FACT SHEET FOR HEALTHCARE PROVIDERS

What is COVID-19 Disease?
There has been an outbreak of respiratory disease caused by a novel coronavirus that was first detected in China. The virus named Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), also known as "the COVID-19 virus", causes the Coronavirus Disease (COVID-19). The WHO declared COVID-19 disease to be a pandemic in early March. Reported illnesses have ranged from very mild (including some with no reported symptoms) in the majority of the cases (80%) to severe in 20% cases, including illness resulting in death (in 1-4% cases). The virus that causes COVID-19 is thought to spread mainly from person to person, mainly through respiratory droplets.

What do I need to know about COVID-19 testing?
There is no single 'Gold Standard' for the diagnosis of COVID-19 infection. The different diagnostic methodologies provide different information regarding COVID-19 infection and a complete clinical picture is made possible by using information provided by all testing methodologies.

Molecular Testing for COVID-19
COVID-19 disease diagnosis can be made during incubation period and first week of the disease since onset of symptoms by detecting the virus nucleic acid using RT-PCR performed on a nasopharyngeal swab.

Serological Testing for COVID-19
In the first week after the onset of symptoms and viremia, IgM antibodies appear in the blood as the initial immune response to the primary COVID-19 virus infection. These IgM antibodies may become undetectable subsequently. IgG antibodies appear in the blood after the first week of the disease and IgG antibody titers remain elevated as immunological memory.

RapCov™ COVID-19 Rapid Test is a serological test for the qualitative detection and differentiation of IgG antibodies to the COVID-19 virus in human whole blood fingerstick samples.

What is the ADVAITE RapCov™ COVID-19 Rapid Test?
Proprietary Name: RapCov™ COVID-19 Rapid Test
Established Name: qSARS-CoV-2 IgG Rapid Test

Intended Use: RapCov™ COVID-19 Rapid Test is a lateral flow immunochromatographic assay intended for the presumptive qualitative detection of IgG antibodies to the SARS-CoV-2 in fingerstick whole blood from individuals who are suspected of COVID-19 virus exposure. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate and high complexity tests and/or by healthcare workers at the point-of-care, and is not recommended for at home testing. This test 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 is only for use under the Food and Drug Administration's Emergency Use Authorization (EUA).

When the FDA authorizes point of care tests under an EUA, such tests are deemed to be CLIA waived tests. Accordingly, for the duration of the emergency declaration, such tests can be performed in a patient care setting that is operating under a CLIA Certificate of Waiver. Such settings include hospitals, physician offices, urgent care, outreach clinics, and temporary patient care settings that have appropriately trained personnel to perform the test.

Examination and Interpretation of Patient Specimen Results: The RapCov™ COVID-19 Rapid Test must be performed as decribed in the Instructions For Use (IFU) document. Assessment of clinical specimen test results should be performed after the internal control has been examined and determined to be valid and acceptable. If the internal control is not valid, the patient results cannot be interpreted.

To use the RapCov™ COVID-19 Rapid Test, the device cassette, specimen, and buffer solution are allowed to equilibrate to room temperature.

Fingerstick whole blood specimen (10 µL) is transferred to the center of the sample well. After the sample well is free of liquid, two drops of Buffer are then added to the sample well. Wait for fifteen minutes and read the test results. Results are not to be read after twenty minutes. Positive Result occurs when a pink colored band appears at both the IgG Test Line (G) and Control Line (C) and indicates that antibodies against SARS-CoV-2 are present (IgG); and. A Negative Result occurs when a colored band appears at Control Line (C) only and indicates that antibodies against SARS-CoV-2 were not detected. An Invalid Result occurs when no colored band occurs at Control Line (C) and the test should be repeated.

Table 1	**Test Lines**		**Test Result**
Status	**(G)** IgG	**(C)** Control	
1	(+)	(+)	Positive
2	(-)	(+)	Negative
3	(+)	(-)	Invalid

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.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Risks to a patient of a false negative result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

Positive results are presumptive and must be confirmed by virus isolation or viral nucleic acid detection by RT-PCR for confirmation of COVID-19 virus infection. 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.

What is an Emergency Use Authorization (EUA)?

The United States (U.S.) FDA has made this test available under an emergency access mechanism called an EUA. EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of in vitro diagnostics, unless revoked.

Where can I go for updates and more information?

ADVAITE, Inc.
5 Great Valley Parkway
Suite 125,
Malvern, PA 19355
Contact email: info@advaite.com
Product Website: www.RapCov.com
Corporate Website: www.advaite.com

CDC webpages:

CDC COVID-19 Guidance for Healthcare Professionals
https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html

COVID-19 Frequently Asked Questions (FAQs)
https://www.cdc.gov/coronavirus/2019-ncov/faq.html

FDA webpages:

FDA guidance document for Notification and EUA
https://www.fda.gov/media/135659/download

FDA FAQs on Diagnostic Testing for COVID-19 virus Disease
https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2