

Laboratory Biosafety Resources Related to SARS-CoV-2/COVID-19 Virus Samples/Materials

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SECTION A

FAQ: Guidance on the Use of Samples/Materials Associated with SARS-CoV-2/COVID-19 Virus

Question 1: What is the relationship between 2019-nCoV, SARS CoV-2 and COVID-19 virus?

These are different names given to the same strain of coronavirus at different time points.

When the virus was first isolated from pneumonia cases in December 2019, it was named 2019 novel coronavirus (2019-nCoV). As more information and genetic analyses became available, the virus was given the official name of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by the International Committee for Taxonomy of Viruses, while the WHO named the disease caused by the virus, Coronavirus disease 2019 (COVID-19).

Question 2: Is SARS-CoV-2/COVID-19 virus listed as a scheduled biological agent under the Biological Agents and Toxins Act (BATA)?

SARS-CoV-2/COVID-19 virus is listed as a BATA First Schedule Part II biological agent as of 30 Jan 2020. An approval to possess from MOH is required for facilities to possess/handle the virus or any samples/materials known to contain the virus **unless viral inactivation** (see Qn 11 for information related to inactivation) has been performed.

If the possession/use/handling of such samples is solely for the purpose of diagnosis, the facility will be exempted from BATA but will have to comply with the Private Hospitals and Medical Clinics (PHMC) Act.

For more details, please see:

- (a) Qn3 for BATA's definition of "diagnosis";
- (b) Qn4 for the conditions that apply to diagnostic activity; and
- (c) [Section C - Biosafety Guidelines for Laboratories and Personnel Handling Samples or Materials Associated with SARS-CoV-2/COVID-19](#) for information regarding the transport and processing of diagnostic samples.

Question 3: What is the BATA's definition of "diagnosis"?

Diagnosis is defined in the BATA (Section 2) as "any activity undertaken solely with the intention of analysing any specimen from a person or an animal in which a biological agent is or is suspected of being present for the purpose of:

- (a) determining the cause of any disease suffered by any person or animal;
- (b) assessing the clinical progress of any person or animal;
- (c) carrying out the clinical management of any person or animal; or
- (d) determining the cause of death of any person or animal in an autopsy".

Question 4: What are the requirements or conditions for conducting diagnostic activities involving samples/materials associated with SARS-CoV-2/COVID-19 virus?

Diagnostic activities shall be carried out according to “MOH Circular 34/2006 on Interpretation of Diagnosis”. All samples positive for SARS-CoV-2/COVID-19 virus, including virus isolated from the clinical samples and the clinical samples where the virus were isolated from, **MUST be inactivated as part of the diagnostic process, destroyed or transferred** to a facility that has been granted an approval to possess the virus as soon as possible after confirmation of diagnostic test results. Click [here](#) for details of the Circular.

Question 5: Can a diagnostic laboratory retain residual SARS-CoV-2/COVID-19 virus-positive clinical samples as positive controls?

For safety purposes, diagnostic laboratories are strongly advised to **use non-infectious materials** (e.g. synthetic or plasmid DNA) or **inactivated materials** as positive controls.

Please see Qn 11 for examples of inactivation methods.

Question 6: Can a diagnostic laboratory handle and store SARS-CoV-2/COVID-19 virus-positive clinical samples for evaluation of diagnostic kits?

A **clinical laboratory** that is licenced under the Private Hospitals and Medical Clinics (PHMC) Act and/or is accredited by a reputable accreditation body such as the Singapore Accreditation Council-Singapore Laboratory Accreditation Scheme (SAC-SINGLAS) or College of American Pathologist (CAP) can obtain a **conditional approval** to store and handle **clinical samples** from patients with COVID-19 for the **purpose of evaluating or validating the performance of diagnostic assays that are CE marked, or have received approval, including provisional authorisation from HSA or FDA**, related to COVID-19, by submitting the completed [Declaration Form A in Annex A](#) to moh_biosafety@moh.gov.sg.

