PRINCETON UNIVERSITY
Informed Consent for COVID-19 Testing

Updated September 2021

In response to the COVID-19 pandemic, Princeton University is conducting testing for SARS-CoV-2, the virus that causes COVID-19 (also known as the "coronavirus"), through the University's CLIA-certified laboratory or a third party CLIA-approved laboratory (in either case, the "Lab"). This document explains the SARS-CoV-2 COVID-19 test and how we may use and disclose your information in connection with the test. By receiving the test and registering your test kit, you agree to the terms of this document.

SARS-CoV-2 COVID-19 TESTING

The test that you will receive is designed to detect if you have the SARS-CoV-2 virus. The results of this test will **not** indicate if you had the virus in the past or if you have immunity to getting the virus in the future. **It only tests for the presence of the virus in your saliva specimen at the time of the test.** Your saliva specimen will be collected through a process that involves spitting into a collection tube. Your saliva specimen will be used to determine your COVID-19 status. Residual (left over) saliva specimens may also be used for lab and test validation purposes (i.e., to check the performance of laboratory procedures, equipment and protocols) and for community surveillance (i.e., to track how the virus evolves and spreads). Personally identifiable specimens will not be used for research without your consent.

The potential benefits of testing include:

(1) Detecting an active infection, which will help you and the University make decisions to limit the spread of the virus to others by limiting your contact; and

(2) While there is no proven cure for COVID-19 at this time, detection may better inform your medical care in the event you test positive for the coronavirus.

The potential risks of testing include:

(1) There may be a potential for false positive or false negative test results;

(2) A positive test result does not rule out that you are not infected with COVID-19 and may result in unnecessary medical treatment or self-isolation; and

(3) A negative test result does not rule out infection with COVID-19. Individuals may come into contact with the coronavirus at any time and may be incubating an early infection that this testing cannot detect.

HOW WE MAY USE AND DISCLOSE YOUR INFORMATION

In order to perform the SARS-CoV-2 testing services and for reporting purposes, the University or third party CLIA-approved laboratory will need certain personally identifiable information about testing participants, including each participant's name, date of birth, gender and race/ethnicity, phone number, address, email address, and University ID number ("Information"). This Information will be used by the University or third party CLIA-approved laboratory to identify your saliva specimen and will be accessible through a secure web portal. The University or third party CLIA-approved laboratory will use your Information to report test results to the State of New Jersey's Department of Health and other federal, state and local government agencies, as required by law.

Except as provided above or otherwise stated in this document, personally-identifiable test results will be accessible only to University Health Services ("UHS") and explicitly authorized University personnel, if any, who have a need to know. If your test result is positive, UHS and other authorized personnel may use necessary components of your Information to facilitate contact tracing (without disclosing your identity to your contacts), building cleaning and disinfection, and, if you are a student, services such as isolation housing and meals. In exceptional cases, other authorized personnel may also use relevant portions of your Information, such as last testing date, when deemed necessary to ensure compliance with the COVID-19 policies the University has put in place to protect the health and safety of the campus community.

For faculty or staff members with a positive test result, UHS will notify your supervisor, manager or chair that you are approved to be absent for the dates specified and are to be cleared by UHS to return to work. Barring exceptional circumstances or a legal requirement, UHS will not disclose the fact that you tested positive to your supervisor, manager, chair or others. This process aligns with the University's short-term disability approval notification process.

The University may issue a general notification of a positive test result within a particular building without identifying the affected individual.

EMERGENCY USE AUTHORIZATION

For testing conducted by a third party CLIA-approved laboratory, the tests that are utilized are covered under an emergency use authorization ("EUA") granted by the U.S. Food and Drug Administration ("FDA") or pursuant to an authorization by the New Jersey's Department of Health (see below). If covered under an EUA granted by the FDA:

- The tests have not been FDA cleared or approved;
- The tests have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- The tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

NEW JERSEY STATE AUTHORIZATION

For testing conducted by the University's laboratory and, if applicable, by a third party CLIA-approved laboratory, the tests offered are pursuant to an authorization by the State of New Jersey's Department of Health, which requires that we provide you with the following information:

- The test has not been FDA cleared or approved;
- The test has been authorized by the State of New Jersey's Department of Health for use by authorized laboratories;
- The test has been authorized only for the detection of nucleic acid (the RNA genes) from SARS-CoV-2, and not for any other viruses or pathogens; and
- The test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner by the State of New Jersey.

CONSENT TO TESTING

I have read and understand the information provided above regarding COVID-19 testing and have, if necessary, discussed it with medical providers. All of my questions have been answered to my satisfaction. I understand that there are risks and benefits associated with undergoing the SARS-CoV-2 COVID-19 test,

including those set forth herein. I assume complete and full responsibility to take appropriate action with regards to my test results. Should I have questions or concerns regarding my results, I shall promptly seek advice and treatment from an appropriate medical provider. I hereby give my informed consent for the testing described in this document, as well as use and disclosure of my Information as described above.

QUESTIONS?

If you have any questions about the test or this document, please contact University Health Services at covidtests@princeton.edu or (609) 258-3141.