



## **Sherlock Biosciences Receives FDA Emergency Use Authorization for CRISPR SARS-CoV-2 Rapid Diagnostic**

*COVID-19 Test is First FDA-Authorized Use of CRISPR Technology*

**Cambridge, Mass., May 7, 2020** – Sherlock Biosciences, an Engineering Biology company dedicated to making diagnostic testing better, faster and more affordable, today announced the company has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for its Sherlock™ CRISPR SARS-CoV-2 kit for the detection of the virus that causes COVID-19, providing results in approximately one hour.

“While it has only been a little over a year since the launch of Sherlock Biosciences, today we have made history with the very first FDA-authorized use of CRISPR technology, which will be used to rapidly identify the virus that causes COVID-19,” said Rahul Dhanda, co-founder, president and CEO of Sherlock Biosciences. “We are committed to providing this initial wave of testing kits to physicians, laboratory experts and researchers worldwide to enable them to assist frontline workers leading the charge against this pandemic.”

The Sherlock™ CRISPR SARS-CoV-2 test kit is designed for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests. Based on the SHERLOCK method, which stands for **S**pecific **H**igh-sensitivity **E**nzymatic **R**eporter **unLOCK**ing, the kit works by programming a CRISPR molecule to detect the presence of a specific genetic signature – in this case, the genetic signature for SARS-CoV-2 – in a nasal swab, nasopharyngeal swab, oropharyngeal swab or bronchoalveolar lavage (BAL) specimen. When the signature is found, the CRISPR enzyme is activated and releases a detectable signal. In addition to SHERLOCK, the company is also developing its INSPECTR™ platform to create an instrument-free, handheld test – similar to that of an at-home pregnancy test – that utilizes Sherlock Biosciences’ Synthetic Biology platform to provide rapid detection of a genetic match of the SARS-CoV-2 virus.

“When our lab collaborated with Dr. Feng Zhang’s team to develop SHERLOCK, we believed that this CRISPR-based diagnostic method would have a significant impact on global health,” said James J. Collins, co-founder and board member of Sherlock Biosciences and Termeer Professor of Medical Engineering and Science for MIT’s Institute for Medical Engineering and Science (IMES) and Department of Biological Engineering. “During what is a major healthcare crisis across the globe, we are heartened that the first FDA-authorized use of CRISPR will aid in the fight against this global COVID-19 pandemic.”

Access to rapid diagnostics is critical for combating this pandemic and is a primary focus for Sherlock Biosciences co-founder and board member, David R. Walt, Ph.D., who co-leads the Mass General Brigham Center for COVID Innovation.

“SHERLOCK enables rapid identification of a single alteration in a DNA or RNA sequence in a single molecule,” said Dr. Walt. “That precision, coupled with its capability to be deployed to multiplex over 100 targets or as a simple point-of-care system, will make it a critical addition to the arsenal of rapid diagnostics already being used to detect COVID-19.”

Sherlock Biosciences is working to rapidly scale the production of its SHERLOCK test kit and will share plans for distribution and availability in the coming weeks. Those interested in receiving future updates about Sherlock CRISPR SARS-CoV-2 kits may sign up [here](#).

### **About Sherlock Biosciences**

Sherlock Biosciences is dedicated to making molecular diagnostics better, faster and more affordable through Engineering Biology platforms. The company is developing applications of SHERLOCK™, a CRISPR-based method to detect and quantify specific genetic sequences, and INSPECTR™, a Synthetic Biology-based molecular diagnostics platform that is instrument free. SHERLOCK and INSPECTR can be used in virtually any setting without complex instrumentation, opening up a wide range of potential applications in areas including precision oncology, infection identification, food safety, at-home tests, and disease detection in the field. For more information visit [Sherlock.bio](https://sherlock.bio).

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