Monkeypox rapid PCR test in development

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Credit: Northwestern University

Last spring, a rapid polymerase chain reaction (PCR) test for COVID-19—developed by Northwestern University spinoff company Minute Molecular Diagnostics—received emergency use authorization (EUA) status from the U.S. Food and Drug Administration (FDA). Now, the team behind this revolutionary test is adapting its platform to detect

monkeypox.

Northwestern and Minute Molecular are collaborating to develop the swab-based test. Infectious disease specialists at Northwestern University Feinberg School of Medicine will then lead clinical testing.

The team currently has a working prototype of the monkeypox test, with plans to submit an EUA application to the FDA early next year. To develop the rapid PCR test, the researchers are using Minute Molecular's DASH Analyzer, a compact, portable system that provides easy-to-read results in approximately 15 minutes.

"To help control the spread of this contagious infection, the development of rapid diagnostic testing is essential," said Northwestern's David Kelso, co-founder, president and CEO of Minute Molecular. "DASH provides central laboratory-quality results at the point of care."

"The simplicity of the DASH test adds an important new tool to combat the monkeypox emergency," said Northwestern's Sally McFall, co-founder and chief scientific officer of Minute Molecular. "DASH enables non-laboratory personnel to insert a swab specimen into the test cartridge and load the cartridge into the analyzer. Then an accurate result is provided in 15 minutes."

Kelso is a clinical professor of biomedical engineering at Northwestern's McCormick School of Engineering. Kelso is co-leading the test's development with McFall, a research professor of biomedical engineering at McCormick and director of research at Northwestern's Center for Innovation in Global Health Technologies.

When current patients are tested for monkeypox, physicians must send samples to a central laboratory facility. The samples are run in large batches, which can take several hours to provide results. By delivering

fast, point-of-care results, DASH could enable monkeypox testing at sexually transmitted infection (STI) clinics, immediate care clinics, emergency rooms and physician offices.

"DASH is distinguished by its simplicity, speed and PCR-level accuracy," said Dr. Chad Achenbach, associate professor of medicine (infectious diseases) and preventive medicine at Feinberg and lead of the DASH 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 and immediate care settings."

"We look forward to working with Minute Molecular to bring a rapid monkeypox test through clinical validation," said Dr. Robert Murphy, the John Philip Phair Professor of Infectious Diseases at Feinberg and a member of the DASH clinical evaluation team. "DASH offers the accuracy of central laboratory PCR tests in a compact, portable platform that can be operated by non-technical personnel at the point of care in 15 minutes."

Although Kelso, McFall and their teams initially designed DASH to help address the novel coronavirus pandemic, the technology also can be used to detect many viral and bacterial agents, including monkeypox. Minute Molecular Diagnostics is currently developing similar tests for the flu, HIV, hepatitis C, several STIs, MRSA and C. diff, using various sample types, including nasal swab, saliva and blood. Its PCR testing system also can quantitatively report viral loads of HIV and hepatitis C.

Provided by Northwestern University