Frequently Asked Questions (FAQs)

1. **What is Advaite?**
    a. Advaite Inc. is a Malvern, PA headquartered biotechnology company focused on developing novel diagnostics and therapeutics to help patients' suffering from debilitating diseases. The team at Advaite consists of industry veterans from Pfizer, GSK and Merck along with scientists with respected backgrounds across immunology, virology and molecular biology encompassing top academia institutions and dozens of publications. Advaite currently has a state-of-the art R&D facility located in Malvern, PA; supporting the full scale development of diagnostics and small molecule therapeutics from feasibility until commercialization and scale-up manufacturing. Advaite also has a presence in Chicago, IL at the UIC Laboratory Incubator Facility operating as a high complexity CLIA laboratory (CLIA #14D2191276), aiding in the high throughput testing of COVID-19 and other diseases using FDA authorized devices.

2. **What is the RapCov™ COVID-19 Rapid Test?**
    a. The RapCov™ Rapid COVID-19 Test is a lateral flow immunochromatographic assay for the presumptive qualitative detection of IgG antibodies to the COVID-19 virus in human whole blood fingerstick samples. When present in the patient sample, COVID-19 specific IgG antibodies bind to anti-human antibodies (IgG) immobilized in a line across the RapCov™ cassette membrane. Colloidal gold complexes containing recombinant COVID-19 nucleocapsid antigens are captured by the patient's IgG antibodies to give a visible pink line. A procedural control is included to indicate that the assay has been performed correctly and is valid.

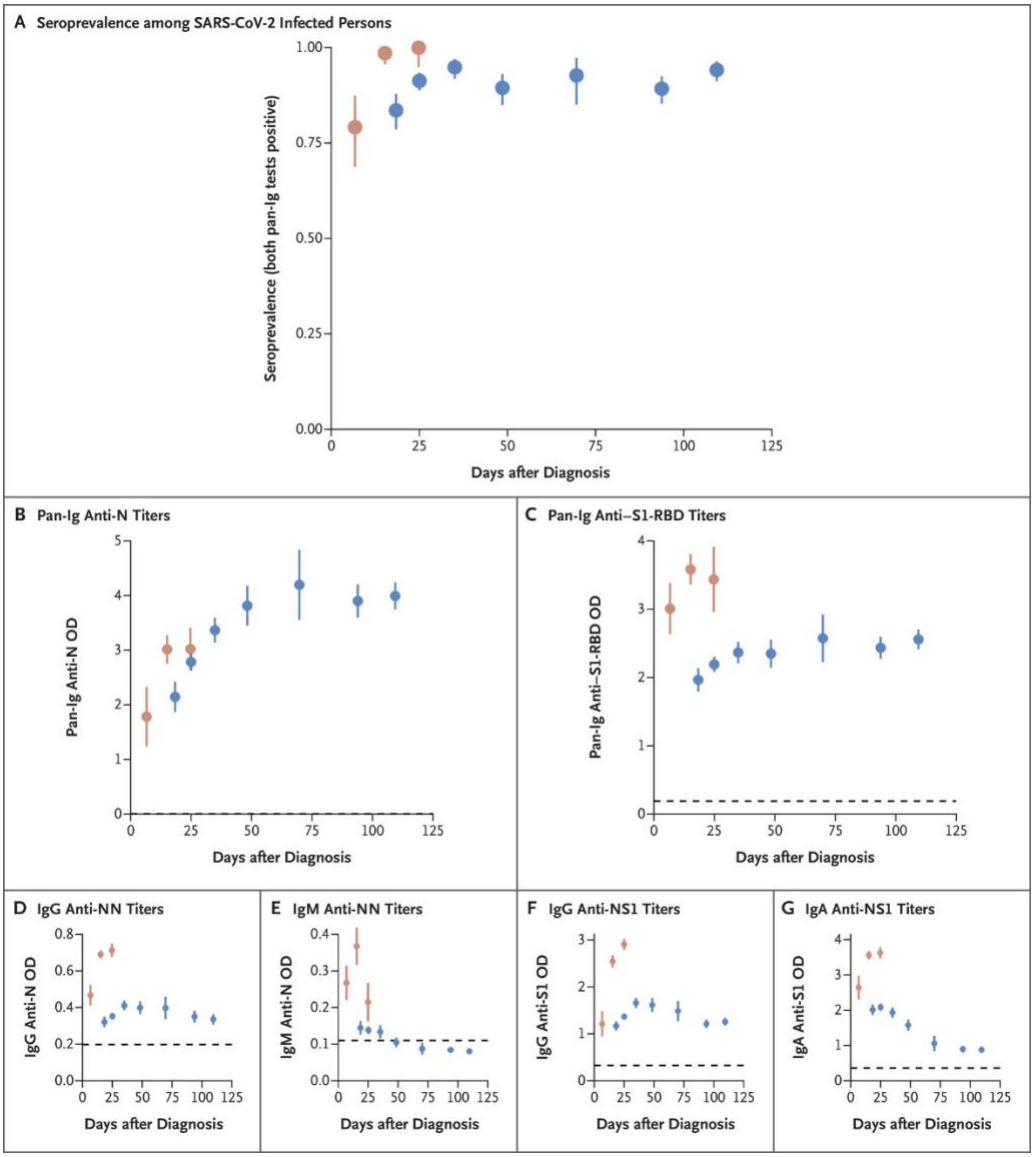
3. **What is the importance of a COVID-19 Antibody Test that can detect IgG antibodies in fingerstick blood?**

    a. Nearly all immunocompetent individuals will develop an immune response following SARS-CoV-2 infection. Like infections with other pathogens, SARS-CoV-2 infection in humans elicits development of various types of antibodies including IgM and IgG antibodies, which are the most useful for assessing antibody response.

