Guidelines for obtaining specimens for laboratory testing from a patient under investigation for a SARS-CoV-2 infection	
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Changes to the last authorized version: **The current version has been extensively modified from prior versions. Please review the entire document.**	

1. Target audience & scope

This document is directed towards nurses, physicians and other health care workers (HCW) directly involved in caring for a patient under investigation for or confirmed to have a SARS-CoV-2 (formerly known as 2019-novel Coronavirus or 2019-nCoV) infection. It pertains to Montreal area acute care hospitals served by the Optilab Montréal - MUHC Laboratory Cluster. These hospitals include the McGill University Health Centre (including the Glen site, MGH, MNI and Lachine), the Jewish General Hospital, St-Mary's Hospital, Hôpital de LaSalle and the Lakeshore General Hospital. A separate document will apply for the Centre intégré de santé et des services sociaux de l'Abitibi-Témiscamingue (CISSSAT).

2. Objective

This procedure is aimed at safely removing specimens from the isolation room of a patient under investigation (PUI) for SARS-CoV-2 and then transporting them to the laboratory. Adherence to these measures will minimize the risk that the surface of a specimen container/tube will act as a fomite and will ensure that we do not inadvertently introduce SARS-CoV-2 to the hospital or laboratory setting. Specifically, it aims to keep HCW and laboratory personnel safe by avoiding the

contamination of personnel or the environment due to leakage/spills or cross-contaminating fomites.

3. Background

There are a rapidly increasing number of requests for testing patients for the novel Coronavirus (nCoV), first identified in Wuhan, China. We have now entered a pandemic situation and community transmission is being documented in Canada. The nomenclature of the virus, initially dubbed 2019-nCoV, has been modified and for the purposes of this document is now referred to by its new official name, "SARS-CoV-2 ". Disease caused by this virus is now dubbed "COVID-19". Our knowledge of the virus' natural history, transmissibility and pathogenicity is evolving on a day-to-day basis, however we know the following:

1) With other emerging coronaviruses (e.g. SARS-CoV-1 and MERS-CoV) human-to-human transmission occurred primarily via the respiratory route via droplets and also through aerosols and aerosol-producing procedures. This is certainly the case with SARS-CoV-2 .
2) SARS-CoV-1 and MERS-CoV can be shed in the stool and urine, although virus is present at levels significantly lower than the respiratory tract and virus infectivity in these specimens has not been established or well-characterized. For SARS-CoV-2, preliminary data reveal very low levels of viral RNA in urine, however there may be significant levels of both RNA and/or infectious virus in stool.
3) Although SARS-CoV-1 and MERS-CoV RNA can rarely be detected in the blood of some infected individuals using molecular techniques, the level of viremia is relatively low and infectivity has not been demonstrated. Preliminary data reveal intermittent SARS-CoV-2 viremia in blood, that is of a much lower magnitude than respiratory secretions. Accordingly, blood specimens are thought to be very unlikely to represent a risk for laboratory-acquired infection. Infectivity has not been demonstrated.
4) There is good evidence that in some cases transmission of such viruses also occurs via fomites (i.e. inanimate objects that may be contaminated with infectious organisms and serve in their transmission). Although enveloped viruses generally lose infectivity quickly in humid and warm conditions, coronaviruses have previously been demonstrated to survive on smooth environmental surfaces (such as plastic or metal) for prolonged periods (2-3 days under ideal conditions, with progressive loss of infectivity). For the moment it is unclear if fomites represent a major risk for transmission.

4. Test ordering:

- These procedures must be followed while the patient is under investigation for or confirmed to be infected with SARS-CoV-2, irrespective of the time required to obtain a SARS-CoV-2 test result.

- The usual procedures in each institution are to be followed for ordering tests. **MANUAL REQUISITIONS ARE PREFERRED** at most sites. Order entry for SARS-CoV-2 testing is possible if this has been specifically implemented at your site.

