
Open Letter To SARS-CoV-2 Test Kit Developers

SPARK is looking to make an impact during this time of crisis by helping to bring a promising SARS-CoV-2 in vitro diagnostic (IVD) device or more comprehensive testing platform to market. An effective, accurate, and easy to use at-home testing kit is going to be the key element for reopening our society and returning our lives to something that resembles “normal.”

As of April 21, 2020, the FDA is already working with over 350 test developers and has issued authorization for more than 50 diagnostic tests (FDA article link, Advamed’s list of EUA IVDs). A test that can not only be performed at home, but also provide results in real time, will be the game changer. Ideally, we will see a secure portal opened up soon so that at-home testing results can be reported to health authorities, obviating the need for symptomatic people to congregate at testing centers and wait for results to return from remote labs, which have limited capacity and are heavily dependent on human resources. Aggregating and analyzing more testing data will also help authorities make more informed decisions. With only ~1% of the American population having been tested to date, and mostly in hot spots, no data driven decisions can be made at this time.

It is not reasonable to think that only one or two companies making testing kits will meet the demand of a nation with over 330 million people, let alone globally. Along with expected negative results, false positive/negative results from inherent error, and other ineffective kits in use right now, it is also likely that SARS-CoV-2 can cause reinfection, all resulting in the need for more than one testing kit per person before this is over. While every person in our society should be making efforts to avoid contracting and spreading all known diseases, nobody wants to fight off COVID-19 twice (or more).

If you are the developer of a promising IVD device, “lab-on-a-chip,” or other rapid testing methodology that has been refined in the lab and proven to work, and you need help transforming it into a viable mass-produced product, we are looking to partner with you to make it happen. Let’s make a difference.

Please contact Sean (shiggins@sparkpd.com) so we can discuss potential opportunity for collaboration.

Key Points:

- SPARK will only take on one client at a time working on a SARS-CoV-2 testing kit of any sort (virus or antibody). We will not share bandwidth or open up the possibility for conflicts of interest with competitive technologies by concurrently working on related efforts.
- SPARK is offering free feasibility evaluations and no nonsense estimates. We will spend time working with your technical team to understand your testing technology, it’s current state, and what needs to be done to prepare it for effective mass production and distribution.
- SPARK will only take on a project that we feel stands a reasonable chance of being successfully completed in a timely fashion to make a meaningful difference in this crisis situation.
- SPARK will not entertain prospects that have no evidence proving the efficacy of their testing technology. White papers are welcome!
- SPARK has deep connections in the medical device manufacturing sector and beyond. We can work with these previously established and trusted partners to seamlessly bring your product into scalable manufacturing quickly and effectively.
- SPARK can connect you with regulatory resources that can help guide you through the Emergency Use Authorization (EUA) process.

Relevant SPARK Work Samples



Morphix | Chameleon
The Chameleon bio-hazard detection armband uses snap-in, water-immersible “chips” which contain compounds that change color when exposed to hazardous chemicals to alert military and first responders to dangerous conditions.



Morphix | TraceX
The TraceX explosives detection kit is a low cost, minimally-sized device meant for military and law enforcement field use. The product allows users to swab a person or surface and detect the trace presence of the most common bomb-making ingredients.



Cerillo | Stratus
Cerillo's Stratus is a highly portable and flexible plate reader meant for scientific research. The device is capable of analyzing various well-count plates for bacterial growth/ density, protein quantification, cell proliferation, and more all within a small and stackable package.