    Antibodies in some infected persons can be detected within the first week of illness onset. In SARS-CoV-2 infections, IgM and IgG antibodies can arise nearly simultaneously in serum within 2 to 3 weeks after illness onset. Thus, detection of IgM without IgG is uncommon. How long IgM and IgG antibodies remain detectable following infection is not entirely known. It is also important to note that some infected persons do not develop detectable IgG or IgM antibodies

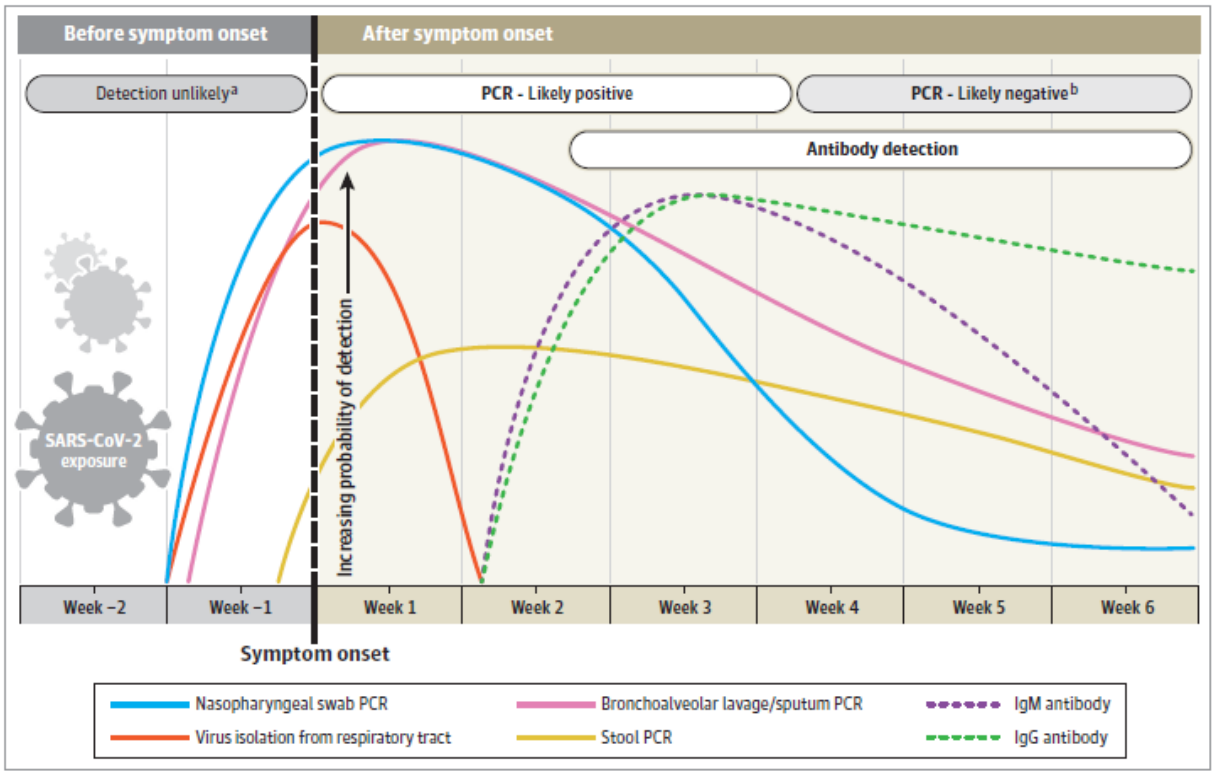
following infection. Thus, the absence of detectable IgM or IgG antibodies does not necessarily rule out that they could have previously been infected.

A recent study on 30,576 persons evaluating the humoral immune response in Iceland indicated that antiviral antibodies against SARS-CoV-2 did not decline within 4 months after diagnosis. [1] Specifically, IgG antibody levels increased during the first 6 weeks after diagnosis; while IgM antibody levels increased rapidly soon after diagnosis and then fell rapidly and were not detected after 2 months.



Detection of SARS-CoV-2 Infection Relative to Symptom Onset [2] (Green Line = IgG)

Figure. Estimated Variation Over Time in Diagnostic Tests for Detection of SARS-CoV-2 Infection Relative to Symptom Onset



Estimated time intervals and rates of viral detection are based on data from several published reports. Because of variability in values among studies, estimated time intervals should be considered approximations and the probability of detection of SARS-CoV-2 infection is presented qualitatively. SARS-CoV-2 indicates severe acute respiratory syndrome coronavirus 2; PCR, polymerase chain reaction.

