WHITE PAPER

When You Need to Know: Why Qorvo Biotechnologies Omnia Platform Is a Better Fit for COVID Testing

Summary

COVID-19 is transitioning to an endemic state where testing for this disease must be simplified to catch outbreaks as soon as possible. Organizations can no longer wait for complicated molecular tests and the length of time it takes to get a result. The endemic state of the virus demands the speed and simplicity of antigen-based point-of-care tests that deliver quick results. Unfortunately, not all tests are created equal. With current circulating variants, many rapid antigen tests can only correctly identify the presence of the virus 60% of the time requiring testing on multiple days for true confirmation, eliminating their advantages[1]. Beyond the above, recent safety announcements were made by the FDA that highlight the concerns for at-home rapid antigen tests going forward[2].

On-site or non-home-based testing solutions therefore require a different solution. The Qorvo Biotechnologies Omnia SARS-CoV-2 Antigen Test provides the solution for excellent performance in a fast turnaround test healthcare professionals are seeking. Omnia is optimized for low viral load detection similar to that of molecular PCR platforms. Combined with 100% specificity (zero false positives over 1,000 samples across four separate clinical trials), simplicity, speed and ease of use, Omnia delivers a cost effective and reliable solution compared to alternatives.

- **High Sensitivity and Specificity** – Low viral load detection similar to molecular PCR with zero false positives combined with Antigen's ease of use.
- **Unaffected by new variants** – Able to detect all current and historical variants with infrastructure to predict and analyze impact on performance for all future variants.
- **Convenient** – The Omnia is configured for fully automated data management capable of storing patient results for review at your convenience.
- **Simple and Effective** – The Omnia is a simple three step workflow that goes from sample to answer in about 20 minutes all in a very competitively priced platform with many future applications.

Below we share the most recent Qorvo Biotechnologies' Omnia testing system data showcasing the unique capabilities of the bulk acoustic wave (BAW) sensor technology that was recently used as part of the FDA authorization (EUA) for use at the point-of-care (i.e., use in CLIA waived settings). The Qorvo Omnia SARS-CoV-2 Antigen Test was authorized for the qualitative detection of nucleocapsid viral antigens from SARS-CoV-2 (COVID-19) in nasal swab specimens from individuals who are suspected of COVID-19 within six days of symptom onset. The test is also authorized for individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days, with at least 24 hours and no more than 48 hours between tests. This EUA significantly expands the use of the Omnia beyond laboratories to include physician offices, urgent care centers, retail pharmacies, employee health testing and any other locations where CLIA waived tests can be performed.

1. Add Sample

2. Insert Cartridge

3. Report Results

Omnia Testing System – Innovation Sponsored by RADx/NIH

The Omnia system is a small footprint, benchtop instrument that requires no additional hardware to operate. The easy-to-use touch screen allows addition of all patient data either manually or through a supported barcode reader. With its simple three step process, you can go from sample to cartridge to the Omnia in less than three minutes of hands-on time. A single operator can run multiple instruments with no need to monitor results in real time. Unlike other antigen tests where results may become unreadable over time, Omnia allows technicians to conduct other work while results are analyzed and uploaded to a desired location for follow on review.

The Qorvo Omnia SARS-CoV-2 Antigen Test utilizes a sandwich immunoassay format whereby two sensors are activated on the device surface; one with mouse monoclonal antibodies to the SARS-CoV-2 nucleocapsid protein; the second with a nonspecific reference antibody that allows for increased low-end sensitivity through common mode rejection. The SARS-CoV-2 assay additionally uses enzymatic signal enhancement, during which insoluble precipitate amplifies the signal; enzymatic signal enhancement is a critical product design aspect that allows for low viral load detection unachievable by most standard lateral flow assays. All reagents are contained on the test cartridge and actuated by the Qorvo Omnia instrument eliminating the need to handle reagents that could otherwise accidentally cause contamination or errant results. These capabilities combined with Qorvo's BAW technology were the defining characteristics that convinced the NIH to select Omnia for funding through the highly competitive RADx initiative selection process.

Following a nasal swab collection, the swab is immersed into a lysis buffer to release antigen present in the sample. The processed sample is simply deposited directly into the sample port on the test cartridge. The test cartridge is inserted into the Omnia instrument. Total time from inserting the test cartridge into the instrument to result generation is approximately 20 minutes.

The Difficulty of Lateral Flow

A very common type of COVID-19 antigen testing is based on lateral flow technology, these tests are common in POC settings and are generally available over the counter (OTC). Lateral flow is not a new technology, in fact it's been used consistently in home pregnancy tests for decades, and this historical usage has also demonstrated the potential pitfalls in this technology as a frontline method. At its core, lateral flow is a very simple technology, the test strip is a pad made from several layers of specifically absorbent materials that has the capacity to transport fluid spontaneously when saturated to a certain degree. At various points on the pad are areas of immobilized antibodies bound to molecules that when released change color when bound to a specific target antigen being analyzed. The pad contains all the necessary reagents to support this reaction.