The conditions for this approval are as follows:

- (a) The laboratory has in place an effective biorisk management system which allows the identification, assessment and control of laboratory biosafety and biosecurity risks to protect the safety of the personnel and the environment;
- (b) The laboratory shall maintain proper inventory and tracking of the samples, including aliquots. Records shall be made available to Biosafety Branch, MOH, when requested;
- (c) There shall be **NO** attempts to purify, isolate or culture SARS-CoV-2/COVID-19 virus from the samples;
- (d) Retention of the samples is limited to until **1 April 2022**, after which, the samples shall be destroyed or transferred to a facility with the requisite approval to possess SARS-CoV-2, unless otherwise advised by the Biosafety Branch, MOH; and
- (e) The use and handling of the samples must comply with all other relevant regulatory requirements, including material and waste disposal.

Question 7: What are the requirements for handling clinical samples from persons with COVID-19 for conducting on-site (outside of clinical laboratory setting) evaluation of rapid or point-of-care-testing (POCT)¹ COVID-19 diagnostic assays?

Clinical samples from persons with COVID-19 can be used for **on-site evaluation of rapid or POCT COVID-19** diagnostic assays that are **CE marked or have received approval (including provisional authorisation) from HSA or FDA**, outside of a laboratory setting, provided that **ALL of the following conditions** are met:

- (a) The work is limited to the handling of COVID-19 clinical samples to conduct evaluation of rapid or POCT COVID-19 testing, in accordance with the procedures specified by the manufacturer. There shall be **NO** other manipulation or processing of the samples;
- (b) The **evaluation** is conducted **on-site**, e.g. a medical clinic, emergency department at hospitals, isolation facility, **that is or close to, the site of sample collection from the subject**, which will also be the setting where the test will eventually be deployed;
- (c) A **proper risk assessment** has been **conducted** and **risk mitigation measures** have been **implemented to ensure that the evaluation is carried out safely**;
- (d) Only **personnel** who **have been trained** and have been **assessed to be competent** to perform the work will be allowed to handle the COVID-19 clinical samples;
- (e) **Standard operating procedures** have been devised for the packaging, transfer, transportation and/or disposal of samples, where applicable, to ensure the safety of persons who may come into close contact with such materials and compliance with regulatory requirements;
- (f) A **system** is in place to **track the usage and movement** of each sample from point of collection until disposal and/or transfer of the samples;
- (g) **On-site testing** using rapid or POCT COVID-19 assay, shall be conducted as soon as possible, upon sample collection. **Within 24-hours of sample collection**, the collected **clinical samples must be disposed** according to regulatory requirements **OR transferred** to a clinical laboratory that has conditional approval from MOH to retain COVID-19 clinical samples **OR transferred** to a facility with approval to possess SARS-CoV-2; and
- (h) The conditional approval for on-site evaluation of rapid or POCT COVID-19 test is valid until **1 April 2022**.

Question 8: What are the requirements for the importation, handling and/or storage of samples from clinical trial participants that are known or suspected to have SARS-CoV-2/COVID-19 virus for laboratory safety testing?

The requirements for activities related to **clinical trials** are specified in [Section B - FAQ: Guidance for Laboratories Handling Clinical Trial Samples from Participants who have COVID-19 Infection.](#)

¹ Point-of-care testing (POCT): The physical location where testing is performed is at or near the site where the patient is, and is outside of the clinical laboratories.

Question 9: What are the requirements for conducting other activities (other than those described in Qn 4 to 8) involving samples/materials associated with SARS-CoV-2/COVID-19 virus?

Examples of activities other than those described in Qn 4 to 8 include (but are not limited to) the storage of samples, virus culture (*see Qn 10 for additional conditions*), virus neutralization assay, development of diagnostic assay, full genome sequencing, identification of disease biomarkers, generation of antibodies against SARS-CoV-2/COVID-19 virus, research and development of attenuated or inactivated vaccine.

Facilities intending to engage in other activities involving non-inactivated samples of SARS-CoV-2/COVID-19 virus MUST satisfy the requirements for the possession of BATA First Schedule Part II biological agents prior to the commencement of work, regardless of the type of laboratory (e.g. diagnostic or otherwise) where such activities are carried out. See detailed requirements in Table 1. These requirements do not apply to activities that fall under BATA exempted purposes².

