Feasibility assessment of mass testing for organizations and public health during pandemics (a validated SARS-CoV-2 endpoint Reverse Transcriptase (RT)-PCR diagnostic assay on an ultra-high-throughput platform)

Summary: Seeking participating organizations in a feasibility assessment to determine whether a single laboratory can process large (100,000) numbers of diagnostic lab samples, in a short period (1 day), during times of high demand (pandemics)

OVERVIEW

The rapid spread and impact of COVID-19 on the world population has created an unprecedented need for the development of accurate, reliable, cost-effective, and widely accessible testing not only to support US efforts, but also for settings where high testing volume is required, including underserved and vulnerable populations.

Returning safely to normal life depends on our ability to increase testing capacity, streamline and speed up the testing process in a variety of settings and locations, and being able to detect asymptomatic individuals particularly in time for the 2020-2021 flu season.

Rapid scale-up testing across the country and enhanced access to those most in need has long been a mainstay of public health. This ultra-high-throughput platform has the scalability to contribute substantially to the nation's COVID testing and to expand capacity to support testing where high testing volume is required but also to screen asymptomatic individuals to detect SARS-CoV-2 to serve employers, universities and underserved groups.

Corteva Agriscience and Quantigen Biosciences with support from The Gates Foundation are developing a next generation highly automated ultra-high throughput diagnostic assay capable of processing 100,000 SARS CoV-2 samples per day. The scale-up capability, speed, and lower cost of this technology will remove barriers to bring testing to the underserved and vulnerable populations.

This versatile technology platform can also be adapted to provide simple, rapid tests for other diseases or for the combined testing of respiratory pathogens such as influenza, in addition this technology will be available in the future when new pathogens emerge with pandemic potential enhancing the nation's public health security and emergency preparedness needed to combat health threats.

Corteva Agriscience has been operating this high-throughput PCR platform in support of their agricultural genotyping needs for over a decade, routinely conducting more genetic testing than any other institution in any field. Corteva will leverage their expertise and experience on the use of this automated platform, as well as assay and process development, to validate a low-volume, direct lysis, endpoint Reverse Transcriptase RT-PCR assay. The method will directly test specimens from nasal swabs without cumbersome and expensive RNA purification procedures, which will make this ultra-high-throughput test of lower cost than other RT-PCR tests available today.

This validated SARS-CoV-2 endpoint (RT)-PCR diagnostic assay is intended for the qualitative detection of nucleic acid from SARS-CoV-2 from an anterior nasal swab. The test uses three different primer/probe sets developed by the CDC that target two viral gene targets in the nucleocapsid gene of SARS-CoV-2, N1 and N2, and an internal control targeting the human RNase P (RP) gene. Detection of RNase P indicates that human nucleic acid is present and implies that human biological material was collected and successfully amplified. It does not necessarily indicate that the specimen is of appropriate quality to enable detection of SARS-CoV-2.

The analysis will be performed at Corteva Agriscience which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, by qualified laboratory personnel specifically instructed and trained in the techniques of PCR and in vitro diagnostic procedures as per the Standard Operating Procedures that will be submitted to the FDA under an EUA.

All samples in this feasibility work are part of a diagnostic test, and not assay validation, the test is validated with samples previously collected for assay/platform development and validation. All validation results are part of an EUA submission.

PROGRAM LOGISTICS

The collection kit consists of a sterile packaged spun polyester swab, a barcoded collection tube, and instructions on how to collect the sample. Kits will be provided to designated collection sites. Sample collection will be done through assisted self-collection of anterior nasal swab. The sample will be collected at ambient conditions and inspected to meet the following criteria:

- Collection tube must be intact and not visible of damage
- The tube barcode label must be present and readable by a phone app
- The tube cap must be properly secured onto the tube

Samples will be transported in dry conditions at room temperature within 24 hours from sampling. Samples will be refrigerated until analyzed with the endpoint (RT)-PCR SARS-CoV-2 diagnostic assay.

Positive results are indicative of the presence of SARS-CoV-2 RNA but do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection.

The shipping stability of dry spun polyester swabs has been demonstrated by Quantigen Biosciences. The Quantigen study demonstrated 72-hour stability for dry

anterior nasal spun polyester swabs. Quantigen Biosciences has granted a right of reference to the stability data to any sponsor pursing an EUA for which a claimed specimen type is dry spun polyester swabs.

The goal of this project is to demonstrate the feasibility of testing approximately 100,000 samples for SARS-CoV-2. The collection of samples will take place at many sites with the testing of the samples at a single site. Results will be returned to participants within 48 hrs. of sample collection. Collected dry samples can be racked at the collection site and shipped to Corteva the same day samples are collected. The successful completion of this feasibility assessment is dependent on the recruitment of partners to collect the specimens in a 24-hr. timeframe.

Those partnering in the effort to collect samples receive benefit and make contribution. Their employees, clients, and customers receive a highly effective test for COVID-19 at no cost. On site assessment is convenient for individuals and less disruptive of workflow in the organization. The opportunity to impact the development of enhanced testing solutions suitable for this and future pandemics could result in procedures capable of saving lives, not only in the organization, but worldwide.

Companies interested in partnering in this feasibility assessment could offer voluntary participation to their employees. Participants will pre-enroll in the project and onsite collection will be on Dec. 16th. If companies have staff to facilitate collection, staff will be trained, and PPE will be provided. Alternatively, we may be able to deploy staff to assist with the one-day onsite collection, and ensure collected samples are packed and shipped to the designated location.

It is widely understood that testing must be rapidly deployed and expanded during pandemics. Most organizations and countries have been woefully unprepared for the COVID-19 pandemic. If we are to be prepared for the next wave and future

pandemics, we all must make some contribution to solutions. This is a rare opportunity to make a critical contribution to future preparedness. Mass testing does not exist. It must exist for our collective future. This effort will demonstrate our ability to collect and test mass quantities of samples so that we can respond more quickly and effectively in the future. Will you help make that happen by making this opportunity available to your staff/clients and provide the necessary resources in your organization to help collect samples?

The project will be limited to asymptomatic subjects 18 years and older. Diagnostic tests will be provided at no cost to the participants and results will be made available to each individual. Subjects will receive a notification via email and results will be returned electronically to all participants. All positive results will be reported to subjects via phone call and will also be reported to the appropriate public health authorities.

This assessment has the potential to dramatically improve the way in which high prevalence infectious disease testing is performed. The capacity to analyze large numbers of samples has utility in both public and private sectors on a local, national and global scale. High capacity throughput testing is a critical link to pandemic preparedness. Toward that end, we are looking for partner organizations to participate in this feasibility assessment who have the potential to contribute to large-scale positive impact.