Rapid PCR test receives FDA emergency use authorization

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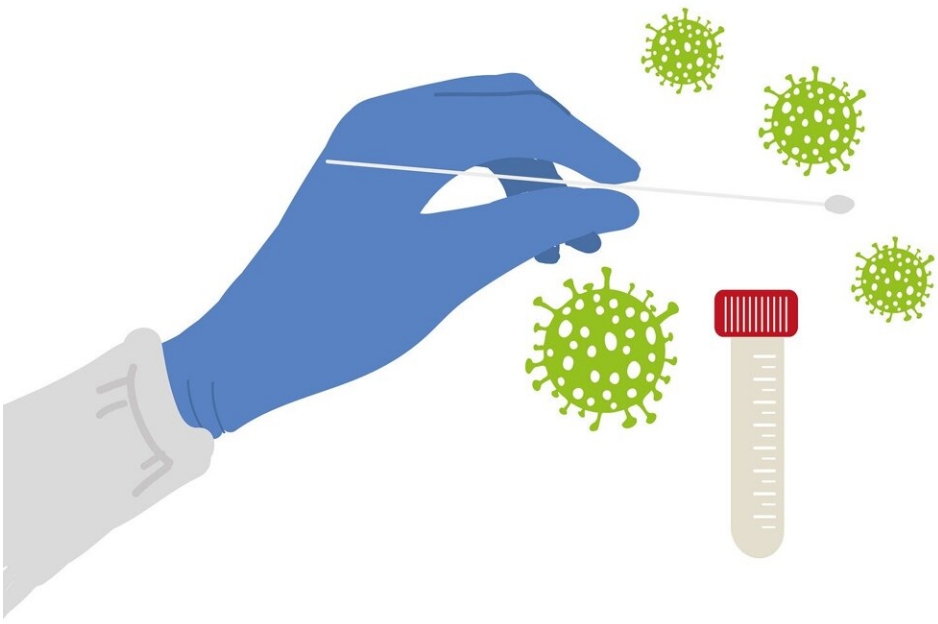

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A new highly sensitive, easy-to-use test for COVID-19 that requires a single swab and 15 minutes has received emergency use authorization

(EUA) status from the U.S. Food and Drug Administration (FDA).

Developed at Northwestern University's Center for Innovation in Global Health Technologies (CIGHT), the point-of-care technology is being commercialized by Northwestern spinoff company, Minute Molecular Diagnostics.

Last year, Minute Molecular received $21.3 million from the National Institutes of Health (NIH) to manufacture the novel device.

Called DASH (Diagnostic Analyzer for Specific Hybridization), the device is about the size of a cereal box—small enough to sit on a countertop or desk. The test uses a polymerase chain reaction (PCR) technique that amplifies DNA, increasing incredibly small virus samples to detectable levels. To use the DASH test, a user simply performs a nasal swab, puts the swab into a chamber within a small cartridge and then inserts the cartridge into the testing unit. After 15 minutes, an easy-to-read positive or negative result appears on the unit's touchscreen.

"We are pleased with the FDA's decision and are ramping up our production to assign in the fight against COVID-19," said Northwestern's David Kelso, co-founder, president and CEO of Minute Molecular. "DASH provides central laboratory quality COVID-19 PCR results at the point of care in approximately the same time as an antigen test."

"DASH enables non-laboratory personnel to insert a nasal swab specimen directly into our test cartridge and then load the cartridge into the DASH instrument, providing an accurate result in about 15 minutes," said Northwestern's Sally McFall, co-founder and chief scientific officer at Minute Molecular. "The simplicity of the DASH test adds an important, new tool for schools, universities, congregate care settings, and workplaces."

Kelso is a clinical professor of biomedical engineering at Northwestern's McCormick School of Engineering. Kelso co-led the device's development with McFall, a research associate professor of biomedical engineering at McCormick and CIGHT's director of research.

"What distinguishes DASH from existing options are its simplicity, speed and PCR-level accuracy," said Dr. Chad Achenbach, associate professor of medicine (infectious diseases) and preventive medicine at Northwestern University Feinberg School of Medicine, who led DASH's clinical evaluation. "The DASH interface walks the user through all the steps making it just as easy to use as a coffee maker. DASH is ideal for point-of-care testing in clinics, corporate or community settings."

"DASH offers the accuracy of other PCR tests in a compact portable platform that can be operated by non-technical personnel at the point-of-care in 15 minutes," said Dr. Robert Murphy, the John Philip Phair Professor of Infectious Diseases at Feinberg and member of the DASH clinical evaluation team.

To accelerate delivery of its DASH Analyzer, Minute Molecular is currently seeking government and private partnerships. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Qualified laboratories can learn more about DASH Analyzers at www.m2dx.com.

Provided by Northwestern University