The above activities involving inactivated samples can be carried out in a BSL2 laboratory with due precautions. *Please see Qn 11 for examples of inactivation methods.*

Prior to the commencement of any activities involving samples/materials associated with SARS-CoV-2/COVID-19 virus (**whether inactivated or otherwise**), individual facilities shall perform a thorough risk assessment and implement appropriate risk mitigation measures, which must be reviewed and approved by the Biosafety Committee (if performed in a BSL3 facility) or personnel with good biosafety and microbiology knowledge and experience. In addition, the facilities shall implement a robust inventory system and document all movement (or transfer) of the samples. Facilities are also required to notify MOH of any adverse incident involving the handling of such samples.

² BATA exempted purposes listed under Section 4 include:

- (a) the disposal of any biological agent or toxin by a hazardous waste contractor
- (b) the handling of any biological agent or toxin in the course of carrying out a diagnosis or an autopsy;
- (c) the collection of food samples or samples from the environment for the purpose of carrying out any laboratory analysis to determine or identify, for public health purposes, the nature of any biological agent or toxin that is present in such samples or in the environment from which such samples have been taken; or
- (d) the use or possession by any of the following persons of any finished cosmetic or medicinal product consisting of any toxin:
 - i. any person lawfully manufacturing, supplying, selling or dispensing the finished cosmetic or medicinal product;
 - ii. any registered medical practitioner using the finished cosmetic or medicinal product in the course of treating another person;
 - iii. any person using the finished cosmetic or medicinal product for the cosmetic or medical purposes for which it is intended.

Table 1: Requirements for handling samples/materials associated with SARS-CoV-2/COVID-19 virus, for other activities

	Sample Types	Requirements
1	<p>Samples <u>confirmed or known</u> to contain infectious/replicative competent SARS-CoV-2/COVID-19 virus. Examples: (a) SARS-CoV-2/COVID-19 virus isolate (or culture) (b) Clinical samples from COVID-19 patients (e.g. respiratory samples, blood, urine, bodily fluids, stool)</p>	<p>(a) Handle in a BSL3 facility with requisite approvals for the virus; (b) All work procedures, risk assessments and safety measures shall be approved by the facility's Biosafety Committee; and (c) Can only be handled outside of a BSL3 facility after inactivation of the materials using a validated method.</p> <p><i>Please refer to Qn 11 for more information regarding inactivation.</i></p>
2	<p>Samples/materials with <u>high potential</u> to contain infectious/replicative competent SARS-CoV-2/COVID-19 virus or where the absence of infectious/replicative SARS-CoV-2/COVID-19 virus has not been confirmed. Examples: (a) Samples from individuals who are close contacts of confirmed COVID-19 individuals; (b) Environmental samples collected from areas or isolation ward where COVID-19 patients reside.</p>	
3	<p>Samples/materials from individuals who have <u>recovered</u> from COVID-19 i.e. samples collected from COVID-19 patients who have been cleared for discharge and (a) are clinically well by Day 21 of onset of illness; OR (b) for those with a history of being immunocompromised, tested SARS-CoV-2/COVID-19 virus PCR negative, twice consecutively at least 24 hours apart.</p>	<p>Can be handled outside of a BSL3 facility as per risk assessment. If any downstream activities suggest the presence of infectious/replicative competent SARS-CoV-2/COVID-19 virus in the sample/material: (a) MOH Biosafety shall be informed immediately; and (b) Facilities are to secure and handle the sample/material in accordance with the BATA, i.e. to destroy or transfer it to a facility with an approval to possess the virus.</p>
4	<p>Environmental samples with low potential to contain infectious/replicative competent SARS-CoV-2/COVID-19 virus Example: Samples (environmental swab or air sampling medium, wastewater) collected from common areas accessible by public.</p>	

