo is clear. If needed, take multiple pictures and submit the one that provides the clearest and most well-lit image.

• Results measured after 20 minutes are invalid.
INTERPRETATION OF TEST RESULTS

| Positive | Negative | Invalid |
|----------|----------|---------|
| ![Image](image.png) | ![Image](image.png) | ![Image](image.png) |

a. **Positive for IgG**: Both the test line (T) and the quality control line (C) are colored. Regardless of the color saturation present of the band on the test line (T), even a weak band should be judged as a positive result.

b. **Negative for IgG**: The test line (T) does not develop color, but the quality control line (C) is colored.

c. **Invalid**: There is no colored control line (C) band. The results are invalid regardless of whether the red band appears on the test line (T); additional testing may be required, please contact the study team for direction.

d. **Please also see the “How to Interpret the Results of Your SARS-CoV-2 Test, and Limitations of the Test” sheet also included in this packet for additional information on the interpretation of the results.**

REPORTING YOUR RESULTS

a. Take a picture of the Detection Cassette with your cellular device or any other device that can capture and store an electronic picture file. Make sure you take the picture 8-10 minutes after you have applied to solution to the cassette. See instruction step 5.0 above for details on getting the best possible picture to share with the study team.

b. Electronically attach the best image of the Detection Cassette result where indicated at the end of the REDCap questionnaire you were provided a link for by the research team. If you are unable to attach the picture to the REDCap database, please reach out to the study coordinator for further guidance.
How to Interpret the Results of Your SARS-CoV-2 Test, and Limitations of the Test

The overall purpose of this study is to help determine the extent to which the community of health care workers at MUSC may develop infection and immunity to SARS-CoV-2 over the course of the current outbreak. The test you have performed is neither approved for nor designed to help you make decisions about your own health. It is not meant to allow you to draw conclusions about your personal prior exposure to SARS-CoV-2 and whether or not you may be immune to infection if exposed in the future.

The test used in this study has been approved for marketing in a laboratory setting and has not been reviewed by the Food and Drug Administration (FDA). This test has not been approved by the FDA for in-home administration or for clinical use. It is not known if past infection with other viruses you may have had could cause a positive result on this test. It is not known whether a mild infection with SARS-CoV-2 would generate enough of an immune response to make this test turn positive.

You are not obligated to share the result of your test with anyone other than the study team. You do not need to share your result with your employer or anyone at work. The results of your test should not be used by you or anyone else to make decisions about your work environment or your risk of future infection with SARS-CoV-2 virus.

If your IgG test is negative, this suggests, but does not prove, that you have not had a prior SARS-CoV-2 infection. It is possible you could have had a mild infection but not generated enough of an immune response to turn the test positive.

If your test is positive, this suggests, but does not prove, that you have had a prior infection caused by SARS-CoV-2. The kit used in this study could detect an immune response to viruses other than SARS-CoV-2, so there is a chance a positive IgG result does not reflect prior infection with SARS-CoV-2. A positive IgG test does not necessarily mean you are immune to future SARS-CoV-2 infection.

This test does not determine whether you may or may not have an active infection with SARS-CoV-2. Some individuals may have an active SARS-CoV-2 infection and have minimal or no symptoms. If you have concern for an active infection or exposure based on either your symptoms or any exposures you may have had at any time during the course of this study, you should follow the current guidance of MUSC Health to determine the steps you should take to be evaluated.

If you have any questions or concerns about this study, please contact the Principal Investigator, Dr. Eric Meissner at 843-792-4541.
Below is the language included in the package insert for this product regarding interpretation of the test:

Limitations of Detection Method:

a. 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.
b. 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.
c. 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.
d. Cross reactivity to other viral antibodies has not been determined (FluA, FluB, HCV, HBV, RSV, etc).
e. The product is designed only for use with human serum or whole blood samples for the qualitative detection of novel coronavirus (SARS-CoV-2).
f. Coronavirus may not be detected even though coronavirus antibodies are present in the sample, leading to a false negative. This may occur if the amount of coronavirus antibodies is below the detection level of the kit. To decrease the chance of obtaining a false negative, it is recommended that both coronavirus IgG and IgM are tested (catalog #CG-CoV-IgG, # CG-CoV-IgM).
g. If the product gets wet prior to use, or is stored improperly, it may cause incorrect results.
Instructions for Proper Disposal of Kit Reagents

Please follow these instructions to properly dispose of all substances associated with the testing kit, including anything that may be soiled with blood. These recommendations are based on the South Carolina Department of Health and Environmental Control guidance for disposal of sharps that have been used for medical procedures. The sticker you will attach to the bleach or detergent bottle you will use for disposal is included in the packet you received. If a bleach or detergent bottle is unavailable, any rigid, leak-proof, puncture-resistant container that is capable of being sealed may be used. Because you may have the opportunity to repeat the testing approximately every 30 days for up to 4 times, you have the option to wait until the end of the study to dispose of the waste container.

The bleach or detergent bottle you use should be discarded in your regular waste and should not be discarded in your recycling bin.

Step 1: Affix sticker to bottle.
Step 2: Place used kit materials in the bottle.
Step 3: Put the cap on the bottle.
Step 4: Secure the cap and throw the bottle into the trash.

VERY IMPORTANT: Always remember to place the warning sticker on bottles!

The bleach or detergent bottle you use should be discarded in your regular waste and should not be discarded in your recycling bin.