Molecular testing for SARS-CoV-2 (COVID-19)

- Unless your institution has arranged for order entry (with obligatory entry of all required information), all requests for SARS-CoV-2 testing **MUST** be accompanied by the requisition for **COVID-19 screening** (see Appendix A) which indicates the **specimen type, the priority category and the patient description.** In addition the requisition must indicate: patient demographic data, prescriber's (physician /collective order/ nurse practitioner) name and license number, travel history if any (country and dates of departure and return) and symptoms (including duration).
- This requisition captures data required by Santé Publique AND allows appropriate **prioritization of specimens for testing**. THE TEST WILL BE CANCELLED IF THIS REQUISITION IS NOT RECEIVED. At some institutions, order entry that captures such data has been implemented.
- Molecular testing for SARS-CoV-2 can only be ordered once the patient has been evaluated by a physician or a nurse practitioner. **Such specimens will not be processed if the ordering professional's name and license number is not provided.**
- **The preferred initial specimen is a nasopharyngeal swab. ONLY ONE nasopharyngeal swab** (flocked) in a universal transport media (UTM) tube is required. This will be tested for SARS-CoV-2 at either the MUHC Glen site or the JGH.
- In some clinical sites or institutions, alternate collection methods might be used (e.g. saline, Hanks buffer or cobas PCR media). These collection methods must have been validated previously before they can be used for different nucleic acid extraction methods. If the laboratory receives a specimen obtained with an inappropriate or non-validated swab or transport media, the specimen will be rejected.
- Other samples which may be sent for SARS-CoV-2 molecular testing include **sputum, endotracheal aspirates and bronchoalveolar lavage fluid**.
- Respiratory virus PCR testing (either multiplex or influenza/RSV) as a stand-alone test **CANNOT** be ordered before requesting SARS-CoV-2 testing. Either **SARS-CoV-2 testing can be requested alone** OR additional respiratory virus testing can be requested to be done on the same specimen obtained for SARS-CoV-2 testing. Molecular testing of the inoculated UTM for other respiratory viruses may **ONLY** be performed in certain situations based on the clinical scenario. Such testing will generally only be available for hospitalized patients or patients that require admission and pregnant females or immunocompromised hosts (irrespective of admission status).

Microbiology tests for a patient under investigation for or confirmed to have a SARS-CoV-2 infection

- Brightly green "Code -C" stickers (see Appendix B) **MUST** be affixed to **ALL specimens obtained for Microbiology**. This includes all blood culture bottles, swabs, sputum, urine, stool and any other biological sample sent in a sterile container.

Other tests for a patient under investigation for or confirmed to have a SARS-CoV-2 infection

- An attempt should be made to limit testing to analyses that would impact the care of a patient presenting to the Emergency Department or upon transfer to the Intensive Care Unit with a serious or severe respiratory tract infection, cardiorespiratory process or hemodynamic instability/septic picture of unclear etiology.
- Each Emergency Department, Intensive Care Unit or other designated clinical unit should pre-prepare **packages of vacutainer tubes labelled with brightly** green "Code -C" stickers. Please use these tubes exclusively for PUI for SARS-CoV-2 infection.
- Brightly green "Code -C" stickers **MUST** be affixed to any other specimen obtained. **PLEASE ENSURE THAT ALL SPECIMENS AND ANY REQUISITIONS ARE CLEARLY LABELLED WITH THE PROVIDED BRIGHTLY COLORED GREEN STICKER.**

