

# BioWorld

## Quest launches consumer-initiated, antibody test for COVID-19



Quest Diagnostics in Chantilly, Va. Credit: Quest Diagnostics Inc.

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By [Stacy Lawrence](#)

The capacity of U.S. medical providers and testing capacity for the unfolding COVID-19 pandemic continues to be sorely tested. But there is now a new route for people to pursue serological testing to detect who has already been exposed to the SARS-CoV-2 virus.

Major lab testing provider [Quest Diagnostics Inc.](#) has launched a service to enable consumers to request tests via their own service that includes a physician who evaluates a patient's need for the test. Patients who currently have an active infection are ineligible for the test, which is intended for people who suspect they previously have been infected.

A blood draw for the [\\$119 test](#) can be taken by appointment at any of the Secaucus, N.J.-based company's 2,200 patient service centers. It is not clear yet to what degree specific antibodies may indicate conferred immunity, but some immunity after a viral infection is typical. The SARS-CoV-2 virus is thought to have been present in the U.S. at least since early January.

### Antibody protection?

"Experience with other viruses suggests antibody testing can be an important tool among many in assessing disease risk and creating a safer environment for all of us," Jay Wohlgemuth, senior vice president and CMO of Quest, told *BioWorld*. "Antibody testing aids in identifying prior exposure to the virus that causes COVID-19. While the role of antibodies in preventing COVID-19 disease has yet to be established, antibody testing for other respiratory illnesses provides insight into immunity to future disease (i.e., SARS)."

“The science on COVID-19 is evolving, and direct evidence that antibody testing may confer immune protection has yet to be established. However, in most other viral diseases, IgG responses measurable by serological testing positively correlate with some level of protective immunity,” he continued. “In the case of SARS, which is in the same family of coronaviruses as COVID-19, previous viral outbreaks of SARS (SARS-CoV), IgG has been shown to impute immunity for up to two years.”

Insurers are [required](#) to cover serology testing under the recent Families First Coronavirus Response law. But it is still unclear what rate that testing outlets such as Quest will be compensated for the test. The Centers for Medicare and Medicaid Services (CMS) recently [upped the rate](#) for a nasal swab molecular COVID-19 diagnostic test to \$100, but has not yet determined its reimbursement rate for serology-based antibody testing.

Quest expects that by mid-May it can conduct about 200,000 antibody tests per day. It is currently conducting about 50,000 PCR-based nasal swab diagnostic tests daily. Combined, the volume of these two tests represent roughly half of the normal daily testing volume for the company – but another 50% to 60% of that normal volume has also been displaced by the pandemic, the company said on an April 22 earnings call.

Quest is already a major provider of the molecular, nasal swab COVID-19 diagnostic testing. It had conducted 1.5 million molecular diagnostic tests and 325,000 antibody serology tests by [May 4](#). Quest alone has accounted for roughly one-quarter of the U.S. testing conducted.

The supply of these IVD tests is constrained by access to reagents via the supply chain, the primary limiting factor for ramping up Quest testing capacity. But access to a physician able to order and interpret the serology test, which will be rapidly expanding with this consumer-initiated program, could help serology testing to ramp up faster. The program obviates the need for the patient’s own physician, in favor of remote access to a doctor through Quest.

“We wanted to be cautious about forecasting in any way how meaningful serology would be. But based on all the things we’ve talked about, it could be significant,” said Quest executive vice president and CFO Mark Guinan on the call. “We also don’t know the reimbursement rate yet, but hopefully, fairly soon and I think the trigger for commercial rates will largely be based on where CMS comes out. We’re all waiting on that. So that net loss comment and the 50% to 60% would include the current level of PCR, where we said we’re averaging about 30,000 tests a day. It’s offsetting about 6% of our loss. But it does not contemplate significant upside if it happens from serology testing at some point in this quarter.”

## **Testing immunity**

The company started out using the Euroimmun AG Anti-SARS-CoV-2 ELISA IgG antibody test and then added the Abbott IgG antibody test. It is continuing to use both tests, although the Abbott test has become the primary platform. Euroimmun is a division of Perkin Elmer.

Both tests have received emergency use authorization from the FDA; only [10 serology tests](#) have received this designation from the agency. The Euroimmun IgG test has a reported specificity of 96% and sensitivity of 65%, while the Abbott test claims a sensitivity of 100% and specificity of 99.5%. The FDA has just [cracked down](#) on serology tests requiring supporting validation documentation to be submitted within 10 business days of an initial notification.

There are at least three antibodies being measured by serology tests. IgG antibodies are the most commonly assessed, sometimes in combination with IgM or IgA. The first response is thought to be IgM, which then reduces as IgG starts to be produced.

IgG typically starts to be detectable about two weeks after infection, appearing in 100% of COVID-19 patients by day 19 in a recent 285-patient [study](#). The body is expected to retain a catalog of IgG antibodies that can then rapidly be reproduced if the same infection is reintroduced. A third immunoglobulin, IgA, is thought to be an indicator of likely symptom severity for COVID-19 patients. There are four IgG subclasses and two IgA subclasses.

“After a certain number of days, the best indication is after 14 days of being infected – the person can have an IgG response. That’s the last antibody,” said Quest chairman, President and CEO Stephen Rusckowski. “Therefore, it is obviously a good measurement that you have been infected in the past. It's important for those individuals that have not been tested and might have been asymptomatic. So, it's another good indication of infection rate within the geography or within a population.”

“Based upon other viruses, we believe that there may be immunity for some period of time. And this is what we need to study,” he continued. “The vast majority of viruses in the past have had immunity for a period of time. But we need to confirm this with evidence.”

Keywords [COVID-19](#) [Quest Diagnostics Inc.](#) [serological tests](#)