



U.S. Company to Distribute Millions of Rapid COVID-19 Antibody Kits to Help Meet Testing Demand

The company's tests have been validated by third parties in published clinical studies, demonstrating high sensitivity and specificity to coronavirus.

SAN FRANCISCO, CALIFORNIA, UNITED STATES, April 15, 2020 /EINPresswire.com/ -- Importing high-quality, clinically-tested antibody kits from abroad is necessary to begin closing the test deficiency gap in the US. Other countries like Germany, U.K., and Italy are already importing millions of kits, hoping to use antibody test results to determine immunity and get their people's live back to normal and re-engage their economies. [US officials are now discussing the use of immunity cards](#) to do the same.

The US CDC has recognized the importance of antibody testing in pursuing its own antibody test, but are still likely weeks away from scaling and mass production. CDC Director, Robert Redfield, stated that antibody tests need to be in place for a second coronavirus wave.

Antibody kits are not widely available in the US because manufacturers do not currently have the capacity needed to meet demand. Importing high-quality, clinically-tested kits from abroad is a necessary interim measure. [CovidRapid, Inc.](#) is doing just that and has secured exclusive distribution agreements with reputable manufacturers abroad and has provided notification to the US FDA to distribute under Section IV.D. of the agency's Policy for Diagnostic Tests for Coronavirus-2019. The company expects to distribute 2 million kits per month initially and are scaling up to increase distribution until US manufacturers can catch up, at a cost of \$20 per kit.

The company's kits have been validated by multiple CDCs, and used in numerous countries including Germany, Italy, Netherlands, Singapore, and Denmark without any adverse reports. The kits of one of its manufacturers were validated in an independent, published clinical study commissioned by the Danish government, ranking the kits second out of nine commercially-available immunoassay test kits in specificity and sensitivity to COVID-19. CovidRapid is currently working with the Canadian CDC to further research and supplement existing trials in an attempt to secure EUA approval for in-home use with the US FDA and Health Canada.

Like other antibody kits coming to market, the company's kits provide point-of-care results in 10 minutes by detecting IgM and IgG antibodies to the SARS-CoV-2 virus.

Antibody tests are a valuable diagnostic tool when combined with PCR tests. Importantly, because antibodies remain suspended in human blood at detectable levels for weeks or months after an infection, antibody tests can be used to assess immunity to SARS-CoV-2 and identify asymptomatic carriers of the virus. According to a [health report from the Chinese CDC](#), 80% of individuals with COVID-19 show mild symptoms or were asymptomatic.

With infections accelerating across the U.S. and Canada and continued outbreaks expected for months or years to come, antibody kits can help healthcare providers improve patient care and more efficiently allocate staff, space, and scarce PPE on a minute-by-minute basis by decreasing test turnaround time from days to minutes.

The US FDA stated that the serology tests can play a critical role in the fight against COVID-19 by helping identify individuals who have overcome an infection, are potentially immune, and can return to work. The agency also stated that antibody tests may help identify individuals who can donate convalescent plasma, which could serve as a potential treatment for those seriously ill from COVID-19 by infusing them with antibodies.

Many countries are exploring the use of antibody testing to help their people and economies get back online by easing lockdowns and letting people get back to work. Malaysia announced that they intend to use antibody tests at the end of a 14-day quarantine to clear close contacts of infected people and to reduce backlog of PCR tests.

Antibody testing will likely prove a cost-effective way of simultaneously protecting vulnerable populations and re-engaging lives and economies.

Many states are in desperate, immediate need of test kits but cannot get them because manufacturers abroad are requiring massive orders. CovidRapid is accepting donations for kits to be shipped to state and local public health agencies in an effort to help broaden distribution and also get them to areas with smaller populations. All donated kits will be shipped in bulk to state and local public health agencies for allocation according to need.

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