Study on the exposure of covid-19
Serology phase

Since the start of the COVID-19 pandemic, CARTaGENE has been identified as an important resource for advancing research at both the provincial and federal levels. Along with five other Canadian cohorts, CARTaGENE is part of a Canadian consortium, the Canadian Partnership for Tomorrow's Health, CanPath (https://canpath.ca/en/) formerly the Canadian Partnership for Tomorrow Project, which plays a key role in coordinating and harmonizing research efforts on COVID-19. CanPath's SUPORT-Canada initiative, funded by the Canadian Institutes of Health Research (CIHR), is one of the initiatives that will be able to identify the factors contributing to susceptibility to COVID-19 from biological samples.

Furthermore, the COVID-19 Immunity Task Force (CITF) (https://www.covid19immunitytaskforce.ca/en/), funded by the government of Canada, brings together experts from universities, hospitals and public health agencies to determine the extent of the spread of the coronavirus in Canada. One of the mandates of this group is to support the design and rapid implementation of population studies that will generate reliable estimates of immunity against the coronavirus, also known as SARS-CoV-2. The CITF coordinates the objectives of serological surveys with the aim of quickly transmitting the results of these surveys to federal, provincial and territorial decision makers to guide them in the short and medium term in the management of the COVID-19 epidemic. Thus, funded by the CIHR and CITF, the CanPath cohorts were identified as key players in advancing the research by recruiting 20,000 individuals from all cohorts. Together, research conducted by the Canadian cohorts such as CARTaGENE greatly increases the value of the results.

In this context, your commitment to health research becomes all the more precious and you could make a difference in the fight against the coronavirus by **participating in the COVID-19 study by CARTaGENE which includes two phases:** 1. The questionnaire phase and 2. The serology phase. More specifically, the serology phase of this study consists of collecting a blood spot sample that will determine whether or not you have developed antibodies against COVID-19. You could participate either in the first phase (questionnaire) only or in both phases (questionnaire and serology).

The material presented below is intended to provide you with information on this aspect of the investigation and its progress so that you can give informed consent. Take the time to read this document carefully and do not hesitate to contact us with any questions (unite.cartagene.hsj@ssss.gouv.qc.ca or 1-877-263-2360).

PARTICIPATION IN THE STUDY

Study participants

You are invited to participate in this study because you are a CARTaGENE participant. If you have completed the questionnaire during the first part of the COVID-19 study in June of 2020, we thank you for your participation and invite you to participate in the serology phase of the study. If you did not participate in the first phase of the study, you now have an opportunity to do so. **Even if you have not had any symptoms or a diagnosis of COVID-19 or whether or not you have received the COVID-**

19 vaccine, your participation is valuable to CARTaGENE and will improve the interpretation of the results.

Aim of the study

The goal of this serology phase of the COVID-19 study is to measure the proportion of the Quebec and Canadian population that has been in contact with the virus. The results of the serology phase of the COVID-19 study will produce scientific data that can be used by researchers and public health decision makers to study the evolution of the pandemic and to make decisions in this regard.

Thus, combined with the questionnaire phase, this serology phase will allow a better understanding of the spread, dynamics and physical and psychosocial impacts of the disease. Finally, it is important to know the dynamics of active cases of COVID-19, but also of the people who have contracted COVID-19 without having any symptoms and who may have developed antibodies, as well as the duration of the presence of these antibodies.

To meet these objectives, this study contains two phases: 1. The questionnaire phase and 2. The serology phase.

Course of the study

1. Questionnaire phase

You will be invited to complete a questionnaire on the impact of COVID-19 on your daily life. More specifically, this 30 to 40-minute questionnaire covers symptoms, diagnoses, health care usage (e.g. hospitalization), risk factors, lifestyle habits, as well as socioeconomic and psychosocial aspects of the pandemic. In addition, questions regarding vaccination against COVID-19 will be included in the questionnaire.

