

Consent to SARS-CoV-2 Testing (General Consent and Registration)

Background: Your educational institution is providing SARS-CoV-2 testing to its students. This form explains the SARS-CoV-2 tests and who will get your results. The test(s) that you will receive are designed to detect if you have SARS-CoV-2, also known as the “coronavirus.” SARS-CoV-2 is the virus that causes the disease known as COVID-19. The results of this test will **not** tell you 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 specimen at the time of the test.** More details about the SARS-CoV-2 test, including the Fact Sheets for Patients and how results can be accessed, are attached hereto.

SARS-CoV-2 PCR testing: PCR testing, or molecular testing, is designed to detect the presence of the nucleic acids of SARS-CoV-2. Your sample will be collected through a process that involves swabbing your nose. Your sample will be sent to the Broad Institute’s CLIA-certified laboratory, the Clinical Research Sequencing Platform (CRSP), for the test to be performed.

BinaxNOW COVID-19 Rapid Antigen Testing: Antigen testing is designed to identify proteins of the SARS-CoV-2 virus. Your specimen will be collected through a process that involves swabbing your nose. The test will be performed on site under the direction of a medical professional as authorized by the FDA pursuant to an Emergency Use Authorization.

Initial Test to be Used: You will be receiving one of two tests, depending on the type of testing program selected by your educational institution. One type of test that may be used is the rapid antigen test, which will produce a rapid test result. A second type of test that may be used is the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Assay (the “CRSP PCR Test”), which depending on your educational institution’s testing program, will either be:

- (i) **analyzed individually**, in which case you will receive an individual test result, or
- (ii) **tested on a pooled basis**, meaning your sample will be placed in a tube with samples from a common group of 2-10 individuals and tested to see if any member of the group is positive for COVID-19. Pooled testing does not yield a definitive individual result for each member. You acknowledge and agree that if your sample is tested on a pooled basis, your test result should not be used for diagnostic purposes, meaning that a positive result in your common group does not mean that you are individually positive for COVID-19, and a negative result in your common group does not indicate with certainty that you are individually negative for COVID-19. As a result, whether your pooled test result is positive or negative, you agree to receive further confirmatory testing upon the request of your educational institution.

If your sample is tested on a pooled basis and a negative result is generated from the pool in which your sample is included, you will most likely be treated as negative. You may be asked to re-test on an individual basis for other reasons, such as experiencing symptoms or suspected exposure to COVID-19.

If your sample is tested on a pooled basis and a positive result is generated from the pool in which your sample is included, you will be asked to re-test on an individual basis. You may be required by your educational institution to isolate immediately.

Secondary Test to be Used: Confirmatory testing will involve obtaining a new sample from you and will be performed using the individual CRSP PCR Test or the rapid antigen test, at the discretion of your educational institution. Antigen testing will provide rapid results at the point of testing but may require a further confirmatory test.

Records to be Released From Your Educational Institution: By signing the below, you authorize your educational institution to release to CRSP, and providers of technology platforms used by CRSP, your name, phone number, mailing address, email address, student identification number, date of birth, and other demographic information, as disclosed. You are not required to consent to the release of these records. However, if you do not consent, CRSP will be unable to perform SARS-CoV-2 testing on you.

Duration of Release: Your educational institution will release your information to CRSP as needed to perform the testing.

Purpose of Release: Your information is being released to CRSP for the purpose of performing SARS-CoV-2 testing and reporting such results back to you, the health care provider who ordered your test, your educational institution, and where required by law, certain federal, state, or local government agencies. You acknowledge and agree that to the extent you are

providing a sample for pooled testing, a positive result may not be returned to you individually, and that instead you may be asked to re-test without acknowledgement of the result.

Revocability: You have the right to revoke this consent at any time by delivering a written revocation to Healthservices@curry.edu

Right to Record Disclosed: Under the Family Educational Rights and Privacy Act, you have the right to request from your educational institution the records disclosed to CRSP pursuant to this written consent.

Information to be Released by CRSP: By signing below, you authorize CRSP to release the results of your test to you (where permitted by state law) and your educational institution through a web portal or mobile software application. Your results will also be shared with the health care provider who ordered your test. By signing below, you also authorize CRSP to release your test results to relevant state health authorities, and certain federal, state, or local government agencies as required by law.

What to Do After Testing: If your individual results from the CRSP PCR Test or rapid antigen test are positive, please contact a doctor immediately. If your test is performed on a pooled basis, please follow the instructions provided by your educational institution. Only a doctor can diagnose you with COVID-19 and give you information about what you should do next. As further outlined in the Fact Sheets for Patients, negative results mean that the virus was not detected in your specimen. It is possible for the test to produce an incorrect negative result (called a “false negative”) in some people who have SARS-CoV-2. If you test negative but have symptoms of COVID-19 or concerns about exposure to SARS-CoV-2, contact a doctor to determine if you should be retested or take other actions.

Acknowledgment Concerning CRSP: CRSP is a clinical laboratory. CRSP does not give medical advice or provide medical care. You should talk to a doctor about any health care needs you may have, including any related to receiving this test. CRSP is not responsible for any medical care you receive. CRSP is providing this testing as a service to your educational institution and CRSP is not responsible for the ways in which your educational institution may use the results of your test. If you have questions about why you are taking this test or how your educational institution may use the results of your test, please talk to your educational institution. If there is leftover specimen after your test is performed, CRSP may remove information that identifies you from the specimen and use it for quality assurance, validation and laboratory testing development either alone or in collaboration with a public health authority.

By signing below you agree: (i) that you have read and understand the information in this consent form and related documents such as the Fact Sheets for Patients; (ii) to provide a nasal swab specimen for testing; (iii) to permit your personal information to be released to CRSP and providers of technology platforms used by CRSP; (iv) to have your specimen tested by CRSP for SARS-CoV-2 and/or by rapid antigen test; (v) that CRSP and the Broad Institute may disclose your test results as outlined in this form; (vi) to return for confirmatory testing to the extent requested by your educational institution; and (vii) that your leftover specimen and/or information about you may be used without information that readily identifies you after the testing is over for analysis in collaboration with a public health authority, including but not limited to sequencing to identify different strains of SARS-CoV-2. You voluntarily agree to this testing for SARS-CoV-2.

- **Signature:** _____ **Date:** ____ / ____ / ____

- **Name:** _____ **Date of Birth:** ____ / ____ / ____

- **Address:** _____

- **Live on campus YES: (circle)** _____ **1071 Blue Hill Av , Milton, MA 01286**

- **Student ID #:** @ _____ **Email address:** _____

- **Gender:** _____ **Race and Ethnicity:** _____