[a] Detection only occurs if patients are followed up proactively from the time of exposure.

[b] More likely to register a negative than a positive result by PCR of a nasopharyngeal swab.

High titers of IgG antibodies have been shown to positively correlate with neutralizing antibodies.[3]

[1] Alter Galit, Seder Robert. (2020) The Power of Antibody-Based Surveillance. N Engl J Med DOI: 10.1056/NEJMe2028079.

[2] JAMA. 2020;323(22):2249-2251. doi:10.1001/jama.2020.8259

[3] To KK-W, Tsang OT-Y, Leung W-S, et al. Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. *Lancet Infect Dis.* 2020;20(5):565-574. doi:10.1016/S1473-3099(20)30196-1

b. See more benefits and references here: https://rapcov.com/covid-19-virus-disease/

4. **Is the RapCov™ COVID-19 Rapid Test FDA approved?**
    a. **RapCov™ COVID-19 Rapid Test is currently under review by US Food and Drug Administration (FDA).** As of September 11, 2020, Advaite has completed the FDA's notification process for the RapCov™ COVID-19 Rapid Test, allowing distribution of the test under CLIA to laboratories certified to perform high complexity testing, and at the point-of-care when covered by the laboratory's CLIA certificate for high-complexity testing. Advaite's product is listed on FDA's website under the FAQs for Section IV.D https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2 (See "What Laboratories and Manufacturers are Offering Tests for COVID-19?", Question 6 – What commercial manufacturers are distributing serology test kits under the policy outlined in Section IV.D of the Policy for Coronavirus Disease-2019 Tests? (Updated 9/10))

    b. As stated in Section IV.D of the FDA's Policy for Coronavirus Disease-2019 Tests, the FDA does not intend to object to a commercial manufacturer's development and distribution of serology tests to identify antibodies to SARS-CoV-2 for a reasonable period of time, where the test has been validated and while the manufacturer is preparing its EUA request, where the manufacturer gives notification to the FDA and information that helps users and patients understand the test results, such as the following, is included in the instructions for use:

        i. This test has not been reviewed by the FDA.
        ii. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.
        iii. Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection.
        iv. 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.

    c. Advaite Inc. is currently awaiting final Emergency Use Authorization (EUA) under Submission **EUA#202686**, for its RapCov™ COVID-19 Rapid Test for the following intended use to include at the Point-of-Care (PoC) CLIA-Waived setting:
        i. The RapCov™ COVID-19 Rapid Test is intended for use as an aid in identifying individuals with an adaptive or acquired immune response to SARS-CoV-2, indicating recent or prior infection. Adaptive immune responses are highly specific to the particular virus such as SARS-CoV-2 that induced them. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. 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.

ii. As of September 11, 2020; no serology test has been authorized by the FDA for use at the Point-of-Care (PoC) CLIA-Waived setting.

5. **How accurate is the RapCov™ COVID-19 Rapid Test?**
   a. Advaite completed independent, third-party run, protocol driven studies **in the United States on US subjects** in order to assess sensitivity, specificity, overall accuracy and cross-reactivity. See: https://rapcov.com/clinical-studies/ for more information.
      i. Methodology: The evaluation was performed in US using fingerstick whole blood specimen (n=30) from patients who had COVID-19 disease confirmed with molecular analysis. Control fingerstick blood samples (n=99) were obtained from healthy subjects confirmed to be antibody negative. Fingerstick whole blood samples were tested using RapCov™ Rapid COVID-19 Test per the manufacturer's Instruction for Use (IFU). Positive RapCov™ test was defined as presence of IgG COVID19 antibodies.
      ii. Results: Positive Percent Agreement (PPA) was 90% with RT-PCR positive COVID-19 virus infection.and Negative Percent Agreement (NPA) was 100%.
      iii.

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
IgG	Sensitivity (PPA)	90.0% (27/30)	(73.6%; 97.3%)
IgG	Specificity (NPA)	100.0% (99/99)	(95.5%; 100.0%)
IgG	PPV at prevalence = 5%	100.0%	
IgG	NPV at prevalence = 5%	99.5%	

6. **Where are the RapCov™ COVID-19 Rapid Tests manufactured?**
   a. The start to finish manufacturing and final release of the RapCov™ COVID-19 Rapid Test is all done in Pennsylvania, USA at local sites in the Philadelphia region. Advaite uses a reputable, well established CMO named Frontida Biopharm Inc. (based in Philadelphia, PA) to manufacture, package and release final product from their GMP facility. Advaite manufactures all bulk substance in-house including recombinant protein out of Malvern, PA. A majority of the RapCov™ test kits components are US based, including the MicroSafe pipettes, lancets and other raw materials that make up the composition of each test. The personnel involved in the commercial production of the RapCov™ test kits include many bioengineers, molecular biologists, and biochemists with advanced training and years of skillset working in assay development.