5 Great Valley Parkway, Suite 125, Malvern, PA USA
Telephone: 773-896-8562;
info@advaite.com; www.advaite.com

RapCov™ Rapid COVID-19 Test

Catalogue No. A-RAPCOV01

For Emergency Use Authorization only.
For prescription use only.
For in vitro diagnostic use only.

INTENDED USE

The RapCov™ Rapid COVID-19 Test is a lateral flow immunoassay intended for the qualitative detection of IgG antibodies to the SARS-CoV-2 virus in human fingerstick whole blood samples. The RapCov™ Rapid COVID-19 Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The RapCov™ Rapid COVID-19 Test Device should not be used to diagnose or exclude acute SARS-CoV-2 infection.

Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate, high and 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.

Results are for the detection of SARS CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of the RapCov™ Rapid COVID-19 Test early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for the RapCoV Rapid COVID-19 Test may occur due to cross-reactivity from pre-existing antibodies to other coronaviruses or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different SARS-CoV-2 IgG assay.

Samples should only be tested from individuals that are 15 days or more post symptom onset.

The RapCov™ Rapid COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

INTRODUCTION

The virus named Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), causes the Coronavirus Disease (COVID-19). There has been an outbreak of respiratory disease caused by a COVID-19 virus that was first detected in China. Reported illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, reports suggests serious illness occurs in 20% of cases.

In the RapCov™ Rapid COVID-19 Test, presence of IgG antibodies to COVID-19 virus are determined using fingerstick whole blood. IgG antibodies can generally be detected by this assay after the first two weeks following the onset of symptoms.

PRINCIPLE

The RapCov™ Rapid COVID-19 Test is an immunoassay for the qualitative detection of IgG antibodies to SARS-CoV-2 in human fingerstick whole blood samples. The cassette contains a test strip that is located inside a plastic housing. When the sample and sample buffer are loaded onto the sample well, the specific IgG antibodies to SARS-CoV-2 flow through the membrane and move to the test line area and are captured by antibodies immobilized on the membrane, respectively. The antigen (Recombinant SARS-CoV-2 Nucleocapsid Protein) is conjugated to colloidal gold nanoparticles and the antigen-gold conjugate moves to the test line area and attaches to the specific IgG antibodies to SARS-CoV-2. This leads to the generation of a pink colored band. The user interprets test results by eye, according to the instructions for use. A procedural control is included to indicate that the assay has been performed correctly and is valid.

KIT COMPONENTS

Each kit contains the following components in sufficient quantities to perform the number of tests indicated on the package label.

- 25 x Test Cassette Pouches. *Each pouch contains one test cassette.*
- 25 x Sample Collector Pouches. *Each pouch contains one TRUEplus Pressure-Activated Safety Lancet (28G Needle, 1.6 mm Depth, Single Drop), one MicroSafe® pipette, one alcohol swab, and one dropper containing buffer solution.*
- 1 x Instructions for Use.

MATERIALS REQUIRED BUT NOT SUPPLIED

- Timer
- Gloves

STORAGE AND SHELF LIFE OF REAGENTS

1. The RapCov™ Rapid COVID-19 Test can be shipped and distributed under room temperature.
2. The shelf life of RapCov™ Rapid COVID-19 Test is 8 months at 2-37°C.Do not freeze kit components.
3. If stored at 2-8˚C, ensure that the kit is brought to 15-30˚C before opening.
4. The test kit may be used until the expiry date marked on the package label.

REPORTING

The RapCov™ Rapid COVID-19 test does not produce an actual test report. The testing laboratory or health care workers at point-of-care must include the test result information in their report.

WARNING AND PRECAUTIONS

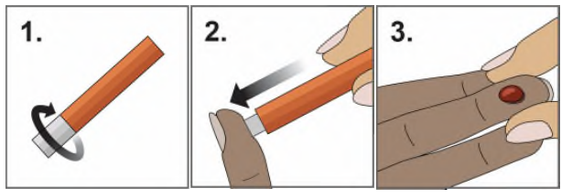
1. Test cassettes are single use only. Do not reuse test cassettes.
2. For prescription use only. For use under Emergency Use Authorization only. For IN VITRO Diagnostic use only.
3. This test has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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.
4. This test has been authorized only for detecting the presence of IgG antibodies against SARS-CoV2, not for any other viruses or pathogens.
5. 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.
6. All human blood products should be handled as potentially infectious material. The Centers for Disease Control and the National Institutes of Health recommend that potentially infectious agents be handled at Biosafety Level 2.
7. Never pipette by mouth or allow reagents or patient sample to come into contact with skin.
8. Optimal results will be obtained by strict adherence to this protocol. Reagents must be added carefully to maintain precision and accuracy.
9. Performing the assay outside the prescribed time and temperature ranges may produce invalid results. Assays not falling within the established time and temperature ranges must be repeated.
10. The components in this kit have been quality control tested as a master lot unit. Do not mix components from different lot numbers. Do not mix with components from other manufacturers.
11. Care should be exercised to protect the reagents in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.
12. Do not heat-inactivate samples.
13. Keep storage boxes dry.
14. Do not use test cassettes if foil pouch is punctured or damaged.
15. Testing materials should be disposed of in accordance with local, state and/or federal regulations.
16. Do not use after expiration date.