	Sample Types	Requirements
5	<p>Samples/materials where the presence of infectious/replicative competent SARS-CoV-2/COVID-19 virus have been ruled out</p> <p>Examples:</p> <p>(a) Inactivated SARS-CoV-2/COVID-19 virus culture;</p> <p>(b) Inactivated clinical samples of COVID-19 patients;</p> <p>(c) Inactivated environment samples collected from the ward/isolation area where a COVID-19 patient resided; and</p> <p>(d) RNA extract from (1), (2), (3), and (4).</p> <p><i>Please refer to Qn 11 for more information regarding inactivation.</i></p>	<p>Can be handled outside of a BSL3 facility but facilities are required to ensure that:</p> <p>(a) The method used for inactivation and/or RNA extraction is validated and effective, and approved by the Biosafety Committee (if performed in a BSL3 facility) or personnel with knowledge and expertise on biosafety and microbiology;</p> <p>(b) Personnel are properly trained and competent to perform the inactivation process; and</p> <p>(c) Personnel strictly adhere to the procedures (which may include the equipment³ used, the concentration of the chemical and contact time with the chemical or the temperature used) of the inactivation method.</p> <p>In addition, facilities are advised to:</p> <p>(a) Handle inactivated samples/materials as potentially infectious;</p> <p>(b) Ensure that a thorough risk assessment is performed for activities involving inactivated samples/materials; and</p> <p>(c) Ensure that risk mitigation measures are implemented for the safety of personnel and environment.</p>

Question 10: Are there any restrictions to the volume of SARS-CoV-2/COVID-19 virus that can be cultured?

As the risk of the activity will increase with the volume of the sample/virus handled, facilities are strongly advised to **keep the volume of virus culture to laboratory scale** (up to a maximum of 100mL) at any one time. Facilities shall perform a thorough risk assessment and implement appropriate (and additional, if needed) risk mitigation measures, and these **MUST** be reviewed and approved by the Biosafety Committee.

Additional requirements (e.g. engineering controls, laboratory design, policy and procedures) may be required if culture volume is beyond laboratory scale. Please consult MOH in such instances.

Question 11: What are the methods and/or criteria for inactivating samples/materials containing or highly suspected to contain SARS-CoV-2/COVID-19 virus?

Methods employed for the inactivation of samples/materials **containing or highly suspected to contain SARS-CoV-2/COVID-19 virus** shall be validated against SARS-CoV-2/COVID-19 virus or related coronavirus (i.e. SARS CoV or MERS CoV). Facilities are advised to carry out validation of the inactivation in-house, or to adopt a well-established inactivation procedure validated by others.

³ E.g. water bath versus heating block

Samples that may require inactivation (see Qn 9 above): **Virus culture; Clinical samples** (examples include, but are not limited to blood, serum, plasma, urine, tears, stool, tissue); and **Environmental samples** (examples include, but are not limited to surface swab, air sampling filters, suspension from air sampling).

Inactivation of SARS-CoV-2/COVID-19 virus can be achieved through number of methods. Examples can be found in Table 2 below. **Individual facilities are advised to assess the appropriateness of the respective inactivation method** for their sample types / materials and to ensure that inactivation procedures are closely adhered to, so as not to compromise the efficacy of the inactivation process.

Table 2: Examples of inactivation method

Examples of Inactivation Method ⁴
<p>Heat inactivation Example: Heat at 60°C or higher temperature for a specified minimum duration.</p> <p>Chemical Inactivation Examples: Acetone, formaldehyde, glutaraldehyde, Trizol.</p> <p>Solvent/Detergent Examples: Triton X, Tween 80.</p> <p>Note: The presence of certain substances, such as protein in the samples may affect the effectivity of the inactivation process. Facilities shall conduct their own risk assessment to evaluate the appropriateness of the chosen inactivation method. If in doubt, facilities should consider conducting in-house validation of the inactivation method.</p>

The Biosafety Committee is responsible for ensuring that the inactivation procedures are reliable, that the inactivation procedures are strictly adhered to, and are carried out by properly trained and competent laboratory personnel. The Biosafety Committee is also advised to ensure that personnel handling the inactivated materials will **treat the materials as potentially infectious and take appropriate precautions when handling the materials.**

⁴ References for inactivation methods include:

