Informed Consent for Participants in The University of New Hampshire COVID-19 Safer at Schools Screening Program

Background on the UNH Safer at Schools Screening (SASS) Program

The University of New Hampshire and the State of New Hampshire partnered in a program to provide K-12 schools with testing services to detect COVID-19 in New Hampshire schools by facilitating asymptomatic testing. School participation in SASS COVID-19 testing is completely optional for any school in New Hampshire, and individual testing is completely optional for school staff members and students at participating schools. SASS program guidelines are available at: https://www.dhhs.nh.gov/dphs/cdcs/covid19/documents/safer-at-school-screening.pdf

The goal of the Safer at School Screening program is to identify persons who may be carriers of SARS CoV-2 -- the virus known as "COVID-19"-- even though they are asymptomatic and without known or suspected exposure to COVID-19, so that measures can be taken to prevent further transmission. Identifying asymptomatic individuals with COVID-19 as early as possible is critical to allowing in-person school and educational programs in New Hampshire. The UNH SASS program provides diagnostic PCR tests at no cost to staff and students at participating schools. SASS enables COVID-19 testing for students or staff who are returning to the school setting from an extended break (e.g., summer or week-long school vacations) and for select populations (students/staff who have traveled internationally or on cruise ships, participate in contact sports teams, residential K-12 schools and overnight camps) who are at higher risk of COVID-19 than the general population.

The UNH SASS program is not intended for individuals who have developed new and unexplained symptoms consistent with COVID-19. Any individual who develops these symptoms should promptly consult their healthcare provider and be tested for COVID-19 under appropriate infection control procedures.

The Diagnostic Testing Process

The University of New Hampshire has created a CLIA-certified COVID-19 testing laboratory (the "UNH Lab"). The UNH SASS program requires a nasal swab, which will be collected through either observed self-collection or administered specimen collection. Your sample will be tested using one or more of the following techniques.

1. **RT-PCR Testing**: PCR (or "polymerase chain reaction") is a molecular diagnostic test that first amplifies, then detects, the presence of COVID-19 virus in a sample. Upon receipt of your test kit, UNH Lab uses pooled testing as a processing step in which your swab sample is combined with three (3) other swab samples, and the pool of four (4) is analyzed for the presence of the COVID-19 virus. If the COVID-19 virus appears anywhere in the pool, the laboratory will then analyze each individual sample to determine which sample(s) contains COVID-19. Once the sample(s) with COVID-19 has been detected, the UNH Lab will run a confirmatory test that will yield a positive or

negative test result. PCR testing on administered nasal swab samples yields diagnostic results.

- 2. **Viral genomic screening:** Genome screening is another mechanism for molecular identification of the COVID-19 virus and can also be used to look for genetic mutations of the virus. The technique first amplifies any copies of the COVID-19 virus in the sample, then sequences the entire viral genome. THIS TECHNIQUE DOES NOT SEQUENCE HUMAN DNA. Viral screening can be used to definitively identify known variants of the COVID-19 virus or can be used as a confirmatory test if the patient is exhibiting symptoms consistent with COVID but when results from RT-PCR tests are inconclusive or negative. Current CDC guidelines prohibit UNH from releasing the results of SARS-CoV-2 variants to the participant or the school. Results will be provided to the NH Department of Health and Human Services for the purposes of public health surveillance only.
- 3. **BinaxNOW COVID-19 Ag CARD:** Your school may elect to perform a rapid test for students who present symptoms after arriving at school. TheBinaxNOWTM COVID-19 Ag Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (nares) swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

Test results will be shared with your school nursing team through a secure portal via our partner Transformative Healthcare. The UNH Lab may use a secure portal, text messages, email, or automated voice to make test results available to students/parents as needed for certain circumstances. Results will not tell you if you had the virus in the past or if you have immunity to getting the virus in the future. The diagnostic test only tests for the presence of the virus in your specimen at the time of the test. More information about the specific diagnostic test performed by the UNH Lab can be found here.

Please note that the UNH Lab 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. If your results are positive, please contact a doctor immediately. Only a doctor can diagnose you with COVID-19 and give you information about what you should do next.

The Potential for False Positives & False Negatives

COVID-19 testing sometimes yield false positives. A false positive is a finding indicating the infection is present when it is not. A false positive can result in: a recommendation to isolate, monitoring of close contacts for symptoms, and your temporary inability to work or engage in other activities. In addition, COVID-19 screenings and diagnostic tests sometimes yields false negatives. A false negative is a finding indicating the infection is not present when it is present. A false negative can result in your inadvertently spreading your infection to others. A regular, periodic testing protocol is designed to reduce the risk associated with false negatives.

How We Will Share Your Information

By participating in the UNH SASS program, you are consenting to the following information use and disclosure by UNH. The contact information and demographic data that you

provide to the university with your test will be used to assist in the preparation, analysis, and reporting of COVID-19 testing data. All personally identifiable information related to test results will be securely and confidentially maintained by UNH in limited-access systems, and will be used in accordance with the UNH Health and Wellness (H&W) Patient Rights and Responsibilities, Notice of Privacy Practices and Required Disclosures by NH State Law (see documents here). Identifiable information about testing participation and test results will be shared with Authorized Staff at your school, who have been designated to receive this information to support the public health and safety response. As required by law, both positive and negative test results will be provided to the New Hampshire Department of Health and Human Services (NH DHHS), or for non-NH residents, to other state public health agencies, which may further share that testing information with agencies such as the federal Centers for Disease Control.

Consent to Testing

By signing below and/or by participating in the UNH SASS program, you acknowledge, understand, and agree that you:

- Consent to the testing, and understand and accept the risks associated with the testing program including, but not limited to, obtaining a false positive or false negative result;
- Agree that any and all of your questions or concerns were addressed to your satisfaction prior to engaging in the screening and diagnostic test process; and
- Consent to your information being used and disclosed by UNH in the manner described herein, and authorize UNH to release the results of your test to your school nursing staff through a web portal or mobile software application.
- If you provide an email address or cell phone below you agree to receive results using those methods. Message & data rates may apply.
- This Consent will apply to all testing for the 2022-2023 school year, unless earlier revoked in writing.

Printed Name of Participant	
Signature of Participant	Date
* Email Address of Participant (only if over age 18)	* Cellphone Number (only if over age 18)

If the Participant is under the age of 18:

I am the parent or legal guardian of the Participant and I consent to their participation in the UNH SASS program as described above.	
Printed Name of Parent/Guardian	
Signature of Parent/Guardian	Date
* Email Address of Parent/Guardian	* Cellphone number of Parent/Guardian

^{*} Providing an email address is not required. Email will be used to provide access to secure portal as needed in certain circumstances to make test results available to students/parents.