For participants who have already completed the questionnaire during the first part of the study in June, the questionnaire will essentially consist of an update of your health status since the last questionnaire and of developments related to COVID-19 (new symptoms, new tests carried out, new diagnoses, vaccination). Several questions will already be pre-filled with the old answers. It will suffice to validate or change these answers.

The questionnaire will be accessible via a personalized link in an email that will be sent to you 48 hours after signing the consent form. This will be a unique link that will allow you to answer the questionnaire in a secure manner. You will have 7 days to answer this questionnaire.

2. Serology phase

If you agree to participate in the serology phase, a blood spot sample collection kit will be sent to you to collect a blood spot sample taken from your fingertip. The kit will contain the necessary equipment (alcohol swabs, sampling equipment and instructions including a link to a video) to perform the blood spot sample without the intervention of a caregiver, to minimize the risk of transmission of COVID-19.

If you choose this option, you will need to confirm your mailing address at the time of consent so that we can send the blood collection kit. You will also be asked a few questions to determine your eligibility.

Once your blood sample has been taken, simply place it in the prepaid return envelope and mail it. Sample collection will be centralized by CanPath to ensure consistency in data collection and analysis methods. The blood spot samples will all be analyzed by the same laboratory designated by CanPath in order to limit inter-laboratory variability and to make the results comparable. The laboratory will measure, using state-of-the-art techniques, the presence of antibodies to the coronavirus, also known as SARS-CoV-2, in the blood spot sample provided.

Prerequisites for eligibility for the serology phase

However, to participate in the serology phase, you must meet certain eligibility criteria to participate in the serology phase. If you answer yes to any of these questions, you are not eligible for the serology phase of the COVID-19 study.

1. Do you have a blood-clotting disease such as hemophilia or Von Willebrand's disease? YES/NO

2. Have you had chemotherapy in the past 4 weeks? YES/NO

3. Have you had a double mastectomy (bilateral)? YES/NO
(Note: if you have had a mastectomy on one side only, you can perform the finger prick on the opposite hand.)

4. Have you had any fainting or vomiting from a finger prick or seeing blood? YES/NO

3. Choice of participation
You will have the choice to participate in three ways:

1. Complete the questionnaire only
2. Complete the questionnaire and give a blood sample
3. Complete the questionnaire and give three blood samples for a longer-term serological study
    - Initial questionnaire and 1st blood sample
    - About 6 months after the 1st blood sample: short questionnaire and blood sample
    - About 12 months after the 1st blood sample: short questionnaire and blood sample

For the 3rd possibility, we want to obtain three repeated serological measurements in order to describe the evolution over time of the rate of exposure of the SARS-CoV-2 infection. In addition, this will allow an assessment of the influence of pathologies, the number of exposures and drugs on seropositivity and the severity of infection. Finally, this will make it possible to describe the evolution of antibodies in order to assess potential re-infections in individuals.

You will receive the result of the serological analysis carried out on your sample for each blood sample collected (see paragraph on the communication of results).

However, if the maximum quota allocated by our funding is reached, you may not be contacted to donate a blood sample despite your consent. The funding provides for 4,721 serology tests, including 500 participants selected for a follow-up of 3 serology tests. However, be aware that each participation is valuable, even if it only includes the data collected by the COVID questionnaire. In addition, we would like to reiterate our gratitude to you for your commitment to health research.

PARTICIPANT'S RIGHT OF WITHDRAWAL

You are free to participate or not in this study on COVID-19. If you choose to participate, you can withdraw from the study at any time and request that the data and / or samples you have provided to CARTaGENE and CITF be destroyed. To withdraw, simply contact the CaG-CHUSJ Unit toll free at 1-877-263-2360.

RISKS AND BENEFITS RELATED TO THE QUESTIONNAIRE AND THE BLOOD SPOT SAMPLE COLLECTION

Risks: Fingertip blood collection is the best technique for taking small blood samples while avoiding contact with a caregiver. Minor inconveniences such as a tingling sensation at the time of the sample, a hematoma or a scar, may appear. In cases of poor blood circulation, the sample may be more difficult to take.