5. Specimen Collection

A. Preparation before entering the room

1. Ensure that Infection Prevention and Control (IPAC) directives have been followed.
2. Ensure that a physician or nurse practitioner has evaluated the case and determined that laboratory testing for SARS-CoV-2 should be carried out .
3. Once a patient has been identified as a PUI for SARS-CoV-2 , then all specimens for laboratory testing should be obtained in an isolation room preferably under negative pressure.
4. Ideally, you should identify another colleague (i.e. "buddy") to be stationed outside the room in case you need assistance.
5. Pre-prepared sets of vacutainer tubes, universal transport media and other specimen containers, with brightly colored green labels affixed, should be used for PUI for SARS-CoV-2. This will facilitate identification of the tubes/containers as specimens from PUI for SARS-CoV-2 and provide a visual reminder not to perform certain procedures in the laboratory.
6. Review which tests have been ordered.
7. Gather all necessary tubes/containers required to obtain patient specimens.
8. Prepare all biohazard bags (clear and sealable) that will be required. Each specimen type to be obtained requires two bags to allow double-bagging. Specimens to be sent to the microbiology lab must each be in a separate bag (double bag). Blood specimens in vacutainers for routine biochemistry or hematology tests can be sent to the required laboratory grouped together in one bag.
9. Prepare all specimen labels but do not stick on tubes/containers.
10. Obtain EITHER two disposable under-pad mats (e.g. "diaper mats" with absorbent cotton on one side and blue plastic on the reverse) OR two disposable plastic receptacles (e.g. kidney basins).
11. Ensure that disinfectant wipes (with documented virucidal activity against enveloped viruses) are available both inside and outside the room. **Accel® INTERVention® Wipes** with

0.5% w/w hydrogen peroxide have cidal activity within one minute with proper use and are therefore preferred.

B. Obtaining specimens from the patient

1. Don the necessary personal protective equipment (PPE) as advised by IPAC directives then enter the room with all necessary materials when ready. The "buddy" stationed outside the room should wear PPE as specified by IPAC directives.
2. Before going to the patient, identify a flat surface (e.g. counter or mobile patient tray) that is as far away from the patient as possible (preferably at least two metres away from the patient).
3. On this surface, set up two zones to receive your specimens. EITHER two disposable blue underpad mats ("diaper mats") OR two disposable plastic receptacles (e.g. kidney basins) could be used for this purpose.
4. One blue mat or basin will be used to receive the specimens initially. This is the "**contaminated specimen zone**". The second blue mat or basin will be used to receive the surface disinfected specimen (post cleaning with disinfectant wipes). This is the "**decontaminated specimen zone**".
5. Place all specimen labels and the required number of primary biohazard bags in the "decontaminated specimen zone".
6. Place a disinfectant wipe flat in the middle of each zone (one in "contaminated" zone and one in "decontaminated" zone).
7. **Proceed to collect specimens. Blood or urine specimens should be obtained BEFORE respiratory tract or stool specimens.**
8. **Blood or urine** specimens generally do not require surface decontamination unless they are obtained from a critically ill patient or during an aerosol generating procedure or after an aerosol generating procedure has taken place in the room (e.g. suctioning, intubation, bronchoalveolar lavage).
9. Specimen tubes/containers used to collect upper/lower **respiratory** specimens (i.e. nasopharyngeal swabs in UTM, sputum, endotracheal aspirates or bronchoalveolar lavage) or **stool** specimens must have their **surface decontaminated** with a viricidal disinfectant wipe (preferably Accel® INTERVention® Wipes with 0.5% w/w hydrogen peroxide and cidal activity within one minute with proper use) then allowed to dry before being double bagged and sent to the laboratory. This should be done before specimen labels are affixed to the specimen container
10. **Ensure that any containers are closed tightly**. A leaking specimen container will result in automatic rejection of the specimen and cancellation of the test and if indicated a new specimen will have to be collected.
11. Once collected, place specimens in the middle of the "contaminated specimen zone" then wipe each tube/container thoroughly with a disinfectant wipe.

