Direct-to-patient COVID-19 surveillance study launches in Boston

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As the number of new cases of COVID-19 begin to increase again in our area and as schools face the challenge of how to safely remain open, a new research study could detect when clusters of COVID-19 are on the rise again throughout the fall and winter in the greater Boston area. Clinicians and researchers from Brigham and Women's Hospital, the Broad Institute of MIT and Harvard, and the MGB Center for COVID Innovation are launching TestBoston, a large-scale research study to detect active COVID-19 cases and evidence of previous infection, as well as changes in the rates of both, in a representative group of 10,000

Brigham patients reflecting the demographics of greater Boston.

This program will be led by Ann Woolley, MD, MPH, and Lisa Cosimi, MD, both infectious disease physicians at the Brigham, and Deborah Hung, MD, Ph.D., a core faculty member and co-director of the Infectious Disease and Microbiome Program of the Broad Institute as well as an infectious disease and critical care physician at the Brigham.

Over the course of six months, participants will be sent monthly at-home test kits for viral and antibody testing. Participants will also complete routine symptom surveys and be able to request additional testing if they develop symptoms during the study period. Ongoing study results may reveal critical clues and additional warning signs about how COVID-19 cases are changing in the Boston area, while also helping investigators establish a model for at-home sample collection that is integrated with a medical and public health system. The study will also help clinicians learn more about whether prior infection provides any protection against subsequent re-infection. Current or former Brigham patients interested in participating in the trial can enroll here.

"With ongoing limits on testing availability, we still face serious challenges to our understanding of how many people in Massachusetts have been infected and to our ability to detect new outbreaks, which is made all the more challenging because we know that asymptomatic people can transmit this virus to others," said Woolley.

"The objective of our study is to provide at-home testing that pairs viral testing for active virus with antibody testing to give us a clearer picture of COVID-19 rates now and over time in different communities, as well as an understanding of who is getting infected," said Cosimi. "We believe that this strategy of reaching patients at home is critical to being able to reach meaningful numbers of patients in order to have real impact."

TestBoston will invite participation of patients who have been seen at any Brigham site within the past year and live within a 45-mile radius of Boston. Modeled after projects that the Broad Institute has implemented to directly engage patients in biomedical research, TestBoston will involve individuals enrolling online and then receiving a kit in the mail with instructions on how to collect the samples. Study materials will be available in eight different languages to include individuals who do not speak English.

Samples collected by participants at home will be picked up and returned overnight to the Broad Institute for analysis, leveraging the significant capacity that the Broad has recently developed for SARS-CoV-2 testing. Samples taken using a swab of the front of the nose will be tested for active viral infection with all results being returned to the participant. Samples taken from a dried blood spot obtained by a small finger prick will be tested for antibodies to determine whether the participant has had a previous infection. Antibody results will be aggregated—so that individuals are not identified—and reported at the community level. Together, Broad and the Brigham investigators will analyze all findings in real-time and share them with key stakeholders at the state level, including the Massachusetts Department of Public Health, to enable public health responses to cases of new infection.

"TestBoston holds the promise of giving us real time data on how rates of COVID-19 in the Boston area are changing over time," said Betsy Nabel, MD, president of the Brigham. "This will inform public health efforts and enable us to provide the best possible care to all patients."

"This pandemic has underscored how important it is to collect accurate information to understand a virus that we previously knew nothing about," said Eric Lander, president and founding director of the Broad Institute. "We are thrilled to be able to partner with the Brigham, both to serve their patients and community and to ask key scientific questions

about immunity to SARS-CoV-2."

One of the team's goals is to create a platform for home-based sample collection that is integrated with medical and public health systems that can be scaled, if needed, should the Boston area experience a second surge of COVID-19 infections as well as modeled in other cities impacted by COVID-19 and future respiratory viruses. TestBoston will empower communities around Boston to better understand and end COVID-19 by providing an opportunity for patients to partner in research and public health interventions.

"While it is impossible to fully understand a pandemic when one is in the midst of it, integrating clinical, research and public health efforts, as is the goal of TestBoston, is critical for learning in real- time how we can offer patients the best possible care and informing how we can overcome some of the inequities that currently exist, such as access to testing," said Hung.

Provided by Brigham and Women's Hospital