The risks of identifying participants are very limited, as no identifying information will circulate throughout this project. Thus, collection kits will be identified only using the participant ID code. The questionnaire data that will be collected will also be coded and stored in highly secure facilities within CARTaGENE and CITF.

Benefits: Collectively, this study will identify the factors contributing to susceptibility to COVID-19 and estimate the proportion of the Quebec population that has been in contact with the virus. Participants will be able to be informed of the general results of the research carried out with the data collected in this serology section of the COVID-19 study through the newsletter and the CARTaGENE website (https://www.cartagene.qc.ca/en/participants).

On an individual level, you may receive a direct benefit if you participate in the serology phase of the study and donate a blood spot sample. In fact, the results of the serological tests will be communicated to you by email.

CONFIDENTIALITY AND ACCESS TO DATA AND SAMPLES

Separation of personal information
Personal information is always kept separate from health questionnaires and from the biological samples and is never transfered to researchers. Personal information is held by an entity

independent of CARTaGENE, namely the Unit-CaG-CHU Sainte-Justine under the responsibility of the archives of the Sainte-Justine Hospital. CARTaGENE and the researcher users do not have access to this personal information, but simply to codes identifying the participants.

Storage and data and sample access

1. Data and samples stored at CARTaGENE

The data collected from the questionnaires as well as the results of this serology phase will be coded and integrated into the CARTaGENE databases, where they will be kept until the end of CARTaGENE's activities.

The biological samples will be coded and sent to the *Biobanque Génome Québec - Center hospitalier affilié universitaire régional de Chicoutimi* (Biobanque GQ-CAURC), in Saguenay, to be stored with the other samples from CARTaGENE participants.

The framework relating to data access requests and samples collected in this study remains the same as that which prevailed during your initial participation in CARTaGENE. Once coded, the data and samples can be used by researchers in Quebec or outside for health studies that have obtained the required scientific and ethical approval.

2. Data stored within the CITF (McGill University)

McGill University is legally responsible for the storage of and access to the data that will be stored within CITF. **Only coded data collected from questionnaires and serological test results of this COVID study will be sent to CITF.** No samples or personal information will be sent to CITF.

As mentioned previously, the CITF is a Canadian Task Force that coordinates several studies across the country related to the COVID-19 pandemic with the aim of quickly transmitting the results to federal, provincial and territorial decision makers. This quick transmission of the results will help guide them in the short and medium term in managing the pandemic.

A governance framework similar to that of CARTaGENE prevails within the CITF. Only researchers who have obtained the approval from an access committee and an ethics committee will be able to access coded data held by CITF. The McGill University Ethics Committee is responsible for the CITF project and the data stored there. When CITF ceases its activities, CARTaGENE may request the destruction of the stored data held at CITF.

COMMUNICATION OF RESULTS TO PARTICIPANTS

If you donate a blood spot sample, you will receive your serological test result by email. This could be positive, negative or with technical failures. This test does not report antibodies developed after receiving a COVID-19 vaccine.

Positive result for antibodies

Your sample tested positive for antibodies to COVID-19. Positive antibody results occur after infection with COVID-19 or after receiving a COVID-19 vaccine. It is possible that this may be a false positive result. False positive results for COVID-19 antibodies can be caused by antibodies to other viruses or for other reasons. At this time, it is not known how long antibodies to COVID-19 may last following an infection, or whether having antibodies is associated with immunity to future COVID-19 infections. Because of this, you should continue to follow physical distancing practices, wear a mask in public spaces, wash your hands frequently and adhere to public health recommendations.

Negative result for antibodies

Your sample tested negative for antibodies to COVID-19. Because the antibodies we tested for may not be identifiable in the first few weeks after an infection and it is not known how long antibodies may last, a negative antibody result cannot fully rule out a past COVID-19 infection. It is not known how long these antibodies may last after infection. If you have received a COVID-19 vaccine, you may have developed antibodies not reported by this test. You should continue to follow physical distancing practices, wear a mask in public spaces, wash your hands frequently and adhere to public health recommendations.

