

# **GoDx uses point-of-care test to quickly diagnose gut, COVID-19 pathogens**

Posted on Thursday, May 21, 2020

GoDiagnostics, or GoDx, was formed with the vision to “democratize diagnostics” so that all people can more quickly learn about infections that make them sick.

The founder and chief executive officer of GoDx, Chang Hee Kim, and his team are in the process of gaining regulatory approval of their two diagnostics tests — GutChecker and CoronaChecker.

Kim founded the company to combat deaths related to diarrhea-inducing gut pathogens. With between millions of annual deaths, diarrhea is the second leading cause of death in children under age 5 worldwide. Furthermore, founders have identified an unmet need for quick, inexpensive and effective diagnostics tests in the health care system. GoDx is tackling this need head on.

Traditionally, such pathogen diagnostic tests would take several days to yield a result because samples have to be sent to a lab. In many cases, that isn't enough time to effectively treat a potentially life-threatening pathogen. Most pathogen detection tests are also expensive and require instruments, costly machinery and plenty of time in order to yield accurate results – resources not readily available to many clinics around the world.

The GoDx tests under review is a rapid diagnostic that doesn't need machines, instruments or even a laboratory, and can yield results in roughly 30 minutes.

This non-invasive diagnostic method works by amplifying pathogen DNA and RNA through a process called isothermal nucleic acid amplification. This process uses enzymes to amplify pathogen DNA and RNA, which replaces the need for heat and time required by most traditional diagnostic tests.

After 20 to 30 minutes, a practitioner will test for gastrointestinal pathogens by transferring the amplified DNA or RNA to a paper strip which will identify a positive or negative result for a specific pathogen.

“Think of it like a pregnancy test,” Kim said.

GoDx plans to bring GutChecker to developing countries most affected by diarrheal pathogens.

The company initially used this point-of-care technology for the GutChecker test for GI pathogens with a \$3 million Small Business Innovation Research SBIR grant funding from the National Center for Advancing Translational Sciences of the National Institutes of Health.

With the rise of the coronavirus pandemic, GoDx is also developing a fast-tracked FDA emergency test called CoronaChecker to detect the SARS-CoV-2 virus which causes the COVID-19 disease. For this test, saliva or nasopharyngeal samples will be used.

“There is an urgent need for coronavirus testing at (volumes that are) currently unmet,” Kim said. “We were already working on the technology to find [gastrointestinal] pathogens... We already had our base platform.”

GoDx's instrument-free tests make rapid diagnostics available to hospitals and labs that do not already have the specific and expensive instruments required for the current FDA emergency tests. GoDx also hopes to develop an at-home CoronaChecker test by the end of the year. Amid the current crisis, GoDx is prioritizing the rapid development of CoronaCheck over GutChecker.

Kim projects the company still has about a year and a half of development ahead for the GutChecker rapid diagnostic test.

Kim obtained his Ph.D. from CALTECH in biochemistry, a Howard Hughes Medical Institute postdoctoral fellowship at Harvard with Nobel Laureate Dr. Jack Szostak, and has a background in diagnostics and genomics. While GoDx originated in California in 2017, the company more recently made the move to Madison.

"We love the supportive startup environment here," Kim noted.

Kim thanked Madison-based Merlin Mentors for mentorship support, and noted the company also received funding from the Wisconsin Economic Development Corporation through the Center for Technology Commercialization.

GoDx is among the finalists for the 2020 Wisconsin Governor's Business Plan Contest, which will end at the Wisconsin Entrepreneurs' Conference in June.

— *By Katy Bergeron*

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## *Communication*