Working with sample containing SARS-CoV-2 Standard Operating Procedure

BSOP-05
Approved by: IBC
Date: 2024-10-09

1.0 Introduction

This Biosafety Standard Operating Procedure (BSOP) outlines necessary procedures for the safe handling of samples containing SARS-CoV-2. This procedure will ensure that Memorial University of Newfoundland personnel are handling samples safely while in compliance with relevant Canadian biosafety legislation.

2.0 Scope

This BSOP applies to all Memorial personnel authorized to work with samples containing SARS-CoV-2 under an active, Institutional Biosafety Committee (IBC)-approved biosafety permit.

3.0 Responsibilities

This section outlines responsibilities within the university for the implementation of this BSOP.

a. Institutional Biosafety Committee (IBC)

- Review and amend this BSOP as necessary.
- Review and approve all SARS-CoV-2-related biosafety permit applications/local risk assessments (LRA) after ensuring that all relevant requirements from the Public Health Agency of Canada (PHAC) SARS-CoV-2 biosafety advisory have been implemented.

b. Administrative Heads

- Ensure that all work with SARS-CoV-2 conducted within their area of authority is pre-approved by way of a valid biosafety permit, issued by Memorial's IBC.

c. Laboratory Supervisors/Principal Investigators

- Ensure that a biosafety permit, which describes the work involving SARS-CoV-2, has been reviewed and approved by Memorial's IBC prior to the commencement of work.
- Ensure that all personnel authorized to perform the work outlined on a biosafety permit have received adequate lab-specific training on SARS-CoV-2 safety in addition to the step-by-step procedure(s) that will be performed (i.e. procedures risk assessment (RA) approved by IBC).
    - A walk-through of the proposed work shall be completed by the supervisor/PI and authorized worker(s) using the IBC-approved procedures risk assessment (RA).
    - Once completed, all parties involved shall sign and date the procedures RA as documentation of training.

- Ensure that SARS-CoV-2-related safety training is documented, and records are available for review.

d. Authorized biohazard workers

- Receive adequate lab-specific safety training regarding the work involving SARS-CoV-2 from their immediate supervisor (or designate) prior to commencing work (i.e. procedures RA walk-through).
- Ensure that work with samples containing SARS-CoV-2 is in accordance with the information found in this BSOP, Memorial's biological safety program and the Canadian Biosafety Standards (CBS).

4.0 Hazards associated with SARS-CoV-2 work

- Exposure to biohazards (COVID-19 positive primary specimens). Examples of primary specimens include sputum, blood, plasma, feces, nasopharyngeal specimens and tissues that are collected directly from patients.
- Certain *in vitro* and *in vivo* activities cannot be performed at Memorial because they require a Risk Group 3 license and corresponding Containment Level 3 lab (see below).

5.0 Containment requirements

SARS-CoV-2, the causative agent for COVID-19, is classified as a Risk Group (RG) 3 infectious material. Although diagnostic and clinical activities with primary specimen that do not involve cultivation, collection, or extraction (i.e., isolation) of SARS-CoV-2 (e.g., clinical chemistry studies, urinalysis, hematology and serology testing, fixation of tissues, etc.) are not regulated under the HPTA, they do fall within the scope of Memorial's biosafety program and require **containment level (CL) 2 physical and operational conditions**.

Non-propagative diagnostic activities that may inadvertently concentrate or extract SARS-CoV-2 (e.g. sample concentration prior to inactivation, sample preparation for nucleic acid extraction, antigen/antibody studies, nucleic acid testing, etc.) **require CL2 plus additional biosafety requirements (CL2+)**. These additional requirements are:

- A lab coat, gloves, and eye protection are worn when handling primary specimens.
- Low-speed centrifugation (< 20,000 x *g*) of primary specimens is carried out in sealed safety cups, or rotors, that are loaded/unloaded in a biological safety cabinet (BSC).
- A certified biological safety cabinet (BSC) is used for all procedures that may produce infectious aerosols [e.g., pipetting (e.g., adding lysis buffer), preparing aliquots, diluting specimens, vortexing, etc.].
- Fit-tested respiratory protection (that provides a level of filtration of 95% or greater [e.g. N95]) is worn where aerosol generating activities cannot be contained within a

BSC or other primary containment device (fit testing certificates must be available for review).

- Samples that are handled within a BSC are moved to an analytic equipment [e.g., polymerase chain reaction (PCR) equipment] within a secondary closed container (e.g., gasketed, plates sealed with tape or flexible film).
- Appropriate surface disinfectant (e.g. 10% fresh bleach, 70% ethanol) is used to thoroughly decontaminate all surfaces before and immediately after work is completed.
    - Other disinfectants such as 0.5% hydrogen peroxide, quaternary ammonium compounds, and phenolic compounds may be used if approved by the IBC.

6.0 Restricted activities

Any *in vitro* work that involves the intentional concentration or isolation (e.g. ultracentrifugation (> 20,000 x *g*) of primary samples, culturing specimens, preparatory work for *in vivo* activities, etc.) and all *in vivo* work require CL3 physical and operational conditions and as such, are currently prohibited at Memorial University.

7.0 Disposal of SARS-CoV-2-associated wastes

Disposal of waste generated through activities involving work with SARS-CoV-2 samples shall follow the instructions outlined in BSOP-01: Management of Biohazardous Waste and BSOP-04: Movement and Transport of Biohazards. Emphasis should be placed on the following:

- Clear autoclavable bags used for SARS-CoV-2 waste shall not be filled beyond half full.
    - DO NOT include sharps, radioactive materials or other materials which are not compatible with autoclaving.
- If bags are to be removed from the containment zone (CZ) for processing, bags shall be tied closed with an approved biohazard waste tag and adequately surface decontaminated with 70% ethanol for an appropriate contact time (refer to BSOP-03 Biohazard Decontamination and Spill procedure for details on disinfectants and required contact times).
- After the appropriate contact time has passed, place bag into a second clear autoclave bag, and surface decontaminate as with the primary bag.
- Authorized laboratory personnel shall place bag(s) into leak-proof transport container provided by autoclave technician and seal the lid. Autoclave technicians deliver to autoclave facility (following movement procedures outlined in BSOP-04).
- Autoclaving shall be performed as outlined in BSOP-01: Management of Biohazardous Waste (i.e. validated/verified prior to final disposal).

References:

- Public Health Agency of Canada Biosafety Advisory, SARS-CoV-2
- University of Calgary SOP COVID-19 specimens
- Memorial University of Newfoundland Biological Safety Manual v2.2
- Memorial University of Newfoundland Biosafety Standard Operating Procedure 01: Management of Biohazardous Waste
- Memorial University of Newfoundland Biosafety Standard Operating Procedure 03: Biohazard Decontamination and Spill procedure
- Memorial University of Newfoundland Biosafety Standard Operating Procedure 04: Movement and Transport of Biohazardous Materials

Version History:

Version	Date	Author(s)	Notes
1.0	2020-05-14	Rod Hobbs	First writing.
1.1	2024-10-09	Rod Hobbs	Minor text edits