- (a) A.S. Jureka *et al.* Propagation, inactivation, and safety testing of SARS-CoV-2. *Viruses* (2020) 12: 622- 634.
- (b) H. F. Rabenau *et al.* Stability and inactivation of SARS coronavirus. *Med Microbiol Immunol* (2005) 194: 1–6.
- (c) J.A Bow *et al.* Virus inactivation by nuclei acid extraction reagents. *Journal of Virological Methods* (2005) Vol 119(2): 195-198.
- (d) M.E. Darnell *et al.* Inactivation of coronavirus that induces severe acute respiratory syndrome, SARS-CoV. *Journal of Virological Methods* 121 (2004) 85–91.
- (e) M.E. Darnell & D.R. Taylor. Evaluation of inactivation methods for severe acute respiratory syndrome coronavirus in noncellular blood products. *Transfusion* (2006) Vol 46:1770-1777.
- (f) T.J. Kochel *et al.* Evaluation of TRIzol LS inactivation of viruses. *Journal of ABSA International* (2017) Vol 22(2): 52-55.
- (g) WHO (2003b) First data on stability and resistance of SAR coronavirus compiled by members of WHO laboratory network.
- (h) WHO (2004) Guidelines on viral inactivation and removal procedures intended to assure the viral safety of human blood plasma products.

Question 12: Are there any other biosafety guidelines and resources for laboratories handling samples/materials associated with SARS-CoV-2/COVID-19 virus?

The following international biosafety guidelines on the safe handling of samples/materials associated with COVID-19 virus may be useful for laboratories:

- (a) Australian Government Department of Health – [Coronavirus \(COVID-19\) resources](#)
- (b) Centers for Disease Control and Prevention – [Information for Laboratories about Coronavirus \(COVID-19\)](#)
- (c) European Centre for Disease Prevention and Control – [COVID-19 Guidance and Technical Reports](#)
- (d) Public Health England – [Guidance for health professionals](#)
- (e) World Health Organization – [Coronavirus disease \(COVID-19\) technical guidance: Laboratory testing for 2019-nCoV in humans](#)

SECTION B

FAQ: Guidance for Laboratories Handling Clinical Trial Samples from Participants who have COVID-19 Infection

Question 1: Who should refer to this guide?

This guide is intended for facilities performing **laboratory testing** on samples from **clinical trial participants**.

Question 2: What is the purpose of this guide?

To provide guidance for handling samples from clinical trial participants who are known, incidentally found or suspected to have **COVID-19**. This refers to the handling of **samples** that are **known or are suspected to contain SARS-CoV-2/COVID-19 virus**.

Question 3: Am I allowed to receive and perform laboratory testing on samples collected from clinical trial participants who are known or suspected to have COVID-19?

You may receive and handle samples from clinical trial participants, who are known, incidentally found or suspected to have COVID-19, by adopting the guidelines in [Section C - Biosafety Guidelines for Laboratories and Personnel Handling Samples or Materials Associated with SARS-CoV-2/COVID-19 virus](#), where applicable. In addition, you are also required to adhere to the following procedures:

- (a) Secure a **valid import permit**⁵ prior to the importation of such samples from overseas collection sites;
- (b) Maintain **proper inventory** and tracking of such samples including aliquots, from the time of sample receipt or once the sample status is known. Inventory records shall be submitted to MOH Biosafety Branch (moh_biosafety@moh.gov.sg) on a quarterly basis;
- (c) **Access** to such samples shall be **restricted** insofar as possible;
- (d) Upon completion of laboratory testing, the samples must be **disposed of or exported or transferred to a facility with the requisite approval to possess SARS-CoV-2/COVID-19 virus**, preferably **within 7 days, up to a maximum of 14 days**. In the **interim**, samples shall be **stored under lock and key with adequate safety and security measures** in place;
- (e) **Dispose of the samples in accordance with regulatory requirements** for disposal of biological waste materials; and
- (f) **Notify MOH Biosafety Branch** in the event of any of the following:
 - i. Import permit was not obtained for the sample as the status of the sample i.e. collected from a participant with COVID-19, is known after importation; and
 - ii. Occurrence of any adverse incident related to the handling of the samples.

⁵ More information about application of import permit is available [here](#).

Question 4: What MOH product code should I use when applying for import permit for the importation of clinical trial samples from COVID-19 patients?

Please contact MOH Biosafety Branch to request for a facility import specific product (ISP) code for the application of import permit related to COVID-19 clinical trial participants. Please provide the following information when submitting request for ISP code:

- Site(s) where samples will be imported from;
- Types of sample(s) that will be imported;
- List of biological agent(s) that are known or likely to be present in the samples;
- Test(s) that will be performed;
- Estimated number of samples;
- Duration of study, including expected start and end date; and
- Duration of sample retention.

