McMaster University | RESEARCH
PRESIDENTIAL BIOSAFETY ADVISORY COMMITTEE

IMPLEMENTATION DIRECTIVE

USE OF SAMPLES CONTAINING SARS-COV-2

Approved: XXXX

McMaster University

CONTENTS

INTRODUCTION

SARS-CoV-2, the causative virus of COVID-19, is classified as a Human Risk Group 3 pathogen and an Animal Risk Group 2 pathogen. Handling and permit requirements are based on sample and activity type, and whether or not the material containing SARS-CoV-2 is imported, respectively. Laboratories receiving samples containing, or potentially containing the SARS-CoV-2 virus must be aware that improper handling of these materials poses a risk of exposure, which could seriously impact the health of laboratory personnel, the community, as well as animal populations.

The Public Health Agency of Canada (PHAC) Biosafety Advisory distinguishes work with SARS-CoV-2 virus, or virus containing material based on the potential propagation of the virus. All research activities with SARS-CoV-2 virus, including all in vivo SARS-CoV-2 must be undertaken at Containment Level (CL) 3. Research samples that may contain SARS-CoV-2 but are handled with no propagation of the virus may be worked with outside of CL3.

DETERMINATION OF CONTAINMENT LEVEL FOR RESEARCH SAMPLES

Samples with a known risk of containing SARS-CoV-2 must be evaluated for the appropriate containment level using the decision tree outlined in Figure 1. This assessment is in addition to the evaluation that must be done to assess infectious state of human specimens as outlined in the Use of Human Specimens in Research and Teaching Laboratories PID. If the samples are reasonably expected to contain multiple pathogens, the samples must be handled at the highest containment level prescribed.

In the current COVID-19 pandemic, human samples may pose an unknown risk of containing SARS-CoV-2 virus. All human samples must be assessed for the likelihood of containing SARS-CoV-2 as outlined in Figure 1. The likelihood of risk in asymptomatic human samples must be determined by the Supervisor based on the history, community risk, or current status of the participants being sampled. If the Supervisor has determined there is not sufficient information to evaluate the risk out of an abundance of caution the samples must be considered moderate or high risk.

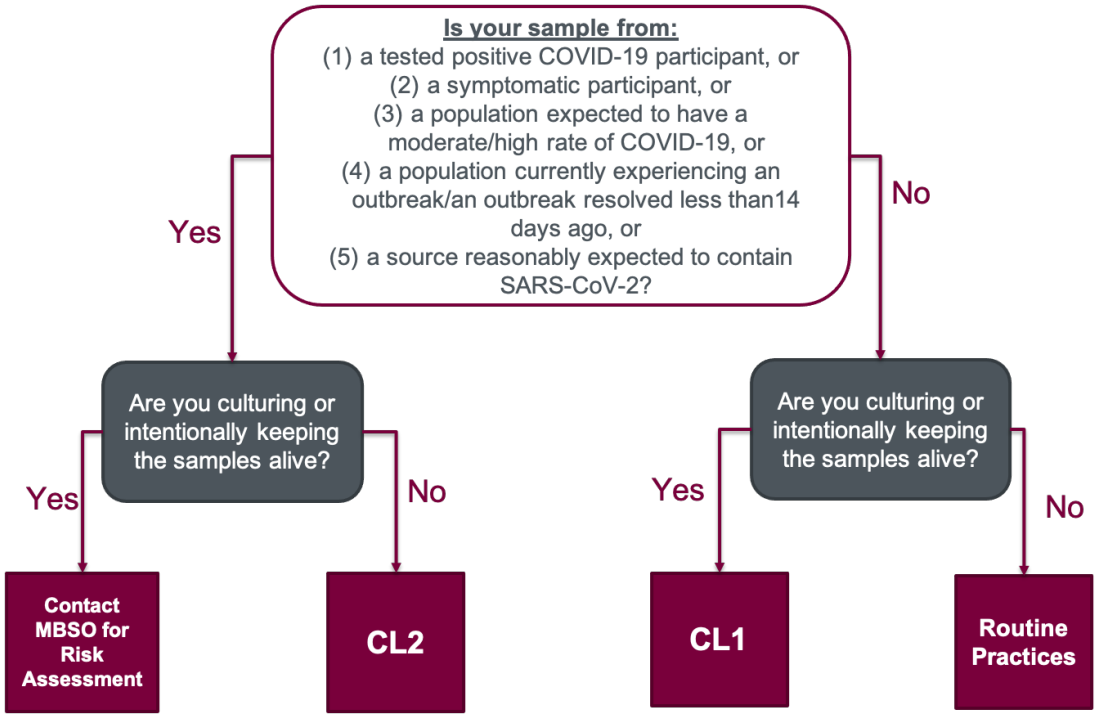

FIGURE 1. Decision tree for handling SARS-CoV-2 containing samples

Required PPE for Handling SARS-CoV-2 Containing Samples At CL2

Personal Protective Equipment (PPE) required for handling SARS-CoV-2 containing samples includes a lab coat, gloves and face/eye protection. Handling of SARS-CoV-2 containing material must be within a BSC or other primary containment device. A spill outside the BSC would generate infectious aerosols or droplets and spill clean-up will require the use of an N95 mask. Spill clean-up responsibilities should be assigned to an individual within the laboratory that has current N95 training and fit testing. Due to the reduced availability of N95 masks, it is recommended to assign spill-clean up procedures to one or two laboratory workers. In the event of a spill outside the BSC, all workers must exit the area and inform the individual responsible for spill cleanup who will then don the prescribed PPE and clean the spill.

