

COVID-19 TESTING CONSENT FORM - STUDENT

Carroll College (“COLLEGE”) has engaged Biodesix, Inc. (“LAB”) to make LAB’s investigational laboratory testing services (“COVID Testing”) available to you, which includes a nasal/nasopharyngeal test for SARS-CoV-2, the virus (“Virus”) that causes the disease known as “Coronavirus Disease 2019” (“COVID-19”). The Virus assay is authorized by the FDA for use under an Emergency Use Authorization only by professionals in an Authorized Laboratory.¹ Please note, LAB does not know if these tests can find all people who may get sick with COVID-19.

According to LAB’s instructions and with guidance provided by a designated COLLEGE employee, you (“You” or “Student”) will be given a sampling kit for self-sampling. You must perform the self-sample in the presence of a COLLEGE authorized employee. LAB will perform testing on the self-sampled nasal/nasopharyngeal test sample that you performed and report the results to you and to COLLEGE officials.

There is no health care provider-patient relationship between you and the COLLEGE with respect to the COVID Testing or reporting of COVID Testing results.

WHAT ARE YOU BEING TESTED FOR?

Your COLLEGE has requested that you receive COVID Testing. Please note: the paragraphs that follow describe risks and contain information related to the COVID Testing.

WHY ARE YOU BEING TESTED?

You are being asked to have COVID Testing because the COLLEGE wishes to make COVID Testing available to its students to encourage student safety, as well as the safety of the COLLEGE’s campus and the greater Helena Community. Determining whether you have the Virus can be a critical step in protecting you, those you interact with, the COLLEGE’s other students, employees, visitors, and others who may enter the COLLEGE’s campus.

IF A COVID TEST(S) IS POSITIVE, DOES THAT MEAN YOU HAVE COVID-19?

There is a chance that the COVID Test may give a positive result for the Virus when the Virus is not present (false positive). Positive results for the Virus are indicative of the presence of the virus that causes COVID-19; however, clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status and history. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent(s) detected in the COVID Testing may not be the definite cause or result of disease. You may consider seeking medical advice for positive results. **Neither the COLLEGE nor LAB can provide medical advice or make any recommendations to you in this regard.**

You or COLLEGE may also be required under Federal, State or local law to practice or require you to practice self-isolation and/or quarantine measures with a positive COVID Test. If a COVID Test result is positive, LAB is required by law to report that result to certain public health agencies, including, but not limited to, the Centers for Disease Control and Prevention (CDC), and Montana

¹ Authorized Lab in the letter of authorization refers to, “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests” as “authorized laboratories.”

and local public health authorities. COLLEGE also may report positive COVID Testing results to appropriate public health authorities.

In case of a positive COVID Test, you are responsible for complying with the legal requirements applicable to you personally for your own jurisdiction.

IF THE COVID TEST IS NEGATIVE, DOES THAT MEAN YOU DO NOT HAVE COVID-19?

The COVID Test(s) may give a negative result when you actually have the Virus (false negative).

A negative COVID Test result does not prove that a person does or does not have the Virus. A negative result should not be the sole basis for decisions regarding possible infection if you have symptoms or are otherwise concerned about exposure. Negative results should be combined with clinical observations, patient history, and epidemiological information.

The COVID Test is not a substitute for medical diagnosis or advice. A trained health professional should interpret the results in conjunction with your medical condition, clinical signs and symptoms, and the results of other diagnostic tests. Neither the COLLEGE nor LAB can provide medical advice or make any recommendations to you in this regard.

ARE THERE ANY RISKS FROM THE COVID TEST(S)?

There are still many uncertainties about the transmission of COVID-19 and the presence of COVID-19 antibodies. LAB can provide guidance to you or COLLEGE regarding common practices and reasonable safeguards designed to, among other things, prevent transmission of the Virus based on current understandings of the Virus and how it is transmitted. However, neither LAB nor your COLLEGE can guarantee your health or that you will not become infected with the Virus during or as a result of your participation in the COVID Testing program.

The nasal or nasopharyngeal (nasal/nose) swab procedure used to obtain the Virus sample for COVID Testing may be uncomfortable for you. You will collect the sample. Collection entails using a sterile swab with a long shaft for sampling in the nose for approximately 10-15 seconds. Internal abrasions, choking or other injuries may occur even if the sample is collected properly.

WHAT ABOUT PRIVACY?