Question 5: Are there additional requirements that I need to meet in order to perform serological and/or molecular laboratory testing for COVID-19 for clinical trials?

Laboratories that intend to perform testing for **SARS-CoV-2/COVID-19 virus** are advised to contact MOH Regulatory Compliance and Enforcement Division (elis@moh.gov.sg) to ascertain the applicability of requirements under the Private Hospitals and Medical Clinics Act.

Question 6: Am I allowed to import samples from COVID-19 patients who are participating in clinical trials, for the purpose of re-exportation to a laboratory outside of Singapore for testing?

You can import samples from COVID-19 patients for the sole purpose of re-exportation, provided that the re-exportation takes place preferably within 7 days, up to a maximum of 14 days. You are still required to obtain an import permit prior to the importation of the samples. The samples shall be stored in a safe and secure manner while under your custody, pending exportation.

You are advised to contact Singapore Customs (customs_stgc@customs.gov.sg) directly on the requirements, if any, related to the exportation of the samples and refer to [Section C - Biosafety Guidelines for Laboratories and Personnel Handling Samples or Materials Associated with SARS-CoV-2/COVID-19 virus](#) for the requirements of the International Air Transport Associations (IATA).

Question 7: Do I have to comply with the Biological Agents and Toxins Act?

Handling of samples **beyond** laboratory testing to ascertain the safety of the clinical trial participants is subject to regulations under the Biological Agents and Toxins Act (BATA). This includes storage of samples beyond the duration stipulated in 3(d) and the importation⁶ and

⁶ Refer to the [MOH advisory on the importation of biological agents and/or toxins](#).

possession of samples positive or suspected to be positive for any scheduled biological agents and toxins regulated under the BATA.⁷

For clarifications, please contact the MOH Biosafety Branch at moh_biosafety@moh.gov.sg.

⁷ A non-exhaustive list of biological agents and toxins regulated under the BATA is available [here](#).

SECTION C

Biosafety Guidelines for Laboratories and Personnel Handling Samples or Materials Associated with SARS-CoV-2/COVID-19 virus

I. Packaging and Transportation of Samples/Materials

Transport within Singapore

1. High risk clinical samples. Triple-packaging of all samples/materials. The primary container must be break-resistant and leak-resistant. The secondary container should also be break-resistant and leak-resistant, whenever possible. The external packaging must be labelled with the biohazard logo.

During the transportation process, the samples/materials shall be placed in an upright position, and be delivered by hand, if indicated by risk assessment.

For local transportation of all samples/materials, public conveyances shall not be used.

2. Virus isolates or cultures confirmed to contain the virus shall be packaged and transported according to the Biological Agents and Toxins (Transportation) Regulations [<https://www.moh.gov.sg/biosafety>].
3. Necessary precautions shall be taken if other hazardous materials (such as dry ice or liquid nitrogen) are to be used during transportation.
4. Shippers⁸ must be trained and are liable to ensure that all items are properly and safely packaged.
5. The shipper/transferor shall notify the recipient laboratory as soon as possible, once the sample/material is transported.

International Air Shipment

For international air shipment, the requirements of the International Air Transport Associations (IATA) shall be followed –

- (a) Clinical samples: Ship as Category B, UN3373 biological substance.
- (b) Viral cultures: Ship as Category A, UN2814 infectious substances affecting human.

II. Processing and Diagnostic Laboratory Testing of Samples

Each laboratory should conduct a local risk assessment and implement appropriate risk control measures to ensure laboratory testing can be carried out safely and securely.

The following are general precautions for handling and processing samples which contain or are suspected to contain SARS-CoV-2/COVID-19 virus:

⁸ The person who prepared the packaging of the samples to be transferred or exported.

