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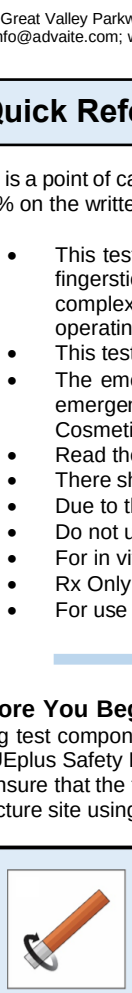
info@advaite.com; www.advaite.com Version 1.1 1/7/2021

Quick Reference Instructions for RapCov™ Rapid COVID-19 Test

This is a point of care test for fingerstick whole blood specimens only. The user should have undergone the 1-hour online training course and demonstrated 100% on the written post course test. Wear appropriate protective attire for your safety when handling patient samples.

- This test has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). Testing of fingerstick whole blood specimens is limited to laboratories certified under CLIA that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- This test has been authorized only for detecting the presence of IgG antibodies against SARS-CoV2, not for any other viruses or pathogens.
- The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Read the complete Quick Reference Instructions before performing the test. For technical assistances, please call 484-842-0220.
- There should be a pink line in the control region (next to “C”) after testing, discard the device and repeat testing if there is no pink line.
- Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG assay
- Do not use after expiration date.
- For in vitro diagnostic use
- Rx Only
- For use under Emergency Use Authorization (EUA) only

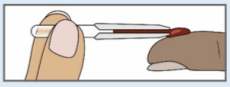
Before You Begin: Refer to the package insert for more information. Read through the entire Quick Reference Instructions before beginning a test. Bring test components shown below to room temperature before starting. Remove the test cassette from the sealed Test Cassette Pouch. Remove the TRUEplus Safety Lancet, MicroSafe® pipette, alcohol swab, and dropper containing buffer solution from the sealed Sample Collector Pouch. Set a timer to ensure that the test is read after 15 minutes. The Health care provider should wash hands and put on gloves. Disinfect the fingerstick site: Cleanse the puncture site using the alcohol pad.



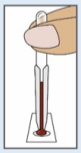
Step 1: Sample Collection
Twist off the tab of the TRUEplus Safety Lancet to break the seal and discard the cap. Please do not directly pull off the protective cap.

Step 2: Sample Collection
Perform the finger-stick using the TRUEplus Safety Lancet. Position the safety lancet firmly against the puncture site as illustrated. Hold lancet between fingers. To activate, press safety lancet firmly against the puncture site.

Step 3: Sample Collection
Let blood drop form. Discard used safety lancet into a sharps container according to your facility’s established procedures.



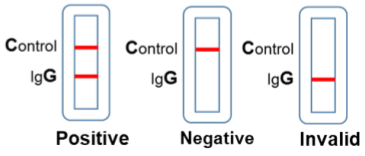
Step 4: Sample Collection
a) Squeeze gently going along finger capillaries up to the puncture site to produce a blood drop on the fingertip.
b) Hold the MicroSafe® pipette horizontally, and touch the tip of the pipette to the blood sample. CAUTION! Never squeeze the tube while sampling. Don't squeeze the bulb; The MICROSAFE® pipette fills by capillary action and will automatically draw the sample to the air vent and it will stop.



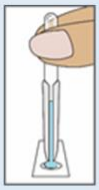
Step 5: Test Cassette Procedure
Align the tip of the MicroSafe® pipette with the sample well on the test cassette and squeeze the bulb of the pipette to expel the blood into the sample well. Allow the blood to absorb entirely into the specimen pad within the sample well.

Step 6: Test Cassette Procedure
Open the buffer dropper by twisting off the top. Hold the buffer dropper vertically and 1 cm (about a width of your fingernail) above the test cassette sample well. Add 2 drops of buffer to the sample well.

Step 7: Test Cassette Procedure
Read the result exactly 15 minutes after adding the buffer to the cassette. Any trace of a pink line in the **rectangular test area window** indicates a positive result. Do not read results after 20 minutes. Discard the test device after recording the test results.



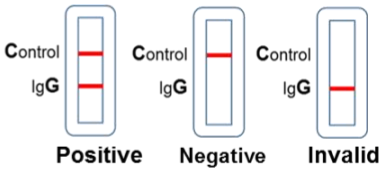
Quick Reference Instructions of RapCov™ Rapid COVID-19 Controls



Step 1: Hold the MicroSafe® pipette vertically above the sample well. Add 1 drop of positive or negative control to the sample well.

Step 2: Open the buffer dropper by twisting off the top. Hold the buffer dropper vertically and 1 cm (about a width of your fingernail) above the test cassette sample well. Add 2 drops of buffer to the sample well.

Step 3: Read the result exactly 15 minutes after adding the buffer to the cassette. Any trace of a pink line in the **rectangular test area window** indicates a positive result. Do not read results after 20 minutes. Discard the test device after recording the test results.



Before You Begin: Refer to the package insert for more information. Read through the entire Quick Reference Instructions before beginning a test. The Health care provider should wash hands and put on gloves. Controls are run in the same manner as specimens. Open the sample collector pouch and remove the RapCov™ Positive Control Container and equilibrate the container to room temperature for 15-20 minutes. Remove the test cassette from the sealed pouch and use it right away. Remove the positive or negative control droppers. Unscrew the cap and use the MicroSafe pipette to draw 10uL of positive or negative control for use in the test cassettes as shown below.

Any suspected occurrence of false positive or false negative results and deviations from the established performance characteristics of the test that you become aware of should be report to reporting@advaite.com