12. Ensure that the outside of the specimen tube/container is not visibly soiled; if visibly soiled then disinfect again thoroughly with wipes. If it remains soiled then discard it inside the patient's room in the biohazard bin and then obtain a new specimen as necessary. **Visibly soiled specimens received in the laboratory will be discarded.**
13. After wiping, transfer each tube/container to the middle of the "decontaminated specimen zone" and allow to dry.
14. Using a disinfectant wipe, clean the surface of your gloves and allow to dry.
15. **ENSURE THAT ALL TUBES/CONTAINERS ARE ADEQUATELY SEALED.**
16. Proceed to label all tubes/containers and then place into a biohazard bag.
17. **PLEASE ENSURE THAT ALL <u>SPECIMENS</u> ARE CLEARLY LABELLED WITH THE PROVIDED BRIGHTLY COLORED GREEN STICKER.**
18. Wipe the outside of all bags with a disinfectant wipe and transfer these to a "buddy" outside the room, directly placing them inside a second biohazard bag. The "buddy" must be wearing gloves and should otherwise wear PPE as specified by IPAC directives.
19. Discard all disposable materials inside the room.
16. Doffing of PPE and their disposal, exiting of the room and hand hygiene should then be performed in the manner advised by IPAC directives.

C. Outside the room

1. Once the specimens are double-bagged, the outside of the second bag should be cleaned with a disinfectant wipe. This step further minimizes risks of inadvertent cross-contamination at time of specimen bagging thus virtually eliminating the possibility that the outer bag will act as a fomite.
2. Place any test requisitions in the outer pouch of corresponding specimens (unless order entry and barcoding of specimens has already been done).

- Please note that the use of pre-prepared tubes/containers labelled with brightly colored green stickers is **MANDATORY**. These are an important visual reminder for our laboratory staff that the specimens come from a patient under investigation for SARS-CoV-2 and that the specimens must be handled with either enhanced precautions (in the microbiology lab) or strict adherence to standard precautions and exclusive use of an autoanalyzer (in the central laboratory).
- **PLEASE ENSURE THAT ALL <u>REQUISITIONS</u> ARE CLEARLY LABELLED WITH THE PROVIDED BRIGHTLY COLORED GREEN STICKER.**
- **FOR RESPIRATORY SAMPLES, USE OF A DULY FILLED COVID-19 REQUISITION IS MANDATORY (UNLESS THIS DATA CAN BE CAPTURED BY ORDER ENTRY)**

D. Additional considerations for blood gas analysis

- Blood gas analysis (including lactate) done near the point-of-care (e.g. ICU) is preferred but may requires strict adherence to standard precautions and avoidance of inadvertent droplet production or cross-contamination of the blood gas analyzer or surrounding surface (see below).

- Some hospital laboratories use instruments and procedures that make it difficult to obtain a sample without air bubbles or clots and thus samples require subsequent manipulation that may produce aerosols. If this is the case, then two options are available:

  i. blood gases should be analyzed in the blood gas or central lab with enhanced protective measures

  or

  ii. blood gases should be analyzed in the patient's isolation room with a handheld instrument.

- In all cases, the following procedures should be followed:

  i. Heparinized syringes with a vented cap should be used. The specimen should be capped at the bedside and venting of air bubbles should occur in the patient's room. Capped syringes can then have their surface disinfected as described above.

  ii. For infants where blood gas syringes may not be used, a capillary gas could be done if the technique used does not generate aerosols (i.e. no expelling of blood or clot or bubbles with pressure).

  iii. For analysis near the point-of-care, as an additional security measure a splash shield may be positioned between the instrument user and the blood gas analyzer probe. This must not interfere with proper technique. Alternatively, a procedure mask with incorporated face shield or eye protection can be used in order to prevent mucosal/airway exposure to inadvertent splashes.

  iv. Expelling of blood or venting of air in the syringe is **NOT** permitted outside the patient's room. If a clot or air bubbles have formed between the time of specimen acquisition and analysis and you have already left the patient's room, the specimen can only be analyzed at a site where the blood gas or central laboratory has implemented enhanced measures to test such specimens safely.

  v. After completing the analysis, discard the syringe in the biohazard or sharps bin then wipe the blood gas analyzer entry pad/screen and the counter in front of

the instrument with a disinfectant wipe (**Accel® INTERVention® Wipes** with 0.5% w/w hydrogen peroxide have cidal activity within one minute with proper use and are therefore preferred). Gloves should be worn while handling the syringe and hand hygiene should be performed after removing gloves.

