

Case Study Submission: Rapid Response Funding Partnership

Company: Spectral Platforms, Inc. (Monrovia, California)

Innovation: Novel, Rapid Point-of-Care Test for Covid-19 and Secondary Bacterial Infections

Summary: Spectral Platforms is proposing the development of 3 new tests that can have near and long term impacts on the ongoing Covid-19 epidemic. These include:

- (1) a rapid (15 minutes), point-of-care or point-of-screening test to determine if the patient is "infected" even during low concentration incubation stages;
- (2) a rapid, point-of-care or point-of-screening test to determine if the patient is "diseased" (i.e. likely to be "severe" or "critical" vs "mild"); and
- (3) a rapid test for characterizing the antiviral susceptibility.

Clinical Impact: Current testing methods are generally limited in their ability to detect SARS CoV19 in the important incubation stage when spreaders may be asymptomatic, and do nothing help doctors predict disease state or test antiviral susceptibility. Once completed, the Spectral Covid-19 Test will be a lower cost, faster test that can detect viable virus at earlier (i.e., incubation) stages of the infection, and which can be used at non patient care screening settings such as airports, borders, and local community sites. Further, when a symptomatic patient presents, doctors could then have access to critical information to stratify patients and identify those who are more likely to become seriously ill (thus requiring more ER/ICU resources), and to determine which antivirals are likely to be effective.

Discussions with BARDA (HHS) and FDA: Spectral is in discussions with BARDA and the FDA to accelerate the deployment of these tests. The FDA has confirmed that the SARS CoV19 Infection Yes/No Test will be considered under their Emergency Use Authorization and BARDA has indicated that once the FDA pre-approves, Spectral is in line for a grant of up to \$750K to further this work.

Based on Clinically Proven Enabling Technology for Pathogen Detection and ID: All three new SARS CoV19 Tests leverage Spectral Platforms' existing InSpector-01 Platform and IP, which is the most sensitive characterization of metabolites produced by living organisms in a test sample. The technology has been successfully tested with human clinical samples at three hospitals (Leeds Teaching Hospital UK, Cleveland VA Hospital, OH and Harbor UCLA Medical Center, CA) for detection and characterization of bacteria. It is the only rapid test that we know of that provides accurate concordance with blood culture. The adaptation for Covid-19 is a very small change to how Spectral detects bacteria.

Next Phase Funding Request and Outcomes: Spectral is seeking \$1M through grant or investment to accelerate plans for scaled deployment and accomplish the following specific milestones:

1. Complete the Spectral Covid-19 Test and submission to FDA under the EUA within 120 days; and
2. Launch Inspector-01 blood test for pathogen presence, ID and AST (susceptibility testing) with our partner hospital in India. Faster ID/AST results may improve outcomes for patients with sepsis (an expected outcome due to secondary bacterial infections in Covid-19 patients).

Team: Experienced scientists and Board of Directors affiliated with leading institutions.

Vision: Global deployment of an improved testing protocol and tools for all viruses and bacteria that can help guide therapy and is appropriate to each patient to prevent onset of serious infections such as sepsis.