SPECIMEN COLLECTION AND PREPARATION

Blood sample is obtained by fingerstick using TRUEplus Safety Lancet and collected using MicroSafe® pipette.

1. **TRUEplus Safety Lancet Procedure for Fingerstick**
   a) The health care provider should wash hands thoroughly and put on gloves
   b) The health care provider should select the fingerstick site: The patient should be sitting or lying down. Have patient hold their hand in a downward position, allowing gravity to help increase blood supply to the hand. Selection of the finger: middle or ring finger is preferable. The fifth finger must not be punctured because the tissue depth is insufficient to prevent bone injury.
   c) Disinfect the fingerstick site: Cleanse the puncture site using an

alcohol pad or according to your facility's established procedure.

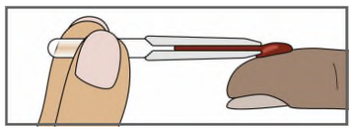


Step 1: Twist off the tab of the lancet to break the seal and discard the cap. Please do not directly pull off the protective cap.
Step 2: Perform the puncture. Position the safety lancet firmly against the puncture site as illustrated. Hold lancet between fingers. To activate, press safety lancet firmly against the puncture site.
Step 3: Let blood sample form. Discard used safety lancet into a sharps container according to your facility's established procedures.

2. **Procedure for Collecting Blood Specimen Using MicroSafe® pipette**

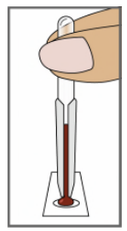
a) Squeeze gently going along finger capillaries up to the puncture site to produce a blood drop on the fingertip.

b) Hold the tube horizontally, and touch the tip of the MICROSAFE® Tube to the blood sample. Capillary action will automatically draw the sample to the air vent and it will stop.



CAUTION! Filling is automatic: Never squeeze the tube while sampling.
Don't squeeze the bulb; MICROSAFE® fills by capillary action.

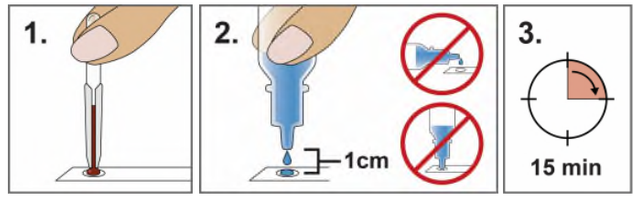
c) To Expel the sample, align the tip of the tube with the sample target and squeeze the bulb. If a sample won't expel, you probably didn't allow for the tube to fill all the way. Touch the tip of the blood sample again and allow it to fill completely. Then align the tip with the sample and squeeze the bulb.



ASSAY PROCEDURE:

NOTE: Ensure all reagents are equilibrated to room temperature (20-25°C) before commencing the assay.
Remove the cassette and buffer dropper from the pouch just prior to use.

1. Add whole blood to the **oval sample well (S)** using the MicroSafe® pipette. Allow the sample to absorb entirely into the specimen pad within the sample well.
2. Open the buffer dropper by twisting off the top. Hold the buffer dropper vertically and 1 cm above the **oval sample well (S)**. Add 2 drops of buffer to the sample well.
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.



QUALITY CONTROL

1. Whole blood samples may cause a red background to appear in the viewing window. If this is not masking the test line, the result remains valid.
2. Quality Control (QC) requirements must be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard QC procedures.
3. A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. The test is invalid and should be repeated if the control line does not appear. If the test is invalid, patient results cannot be reported.
4. Control Materials are not supplied with this kit. The RapCov™ Rapid COVID-19 Test External Controls should be purchased from Advaite Inc. (Cat no: C-RAPCOVPOS01 and C-RAPCOVNEG01). External positive and negative controls should be tested to ensure the proper performance of the assay, particularly under the following circumstances:
   - A new operator uses the kit;
   - A new lot of test kits is used;
   - A new shipment of kits is used;
   - To investigate the cause of repeated invalid results;
   - The temperature used during storage of the kit falls outside of 2-30°C

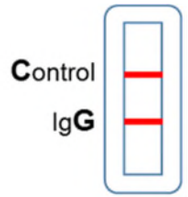
TROUBLESHOOTING GUIDE

PROBLEM	POSSIBLE CAUSE	SOLUTION
Sample does not flow along the viewing window	Insufficient buffer	- Ensure bottle is vertical when adding drops and not in contact with the well. - When dispensing, hold bottle 1cm above the well.
Blood obscuring test window	Blood not absorbed into specimen pad in the well	- Ensure sample is absorbed entirely into material prior to buffer addition. This can take up to 30 seconds
MicroSafe® pipette not functioning	Squeezing bulb when filling Incorrect angle of pipette when filling	- Do not squeeze bulb when filling. Only squeeze the bulb to expel the sample. - Hold pipette horizontally when filling.

