

# Flambeau Diagnostics seeking FDA approval for mobile testing platform

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A Madison-based startup called Flambeau Diagnostics is seeking FDA approval for a mobile testing platform that could expand access to rapid viral testing services.

“We’re really thinking about it as a pandemic preparedness model,” said David Beebe, the company’s chief science officer and a biomedical engineering professor at UW-Madison.

The company was launched about a year ago after being awarded a \$12 million contract through the National Institutes of Health Rapid Acceleration of Diagnostics initiative. While Operation Warp Speed had a major component focused on COVID-19 vaccines, a portion of funding was allocated to companies developing diagnostic technologies.

Flambeau Diagnostics was one of just 25 companies selected out of 716 applicants for the \$500 million effort. Beebe (pictured here) says the startup was one of the “smallest and earliest-stage” companies that received a significant contract.

In a recent interview, he explained the technology enabling high-throughput rapid testing in a mobile laboratory setting was created through another company he co-founded called Salus Discovery. That business emerged from research conducted in his lab at UW-Madison.

Beebe said proprietary sample preparation technology allows the Flambeau Rapidx

platform to isolate genetic information from saliva samples “extremely rapidly.”

In a typical extraction process, analyzing samples one at a time can take up to 30 minutes, he said. By comparison, the Flambeau Rapidx mobile platform has been able to extract and isolate that genetic information from 16 samples simultaneously in less than a minute from the back of a specially equipped van.

“That’s where our sample preparation technology really shines, because it’s so fast and efficient,” Beebe said.

By using a liquid component from Gilson, an established life sciences company also based in the Madison area, the platform is able to “process saliva in a cost-effective and efficient manner,” he said.

Gilson CEO Nicolas Paris said his company has been collaborating with the founders of Flambeau Diagnostics for years, so providing components for the test was a natural partnership. He told WisBusiness.com the mobile testing unit could be used for preventative testing, particularly in rural areas with lower COVID-19 vaccination rates.

“Making sure that when you see clusters, etc., you can isolate very quickly the people in that cluster,” Paris said. “To be able to deploy fast and accurate testing is paramount.”

While FDA approval is pending, Beebe said company leaders are having exploratory discussions with the Federal Emergency Management Agency as well as lab networks including the Mayo Clinic.

He noted the federal government already pays for thousands of ambulances to be on call throughout the country, which are deployed for a number of emergencies. He envisions these mobile units being used in much the same way, filling a need for rapid testing in health care shortage areas including rural parts of the country.

“This is a brand-new test,” Beebe said. “No one has really tried to put a test in a van like this before. So we’re in the process of going through the regulatory steps to actually get approval for the van as an instrument.”

He said potential customers “see this as serving in the pandemic, but also seeing it as evolving into a more broad-based mobile platform beyond the pandemic.” While the technology was developed in response to COVID-19, Beebe said it could be used for many different types of tests.

*-By Alex Moe*