COVID Testing results will be reported by LAB to you and COLLEGE officials in a secure and confidential manner. LAB will keep the COVID Testing results confidential and other than the potential disclosures described above, will only share the COVID Test results as instructed. As noted above, positive COVID Test results may be reported to public health authorities and appropriate COLLEGE officials in accordance with applicable law. With regard to disclosures it makes, COLLEGE will use reasonable efforts to disclose the minimum amount of information necessary to comply with applicable law or legal orders, or to notify those COLLEGE officials with a need to know. COLLEGE has no control over LAB's use or disclosure of COVID Test results.

As per federal guidelines, the LAB must obtain a unique identifier (Student ID), name, date of birth, gender, race, ethnicity, full address, phone number, and e-mail address. Your COLLEGE has collected this data as part of your educational record and has already provided LAB with fields designated as directory information in the COLLEGE's FERPA policy, unless you have previously

requested that the COLLEGE not share your directory information. The COLLEGE must provide the LAB with all of the information necessary to process your COVID Test, as stated in the Informed Consent for COVID Testing section below.

ASSUMPTION OF THE RISK AND RELEASE

There are certain inherent risks associated with undergoing COVID Testing. The undersigned hereby knowingly and voluntarily consents and your heirs, executors, administrators, assigns or personal representatives, to having my nasopharyngeal cells collected through self-sampling and analyzed by LAB ("Activity"). To the extent permitted by law, the undersigned hereby waives any and all rights, claims, causes of action, damages, and/or costs of any kind whatsoever arising out of my participation in this Activity, and do hereby release and forever discharge LAB and COLLEGE, along with its parents, subsidiaries, affiliates, managers, members, agents, attorneys, staff, community owner(s), volunteers, representatives, predecessors, successors and assigns, from any liability for any physical or psychological injury, including but not limited to illness, death, economic or emotional loss, that Student may suffer as a result of your participation in this Activity and/or resulting from, a false positive COVID Test result or a false negative COVID Test result. In the event that the Student should require medical care or treatment following the Activity, the undersigned Student agrees to be financially responsible for any costs incurred as a result of such treatment.

INFORMED CONSENT FOR COVID TESTING.

The undersigned acknowledges and agrees that he/she has carefully read and understands this Consent Form and consents to the following:

- a. I hereby authorize LAB to perform COVID Testing on me, as described in this Consent Form, through the self-sampling of the nasopharyngeal swab.
- b. I hereby authorize my COVID Testing results to be disclosed to county and state public health authorities, or to any other governmental entity as may be required by law, including the CDC.
- c. I hereby authorize and request that my COVID Testing results be disclosed to, and used by, appropriate COLLEGE officials, including but not limited to appropriate officials at the COLLEGE's Wellness Center, in order to encourage a safe COLLEGE campus, workplace, and learning environment, and to enhance the safety of COLLEGE's students, employees, residents, and visitors.
- d. I understand that a positive COVID Test result, although not proof that the Student has COVID-19, may require COLLEGE to implement strict isolation protocols and/or to cause the Student to self-isolate in an effort to avoid infecting others or otherwise take actions to comply with the laws of the COLLEGE's jurisdiction.
- e. I hereby acknowledge that I am not creating a patient-healthcare provider relationship with LAB or the COLLEGE by participating in the COVID Testing, or by permitting the COVID Test results to be reported to appropriate COLLEGE officials. I further acknowledge that neither COLLEGE, LAB, nor any health care provider affiliated or associated with LAB or COLLEGE (including, without limitation, any medical professionals who initially ordered my COVID Testing from LAB or any medical professionals who received my COVID Testing

results), is acting as my medical provider. COVID Testing does not replace treatment by my medical provider. I assume complete and full responsibility to take appropriate action with regards to my COVID Test results, including seeking medical advice, care and treatment from my medical provider if there are questions or concerns, or if my condition worsens.

- f. I acknowledge that, as with any medical test, there is the potential that false positive or false negative COVID Testing results can occur.
- g. I hereby authorize the COLLEGE to share my student ID, student email, gender, race, and ethnicity with the LAB. I further authorize the COLLEGE to share my directory information including date of birth, full address and phone number with the LAB even if I have previously requested that the COLLEGE not share my directory information.

I, the undersigned, have been informed about the COVID Testing purposes, procedures, possible benefits and risks, and I have received a copy of this Consent Form. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree that I will submit to testing for the COVID-19 Virus.

Name of Student:

Signature:

Date: _____