

MBio To Seek FDA Approval for LightDeck® Platform

Future Use in Outbreak Management Expected, via DARPA Partnership

Boulder, CO, April 6, 2020 – MBio Diagnostics today announced an expanded scope contract with the US Defense Advanced Research Projects Agency (DARPA), where DARPA will apply additional resources and funds to accelerate progress towards FDA approval for MBio's LightDeck® platform. MBio has been working with DARPA on a program, "Point-of-care Monitoring of the Host-Pathogen Interaction During Infection," since February 2018.

The contract enhancement includes an additional \$1.5M in funding to allow MBio to augment its clinical and regulatory capabilities, in anticipation of the company seeking first FDA approvals for the platform. FDA approval would significantly expand the applicability of the MBio platform across military and other medical settings.

Under the DARPA funded effort, MBio has been developing human host-response biomarker assays with the goal of identifying gravely ill or highly contagious individuals early in the disease cycle, which may be useful during an infectious disease outbreak as well as standard care in clinical settings.

Michael Lochhead, Ph.D., MBio's Chief Operating Officer, said, "The current global coronavirus disease (COVID-19) epidemic has created an increased sense of urgency for accurate, rapid, point-of-care testing. By measuring specific blood biomarkers associated with the human immune response, it may be possible to identify infected individuals early before symptoms emerge to provide guidance to clinicians both on who may spread disease as well as on which individuals may be at greatest risk of developing severe disease."

Lochhead added, "COVID-19 is showing just how challenging disease management can be when it is spread by people with mild symptoms. The blood tests we are developing with DARPA will be run on MBio's portable system, allowing use in small spaces with mobile testing teams. The tests have the potential to play an important role in quickly identifying the sickest or most infectious patients. We are grateful for the continued support provided by DARPA."

About MBio Diagnostics

MBio Diagnostics provides rapid, on-the-spot testing solutions for our global commercial partners. Our portable LightDeck® platform delivers panels of lab-

quality results in minutes for critical applications in health care, veterinary, and environmental industries.

About LightDeck® Technology

MBio's patented LightDeck® technology system translates laboratory assays into onthe-spot, critical decisions in minutes. Our LightDeck® platform incorporates low-cost, multiplexed cartridges with our fluorescent readers and intuitive software, with the ability to measure more than 50 analytes in a single cartridge. Our partners use LightDeck® technology to test key analytes across all applications and industries, measuring proteins, cells, nucleic acids and small molecules.

Disclaimer

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