N95 Mask Training and Fit Test

Workers responsible for spill cleanup must be trained in and fitted for the use of an N95 respirator. Information is found in the McMaster Respiratory Protection Program.

Please contact the relevant safety office to arrange for N95 respirator fit testing. For those persons in FHS, please contact the FHS Safety Office (fhsso@mcmaster.ca) and for those persons not in FHS, please contact EOHSS (eohss@mcmaster.ca).

FHS N95 Respirator training requires an annual update to be completed online through Mosaic, course code FHSN95. Fit testing is required to be done every 2 years. This training and fit testing is to be recorded in the training records and will be audited by the Research Compliance Auditor.

Additional Risk Assessment

An additional risk assessment is required when samples reasonably expected to contain SARS-Cov-2 virus are being cultured or intentionally being kept alive. The risk assessment will be prepared by the Biosafety Officer (BSO), Principal Investigator and appropriate COVID-19 experts to determine if the culture conditions will lead to the propagation of SARS-CoV-2 virus. The risk assessment shall consider sample culture conditions, host-cell permissiveness, and viral replication capacity irrespective of host cell replication.

The risk assessment will be submitted to the Presidential Biosafety Advisory Committee (PBAC). The PBAC will review the assessment and assign a containment level. All work that allows for the propagation of SARS-CoV-2 virus must be conducted at CL3.

Operational Procedures for Additional SARS-CoV-2 Containing Materials

Samples that do not contain live SARS-CoV-2 virus may still require specific handling and containment practices. SARS-CoV-2 RNA is classified as Risk Group 2 because SARS-CoV-2 virus is a single-stranded positive-sense RNA virus can potentially be infectious and produce infectious viral particles. Heat Inactivated SAR-CoV-2 is also classified as Risk Group 2 because SARS-CoV-2 RNA has been shown to be intact even after heat inactivation. Figure 2 outlines the containment level for additional SARS-CoV-2 containing material.

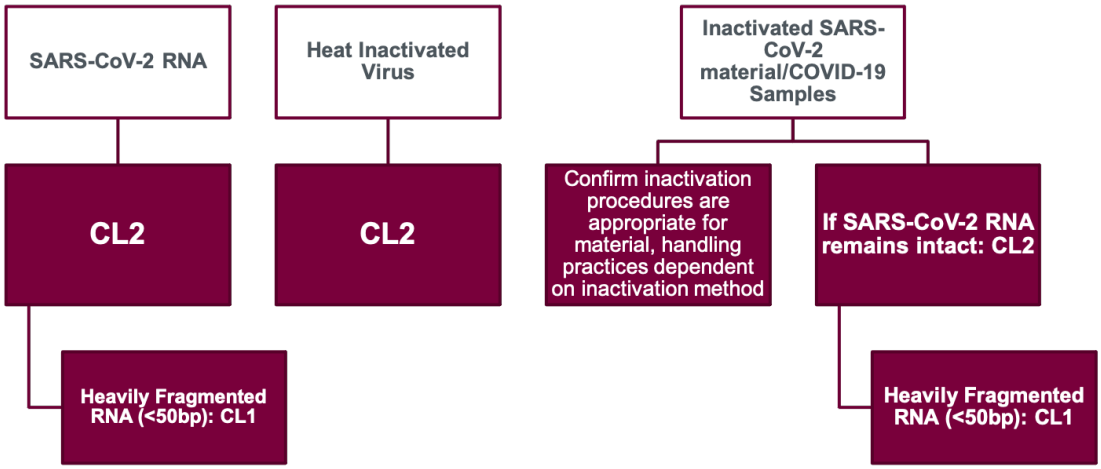

FIGURE 2 Containment Level for additional COVID-19/SARS-CoV-2 Material

Heat inactivated virus can be purchased commercially after the BSO and Customs Officer have been notifying through the BUP portal. Heat-inactivating samples within a research lab must be performed according to published protocols and take into account the sample type, volume, viral load and protein load of the samples. Heat Inactivated SARS-CoV-2 must be listed in the Biohazard Utilization Protocol Inventory Items and used at CL2. Prior to handling

inactivated SARS-CoV-2/COVID-19 samples it is the Supervisor's responsibility to verify the inactivation method renders any infectious material within the sample non-infectious through a literature review.

Shipping and Receiving SARS-COV-2 containing Materials

All shipping and receiving of all biological samples must be submitted to the BSO and Customs Officer prior to arranging for shipment through the BUP portal.

The transportation of SARS-CoV-2 specimens is subject to the Transportation of Dangerous Goods Regulations (TDG Regulations). SARS-CoV-2 cultures or stock virus are assigned to UN2814, INFECTIOUS SUBSTANCE, AFFECTING HUMANS, Class 6.2, Category A. These samples must be shipped directly to the CL3 laboratory, please contact the MBSO for assistance. SARS-CoV-2 samples that are in a form other than a culture are assigned UN3373, BIOLOGICAL SUBSTANCE, CATEGORY B, Class 6.2, Category B. McMaster workers must have valid TDG training (Mosaic course code FSHTDG) to ship or receive the samples.

If the material containing SARS-CoV-2 is an animal product, by-product, or primary specimen (e.g. tissue, serum, blood) an import permit will be issued by the Canadian Food Inspection Agency and can only be imported into a CL2 lab with a valid compliance letter. The MBSO will assist in obtaining the required documentation for import.

Mechanism to Monitor PID Effectiveness

- Number of BUPs with COVID-19/SARS-CoV-2 containing material in inventory
- Number of risk assessments presented to PBAC for containment review
- User feedback directly related to the PID

Contact Information for Assistance

Please use the following contact for assistance in training options and implementation of the above procedures.

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