6. Transporting specimens to the laboratory

1. **Microbiology specimens must be double-bagged.** This measure remains in place to ensure that any tubes/containers that contain fluids and that are improperly sealed do not lead to inadvertent contamination of the pneumatic tube system or the laboratory. Double-bagged microbiology specimens can be delivered either by hand or via pneumatic tube system transport to the Microbiology Laboratory.

2. **Vacutainer tubes** containing blood specimens can be sent to the required laboratory as per usual practice. **Any other fluid specimen must be double-bagged**. This includes blood gas syringes, urine, CSF and any other biological fluid. Vacutainer tubes containing blood specimens can be delivered either by hand or via pneumatic tube system transport to the laboratory.

3. Blood gas specimens in heparinized syringes must either undergo near point-of-care testing or are preferably to be delivered by hand to the central/blood gas laboratory.

7. Additional notes

1. **Specimen rejection:** Leaking specimens will be **rejected** as per current laboratory policy. Specimens with requisitions or order entry data lacking the required information will also be **rejected**.

2. **Anticipated Turn-Around-Time (TAT):** SARS-CoV-2 testing is performed 7 days a week, during day, evening and night shifts. Turn-around-time will vary based on staffing, technical issues and instrument capacity. In general, results should be available for hospitalized patients and health care workers within **12 hours** from delivery of the specimen. It is expected that specimens received from community settings will be tested and results reported within **72 hours**. These anticipated turn-around-times may be influenced by the availability of staff and reagents.

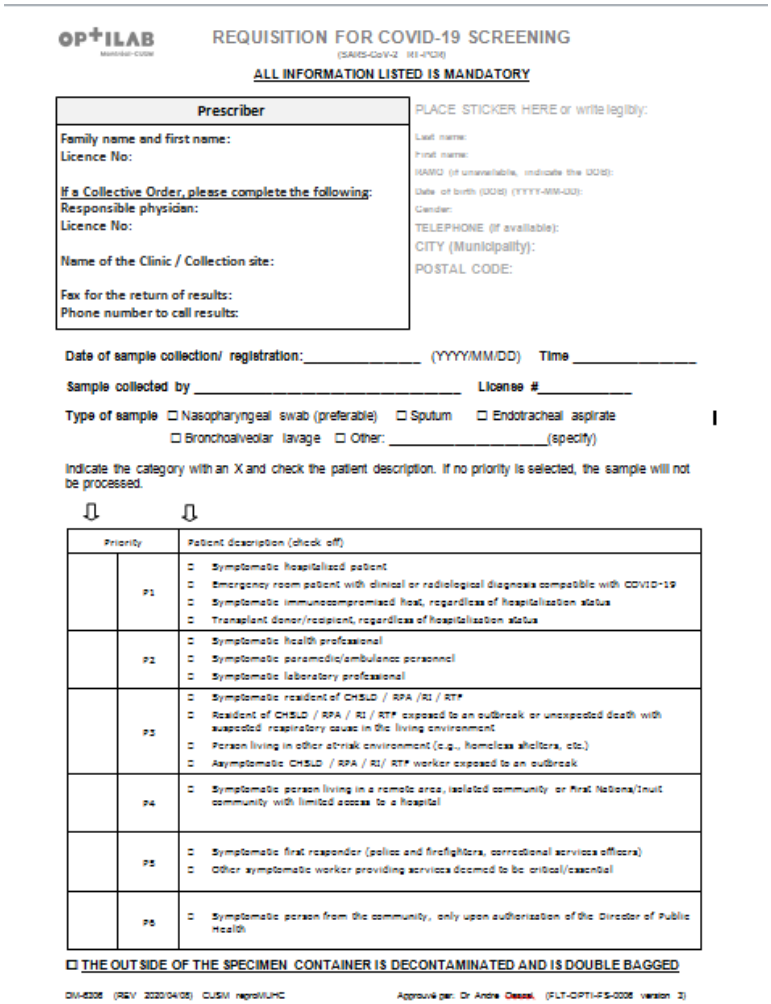
3. **Specimen Prioritization:** Testing of specimens from hospitalized patients and health care workers are always prioritized. Given the limitations of methodology and instruments, a specimen cannot presently be tested on a STAT basis. Where feasible, patients that are in the intensive care, transplant recipients or immunosuppressed/immunodeficient hosts will be prioritized in the queue for the next batch of analyses for hospitalized patients or HCW, but these cannot be tested individually. **PLEASE DO NOT CALL THE LABORATORY ABOUT**