INTERPRETATION OF RESULTS

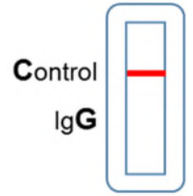
RESULTS IN THE RECTANGULAR TEST AREA WINDOW

Control: (Top line) **IgG: (**Bottom line)



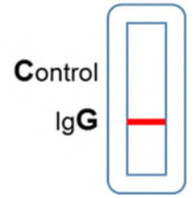
Positive Test

Pink bands appear in the **C**ontrol (top line) and Ig**G** (bottom line). The test is **positive** for IgG antibodies to SARS-CoV-2.



Negative Test

Pink bands appear in the **C**ontrol (top line) only. IgG antibodies to SARS-CoV-2 were not detected.



Invalid Test

No pink band appear in the **C**ontrol (top line). The test is **invalid** and should be repeated.

TEST LIMITATIONS

1. For use under an Emergency Use Authorization Only.
2. The test is for in vitro diagnostic use only.
3. For prescription use only
4. This test is not to be used in at-home testing settings.
5. The test is for qualitative detection of SARS-CoV-2 IgG antibody in human fingerstick whole blood and does not indicate the quantity of the antibodies. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.
6. The test results should be interpreted between 15 and 20 minutes after addition of buffer. The test results should not be interpreted after 20 minutes.
7. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. The sensitivity of the RapCov™ Rapid COVID-19 Test IgG early after infection is unknown. False positive results for IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. False 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.
8. A negative result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or if the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody used in the test.
9. Testing with a molecular diagnostic should be performed to evaluate symptomatic patients for acute SARS-CoV-2 infection, particularly in those who have been in contact with the virus.
10. Results from antibody testing should not be used to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

11. A. positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response. 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.
12. It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection.
13. Not for the screening of donated blood.
14. Serological cross-reactivity across the Coronavirus group has not been tested.
15. Samples should only be tested from individuals that are 15 days or more post symptom onset.
16. The performance of this device has not been established in individuals that have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this assay should not be interpreted as an indication or degree of protection from infection after vaccination.
17. The performance of this test was established based on the evaluation of a limited number of clinical specimens. The specimens for the negative agreement studies were collected at two sites in the USA, in April 2020 in Florida (Delray Beach and Boca Raton, and tested for serologic reactivity – study A), and in March 2021 in Chicago (study B), and tested negative by RT-PCR. The specimens for the positive percentage agreement were also collected from the same two locations in the USA, in the same time frame as the negative specimens, April 2020 in Florida and March 2021 in Chicago. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

CONDITIONS OF AUTHORIZATION FOR LABORATORIES

The RapCov™ Rapid COVID-19 Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website:

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

Authorized laboratories[1] using the RapCov™ Rapid COVID-19 Test Letter of Authorization ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

- Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Advaite Inc.(email: reporting@advaite.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use this product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
- Advaite Inc., authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

PERFORMANCE EVALUATION DATA

Clinical Performance Evaluation study A

a. Methodology: The evaluation was performed in US using fingerstick whole blood specimens (n=30) from patients who had COVID-19 disease confirmed by an EUA-authorized RT-PCR test. Fingerstick whole blood samples presumed to be negative (n=104) were obtained from healthy subjects. Fingerstick whole blood samples were tested using RapCov™ Rapid COVID-19 Test per the manufacturer's Instruction for Use (IFU). Positive RapCov™ Rapid COVID-19 test was defined as presence of IgG COVID19 antibodies.

b. Results: Positive Percent Agreement (PPA) was 90% with RT-PCR positive SARS-CoV-2 infection status and Negative Percent Agreement (NPA) was 95.2%.

Table 1

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
IgG	Sensitivity (PPA)	90.0% (27/30)	(73.6%; 97.3%)
IgG	Specificity (NPA)	95.2% (99/104)	(89.2%; 97.9%)
IgG	PPV at Prevalence = 5%	49.7%	
IgG	NPV at Prevalence = 5%	99.5%	

When estimating the sensitivity of IgG over time from symptom onset for all positive samples, the proportion of IgG positive patients was 90% approximately 15 days after symptom onset.

