

TestBoston Study Information Sheet

TestBoston: The BWH/Broad Direct-to-Patient COVID-19 Testing Study

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Who are we?: We are clinical researchers at the Infectious Disease Department of Brigham and Women's Hospital.

About this study:

We want to understand the risk of SARS-CoV-2 (the virus that causes COVID-19) infection in different people who receive some medical care at Brigham and Women's Hospital and who live in the greater Boston area. We also want to understand who gets infected without developing symptoms and who is more likely to experience more serious disease.

This study will develop a model for implementing at-home COVID-19 testing so that it can be used to test large numbers of people and minimize the need for people to have to come to clinics, emergency rooms, or other testing sites. We will study how to track the infection rate so that we can respond if there are new outbreaks of COVID-19 in the coming months.

What do I have to do in this study: We will ask you to answer a few questions which include how you have recently been feeling and your recent medical history. We will send you an at-home COVID-19 test kit with instructions and a pre-paid return packet. We will ask you to collect 2 samples: a sample from inside the front of your nose and a sample of blood from your finger, and send back these samples to our processing lab at the Broad Institute. We will be testing to see if you have active COVID-19 infection, or if you now have antibodies. After the first month, if you choose to be contacted again, we will send you a COVID-19 test kit monthly and ask you to complete a short health questionnaire for the subsequent months. The number of times you are tested will range from 1-12 and will not be more frequent than every 2 weeks up to 12 months.

Will I get the results of my tests?: You will receive the results of your viral tests. The viral test will be performed in the Clinical Research Sequencing Platform lab at the Broad Institute. Because this is a research study, we will return the result of the COVID-19 viral test to you as a research result and ask you to contact your physician to order another test to confirm the result. We would be happy to help you contact your local doctor to order to obtain confirmation testing and return your results to you if that would be easier. The results will be returned to your doctor who can make sure you receive the proper medical care as needed.

You will not receive the results of the research antibody test. We will report aggregate results (your results combined with other research participants results) to the Massachusetts Department of Public Health and other key stakeholders in public health to determine what percent of study participants had a positive antibody, and to help us better understand the prevalence, or how widespread COVID-19 is.

You can choose to be on an email list to receive newsletter updates about the research we are doing. This newsletter will not announce your results or anyone else's, but it will tell you some information about what we are learning about COVID-19. We may publish what we learn in medical journals.

Sponsor of the research: The Broad Institute of MIT and Harvard

Why we are asking you to participate, and how many people will participate: We are asking you to take part in this research study because you are an adult who has received medical care at Brigham and Women's Hospital within the past 12 months. About 10,000 people will take part in this research study.

What are the risks associated with your participation: Important risks and possible discomforts to know about include discomfort from collecting your own specimen. There may be some physical discomfort when the nasal swab or blood is collected. There is a small chance that you will develop a bruise, feel lightheaded, faint, or develop an infection at the site where you prick your finger to get a few blood spots.

Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all of the safety measures that we will use, we cannot guarantee that your identity will never become known. The risk of this happening is currently very low. It is possible also that someone could get unauthorized access or break into the system that stores information about you. Every precaution will be taken to minimize this risk. There could be other unforeseeable risks that are currently unknown.

Participation in this study: Your decision about whether or not to participate in this study will not change your ability to receive medical care within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

If you have any questions: You can call us or email the study email address info@testboston.org with any questions or concerns you may have.

If you have questions about the study, please contact the research investigators, Dr. Ann Woolley and Dr. Lisa Cosimi at 617-525-8418 during the weekdays between 9-5pm. You can also call Brigham and Women's Hospital ask for them to be paged 24/7: 617- 732-5700, pager #26276 for Dr. Woolley and pager #21519 for Dr. Cosimi.

If you want to speak with someone not directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.