TEST PRIORTIZATION. If the patient is properly categorized on the required requisition (**See Appendix A**), then the specimen will be prioritized. In rare situations, a unique clinical scenario can be discussed with the ID physician or Medical Microbiologist on call (e.g. an initial test was done in an outpatient/community but the person presents to the Emergency Department with worsening illness and is now considered "hospitalized") to modify prioritization of a specimen that has previously been received.

8. Appendices:

Appendix A: COVID-19 REQUISITION REQUÊTE COVID-19

This is requisition is included for informational purposes only.
Please use the most current version of this requisition (document # DM-6306) which is available by contacting: imprimerie@muhc.mcgill.ca



OPTILAB Montréal-CUSM

REQUISITION FOR COVID-19 SCREENING
(SARS-CoV-2 RT-rPCR)

ALL INFORMATION LISTED IS MANDATORY

Prescriber
Family name and first name: Licence No: If a Collective Order, please complete the following: Responsible physician: Licence No: Name of the Clinic / Collection site: Fax for the return of results: Phone number to call results:

PLACE STICKER HERE or write legibly:
Last name:
First name:
RAMQ (if unavailable, indicate the DOB):
Date of birth (DOB) (YYYY-MM-DD):
Gender:
TELEPHONE (if available):
CITY (Municipality):
POSTAL CODE:

Date of sample collection/ registration:_____ (YYYY/MM/DD) Time _____

Sample collected by _____ License #_____

Type of sample ☐ Nasopharyngeal swab (preferable) ☐ Sputum ☐ Endotracheal aspirate
☐ Bronchoalveolar lavage ☐ Other: _____(specify)

Indicate the category with an X and check the patient description. If no priority is selected, the sample will not be processed.

Priority		Patient description (check off)
	P1	☐ Symptomatic hospitalized patient ☐ Emergency room patient with clinical or radiological diagnosis compatible with COVID-19 ☐ Symptomatic immunocompromised host, regardless of hospitalization status ☐ Transplant donor/recipient, regardless of hospitalization status
	P2	☐ Symptomatic health professional ☐ Symptomatic paramedic/ambulance personnel ☐ Symptomatic laboratory professional
	P3	☐ Symptomatic resident of CHSLD / RPA /RI / RTF ☐ Resident of CHSLD / RPA / RI / RTF exposed to an outbreak or unexpected death with suspected respiratory cause in the living environment ☐ Person living in other at-risk environment (e.g., homeless shelters, etc.) ☐ Asymptomatic CHSLD / RPA / RI/ RTF worker exposed to an outbreak
	P4	☐ Symptomatic person living in a remote area, isolated community or First Nations/Inuit community with limited access to a hospital
	P5	☐ Symptomatic first responder (police and firefighters, correctional services officers) ☐ Other symptomatic worker providing services deemed to be critical/essential
	P6	☐ Symptomatic person from the community, only upon authorization of the Director of Public Health

☐ THE OUTSIDE OF THE SPECIMEN CONTAINER IS DECONTAMINATED AND IS DOUBLE BAGGED

DM-6306 (REV 2020/04/05) CUSM reprol/MUHC Approuvé par: Dr André Cassol, (FLT-OPTI-FS-0006 version 2)

Appendix B: Brightly colored green "Code-C" stickers

These stickers (document # DM-6307) are available by contacting: imprimerie@muhc.mcgill.ca