This simplicity supports quick, inexpensive, and easy to use tests, but also creates drawbacks. With these tests it is often difficult to gauge if you have used the correct amount of sample, with too much or too little potentially creating imprecise results, even false negative results (i.e., missing a COVID positive sample). More importantly, lateral flow technology's greatest weakness is its one step format that does not utilize enzymatic activity to enhance the reaction creating a product that is less sensitive and likely more prone to be impacted by small changes to the sample and its potential variants[3].

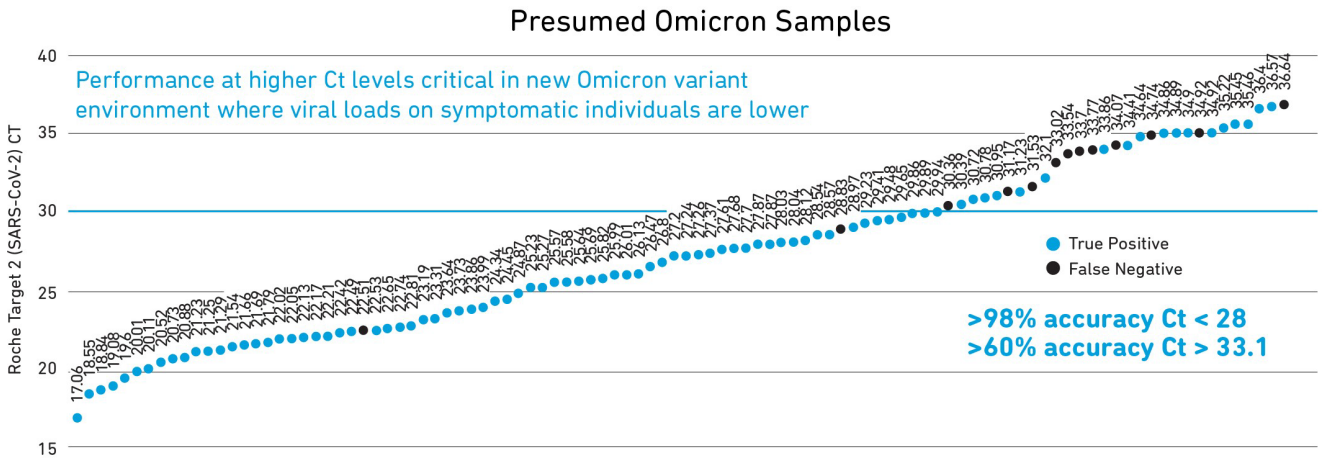
Method of detection is important to accurate and consistent detection. Even though both are antigen-based assays there are different methods in use between the Omnia platform and OTC rapid antigen lateral flow. It's not about what is being detected but rather how it is detected, this is where the Qorvo innovation with BAW detection and the Omnia product design (wash steps for specificity and enzymatic enhancement for low viral load detection) is critical and why all Antigen tests are not created equal.

Research Study Data in a POC Clinical Setting

In January 2022, Qorvo completed an Omicron supplemental research study at the point-of-care in clinical studies sponsored by RADx/NIH*. This was completed given the importance of understanding performance capability in the Omicron variant. During this timeframe, Omicron was the dominant variant nationally and a subset of clinical samples was sequenced and confirmed as Omicron by Emory in partnership with RADx/NIH. The results show that across 102 positive PCR samples, Qorvo demonstrated an 86.4% accuracy to high-sensitivity central lab PCR comparator, Roche Cobas. This level of accuracy was predicted by two factors: 1) epitope mapping completed by RADx Variant Task Force shows no Omicron mutations in Qorvo antibody binding region and excellent antibody affinity, so performance is anticipated to be similar between variants, 2) Qorvo has high accuracy at lower viral load levels (as shown in Figure 1). This is important because viral loads are lower both with asymptomatic individuals and all individuals while Omicron and associated variants are circulating, and Omnia will detect samples with lower viral load when compared to the Lateral Flow Assays (LFAs).

Zero false positive results were observed in these research studies, a continuation of the clinical data in the POC EUA. During an endemic transition, this performance attribute is critically important when testing in low prevalence settings where LFAs may see more false results, needlessly causing isolation and treatment for those not infected with COVID-19.

Figure 1: Clinical Data Demonstrating Low-Viral Load Detection Capability



Conclusion

As we approach an environment of endemic COVID-19, the ability to detect low viral load positive samples, common in early-stage infection where individuals are at a higher likelihood of spreading the virus, will become the difference between operating in a worry-free environment and one of constant concern. COVID testing sites must find solutions that offer strong performance while mitigating slower throughput, higher test cost and increased technician/clinician hands-on time of PCR platforms. For CLIA waived and POC settings, the Qorvo Biotechnologies Omnia SARS-CoV-2 Antigen Test delivers a fast turnaround, cost effective, and simple to use platform with minimal hands-on time and an automated data management capability.

Not all antigen tests are created equal. Omnia is the 'go-to' platform for endemic COVID-19.

**Not submitted to or reviewed by FDA*

Footnotes

[1] https://www.medtechdive.com/news/covid-antigen-test-sensitivity-low-omicron/626461/

[2] https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-fda-safety-communication

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4986465/