

## Hemex Health and Mylab Discovery Solutions Launch Gazelle<sup>™</sup> PathoCatch<sup>™</sup> COVID-19 FIA Test

Portland, Ore., Pune, India– June 21, 2022– Mylab Discovery Solutions, India's leading biotechnology company, and Portland, OR-based Hemex Health, a medical diagnostic device company focused on creating diagnostics to transform frontline healthcare, announced the official launch of the Gazelle<sup>™</sup> PathoCatch<sup>™</sup> COVID-19 FIA test, their collaborative diagnostic solution for point-of-care (POC) testing in India. This portable, lightweight test detects all COVID-19 variants in 20 seconds with 99.4 percent accuracy compared to the gold standard, PCR. The diagnostic is currently under review with US FDA for Emergency Use Authorization and will launch in Africa and the Middle East later this summer.

"Studies show that minimizing testing delay has the largest impact on reducing transmission," **said Hasmukh Rawal, Managing Director, Mylab Discovery Solutions.** "We are excited to introduce this very affordable, highly accurate test into the market. It will be a great solution for hospitals, universities, and airports, where quick results are essential."

The Gazelle PathoCatch test includes a fluorescent lateral flow immunoassay (FIA) and a reader that utilizes image-recognition software for detection of nucleocapsid protein from SARS-CoV-2. The reader uses AI imaging and signal-to-noise enhancement techniques to achieve near-PCR accuracy. Specimens are collected using a nasal swab.

Data from POC clinical studies with symptomatic and asymptomatic subjects, conducted in both Bellingham, WA and Pune and Mumbai, India, demonstrated 96.2 percent combined sensitivity, 99.7 percent combined specificity and 99.4 percent combined accuracy at detecting the virus in comparison to RT-PCR. Data from these studies is currently under peer review.

"The pandemic has driven home the need in all markets for faster, more accessible and more affordable POC diagnostics," **said Patti White, CEO and Co-Founder, Hemex Health**. "Gazelle was positioned to help provide a solution to the testing effort with its fast and detailed analyses. Using our AI and FIA technologies, we discovered we could find even the smallest trace of virus in a sample. We are excited to bring this product to the consumer market to aid in the pandemic fight and be there ahead of the next wave."

## **About Mylab Discovery Solutions**

Mylab Discovery Solutions Pvt. Ltd. is an Indian molecular biology company that develops and commercializes tests used in human diagnostics, food safety, agriculture, and veterinary medicine, empowering labs to obtain reliable, timely, and actionable results. Mylab is India's first company to get approval for a COVID-19 RT-PCR Kit and has been a leading contributor to India's fight against Covid.

## **About Hemex Health**

Hemex Health breaks traditional barriers with its innovative diagnostic system that expands the potential of diagnostics for emerging diseases, making accurate tests accessible to new locations and

new populations. Hemex Health designs diagnostic technologies for the real world by listening to the needs of healthcare providers including those in some of the most remote and challenging settings. The Gazelle technology was developed in collaboration with Case Western Reserve University. Hemex Health is in Portland, Oregon, U.S.A.