Technical failure

A technical failure indicates there was an error with your sample or the analysis at the lab, such that antibody levels could not be reliably measured. We are therefore unable to comment on your possible exposure to COVID-19.

Thank you again for your participation in the CanPath and CARTaGENE COVID-19 Antibody Study. Regardless of the outcome of your sample, you continue to make a valuable contribution to COVID-19 research.

In addition, you will have access to the general results of the research carried out with the data collected as part of this serology phase of the study on COVID-19 by the CARTaGENE website (https://www.cartagene.qc.ca/en/participants) or by the newsletter published by CARTaGENE.

For more information

- Consult the CARTaGENE **website** at: https://cartagene.qc.ca
- For any questions regarding CARTaGENE or for a withdrawal request, contact the CaG-CHUSJ Unit
  By phone: 1-877-263-2360 (toll free)
  By email: unite.cartagene.hsj@ssss.gouv.qc.ca
- Any complaint related to your participation in CARTaGENE can be addressed to the Complaints and Service Quality Commissioner of CHU Saint-Justine

  By phone: (514) 345-4749
  By mail: Commissaire aux plaintes et à la qualité des services
  CHU Sainte-Justine, bureau A921
  3175, chemin de la Côte-Sainte-Catherine

Montréal (Québec) H3T 1C5

By email: commissaire.message.hsj@ssss.gouv.qc.ca

Thank you for making the difference!

CONSENT

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Executive director: Me Alexandra Obadia, LL.B., LL.M.

Host institution : Centre Hospitalier Universitaire Sainte-Justine.

Funding: CARTaGENE is funded by the Canadian Partnership Against Cancer and by Génome Québec. The COVID-19 study is funded by the Canadian Institutes of Health Research (CIHR) and the COVID-19 Immunity Working Group (CITF).

Purpose of the COVID-19 study : The aim of the study is to identify the factors contributing to susceptibility to COVID-19 and to estimate the proportion of the Quebec population that has been in contact with the virus.

By signing this consent form, I agree to participate in the COVID-19 study and I affirm that:

- I have read and understood the information contained in this document and acknowledge that I have had the opportunity to ask questions.

- I agree that the data collected in this study from the questionnaires and the results of serological analyzes, if applicable, will be encoded, transmitted, and stored within CARTaGENE and CITF.

- I agree that my blood samples will be sent, in coded form, to a central laboratory assigned by CARTaGENE and CanPath to perform serological analyzes and that the remaining samples will be sent to the *Biobanque Génome Québec-Centre hospitalier affilié universitaire régionale de Chicoutimi (Biobanque GC - CAURC).*

- I agree that my blood samples will be tested for serology and that the results will be sent to me by email.

- I also authorize the laboratory (ies) or institution (s) holding my COVID-19 screening test results to transfer them to CARTaGENE for validation purposes.

- I agree that my data and my samples, once coded, may be used by researchers in Quebec or elsewhere in the context of health studies that have obtained the required scientific and ethical approval.

- I agree that my encrypted data will be shared with other COVID-19 research initiatives, such as CanPath and the COVID-19 Immunity Task Force, to increase statistical power and advance research.

- I understand that I will not receive any financial or other benefit resulting from the possible

commercialization of a test or any other product developed through my participation in this study.

- I understand that after my death, my data and samples will not be withdrawn from CARTaGENE and CITF, unless there are clear instructions to this effect in my will or in any other document having legal value.

- I understand that my participation is completely free and voluntary and that I can withdraw at any time without giving a reason, by dialing 1-877-263-2360.

- I agree to participate in this study and to (choose one option):

☐ Complete only the COVID-19 questionnaire.

☐ Complete the COVID-19 questionnaire and donate one (1) blood spot sample using a collection kit that will be mailed to me.

☐ Fill out the COVID-19 questionnaire, give three (3) blood spot samples (6 months apart) using a collection kit that will be sent to me by mail and complete a short questionnaire during the 2nd and the 3rd collection phase.

Thank you for making the difference!