Table 2. The sensitivity estimates for IgG over time

# Days after PCR testing*	Number of PCR positive samples	IgG Antibody Test Result	Positive Percent Agreement
		IgG+	IgG
<7 days	0	0	N/A
7-14 days	0	0	N/A
≥ 15 days	30	27	90%
Total	30	27	90% CI (73.6%; 97.3%)

Clinical Performance Evaluation study B

a. Methodology: The evaluation was performed in US using fingerstick whole blood specimens (n=30) from patients who had COVID-19 disease confirmed by an EUA-authorized RT-PCR test. Fingerstick whole blood samples presumed to be negative (n=30) were obtained from healthy subjects. Fingerstick whole blood samples were tested using RapCov™ Rapid COVID-19 Test per the manufacturer's Instruction for Use (IFU). Positive RapCov™ Rapid COVID-19 test was defined as presence of IgG COVID19 antibodies.

b. Results: Positive Percent Agreement (PPA) was 93.3% with RT-PCR positive SARS-CoV-2 infection status and Negative Percent Agreement (NPA) was 100%.

Table 3

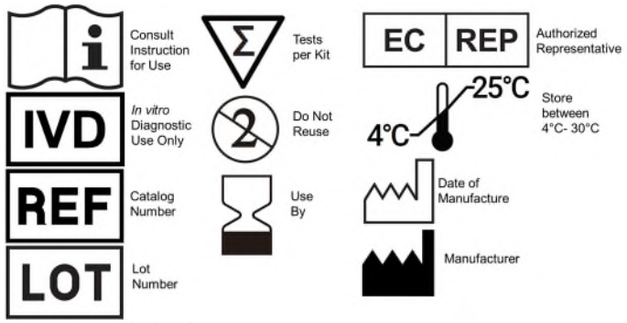
Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
IgG	Sensitivity (PPA)	93.3% (28/30)	(78.7%; 98.2%)
IgG	Specificity (NPA)	100% (30/30)	(88.6%; 100%)
IgG	PPV at Prevalence = 5%	100%	
IgG	NPV at Prevalence = 5%	99.6%	

Table 4. The sensitivity estimates for IgG over time

# Days after PCR testing*	Number of PCR positive samples	IgG Antibody Test Result	Positive Percent Agreement
		IgG+	IgG
<7 days	0	0	N/A
7-14 days	0	0	N/A
≥ 15 days	30	28	93.3%
Total	30	28	93.3% CI (78.7%; 98.2%)

When estimating the sensitivity of IgG over time from symptom onset for all positive samples, the proportion of IgG positive patients was 93.3% approximately 15 days after symptom onset.

[1] The letter of authorization refers to authorized laboratories as the following: Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, 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.



Important limitations:

1. Samples were not randomly selected, and sensitivity and specificity estimates may not be indicative of the real-world performance of the device
2. These results are based on serum and ACD plasma samples only and may not be indicative of performance with other sample types, such as whole blood, including finger stick blood.
3. The number of samples in the panel is a minimally viable sample size that still provides reasonable estimates and confidence intervals for test performance, and the samples used may not be representative of the antibody profile observed in patient populations.

Cross-Reactivity Evaluation

a. Methodology: A cross-reactivity evaluation was performed using human serum specimen from patients who had human coronavirus OC43 infection (n=14). Serum samples of patients who had high priority organisms were obtained and cross-reactivity experiments performed. Serum samples containing antibodies to the following viruses were obtained: (i) Influenza A; (ii) Influenza B; (iii) anti-HBV; (iv) anti-HCV; (v) Antinuclear antibodies (ANA); (vi) Haemophilus Influenzae; (vii) Rhinovirus; (viii) anti-respiratory syncytial virus; and (ix) anti-HIV.

Virus/Bacteria/Parasite Antibody positive	Number of unique samples	Cross reactivity Results
Influenza A	5	Negative
Influenza B	5	Negative
anti-HBV	5	Negative
anti-HCV	5	Negative
Antinuclear antibodies (ANA)	5	Negative
Haemophilus Influenzae	5	Negative
Rhinovirus	5	Negative
anti-respiratory syncytial virus	3	Negative
anti-HIV	5	Negative
anti-OC43 (beta coronavirus)	14	one (7%) tested positive for IgG

b. Results: Thirteen (93%) OC43 samples tested negative for IgG, thus showing minimal cross-reactivity with coronavirus OC43 infection. Serum specimen from all tested high priority organisms (Influenza A, influenze B, anti-HBV, anti-HCV, ANA and Haemophilus Influenzae, Rhinovirus, anti-respiratory syncytial virus, and anti-HIV) were negative. Thus, no crossreactivity was observed with the tested high priority organism serum specimens.

INQUIRIES AND GENERAL INFORMATION

Please visit the Advaite website www.rapcov.com

ORDERING

Contact Advaite's distributors or Contact Advaite via email: info@advaite.com

TECHNICAL

Via email: info@advaite.com