Diagnostic Procedures	Requirements*
Virus culture and manipulation of live virus (e.g. virus isolation, virus neutralisation assay, packaging of positive cultures)	To be carried out in a certified Biosafety Level-3 (BSL-3) Laboratory with BSL-3 practices
Serology assay (e.g. antigen or antibody detection) or Molecular assay (e.g. PCR or sequencing) or Pathological examination and processing of formalin-fixed or otherwise inactivated tissues.	Can be carried out in Biosafety Level-2 Laboratory <ul style="list-style-type: none"> • Standard personal protective clothing including laboratory coat/gown and gloves; and mucosal and respiratory protection (e.g. eye protection and N95 respirator or equivalent) if indicated by risk assessment • Procedures or manipulations involving potentially infectious materials (e.g. handling of clinical samples) are to be carried out in a certified Class II Biological Safety Cabinet (BSC) • Special care shall be taken to prevent aerosolisation of samples • Centrifugation of samples are to be carried out using sealed centrifuge cups or rotors that are unloaded in a Class II BSC • Secondary leak-proof containers must be used to transport or store potentially infectious samples within the laboratory • Personnel handling such samples must be trained or have demonstrated proficiency in microbiological practices and techniques • Emergency response procedures shall be in place and staff are trained in the procedures
Laboratory procedures other than the ones listed above	Perform risk assessment and consult MOH Biosafety if uncertain.

*Note: Requirements for non-diagnostic laboratory activities, please refer to [Section A - FAQ: Guidance on the Use of Samples/Materials Associated with SARS-CoV-2/COVID-19 Virus.](#)

III. Sample/Material Inventory

A **robust inventory management system** must be implemented to ensure all samples/materials are properly labelled, accounted for and their movement could be efficiently tracked.

All samples/materials are to be secured within the laboratory with restricted access control implemented. **Sharing or distribution of samples** (e.g. inter-laboratory transfer) is discouraged unless necessary for patient management purposes. In such a case, the recipient laboratory must have all the necessary safety and security measures in place prior to the receipt of samples.

IV. Disinfectants

The following disinfectants that are effective on Severe Acute Respiratory Syndrome (SARS) coronavirus⁹ and shall be considered for use:

- Sodium hypochlorite
- Ice-cold acetone
- Ice-cold acetone/methanol mixture (40:60)
- Ethanol (70%)
- Paraformaldehyde
- Glutaraldehyde

V. Waste Management

All waste management procedures shall be conducted in accordance with requirements of the relevant local authorities.

VI. Occupational Health

All laboratory personnel should practice self-monitoring for fever or any other related symptoms. Personnel presenting symptoms of respiratory infections and/or has reason to believe that they were exposed to the virus shall immediately report the matter to their supervisor or the medical authorities so that they can receive appropriate medical advice or management.

Any adverse incident or accident involving potential or actual exposure to the virus should be reported to the supervisor for evaluation and advice. MOH Biosafety must also be notified as soon as possible, within 24 hours.

⁹ Public Health Agency of Canada Pathogen Safety Data Sheet for Severe Acute Respiratory Syndrome (SARS) Associated Coronavirus (<https://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/sars-sras-eng.php>)

Annex A

Declaration Form A

Clinical Laboratory Storing and Handling of COVID-19 Clinical Samples for the **Restricted Use of Evaluating or Validating COVID-19 Diagnostic Assays (including rapid or POCT Tests)** Registered or Approved by HSA, FDA or Bearing CE Mark

Name of Laboratory:

Address of Laboratory:

Person-in-Charge of Laboratory (Name, Designation, email contact and telephone number):

My laboratory is

(a) Licensed under the Private Hospitals and Medical Clinics Act:

Yes (*please specify the validity period*): _____

No

(b) Accredited by (*please specify the name of the accreditation body and validity period of the accreditation*):

Annex A

I declare that my laboratory

1. Has in place an effective Biorisk management system to ensure biosafety and biosecurity related to the storage and handling of samples positive or potentially positive for SARS-CoV-2 or COVID-19 virus (henceforth COVID-19 clinical samples).

Note: An effective Biorisk management system shall include the conduct of a proper risk assessment to identify all potential hazards and implementation of mitigation measures to protect personnel who may come into contact with the samples, and to minimise the risk of non-authorized access to the samples.

2. Has a proper inventory and tracking system for all COVID-19 clinical samples.
3. Will **NOT** carry out any activities (such as purification, isolation or culture) with the intention to generate or produce **live** SARS-CoV-2/COVID-19 virus from the clinical samples.
4. Will destroy or transfer all COVID-19 clinical samples in my laboratory to a facility with the requisite approval to possess SARS-CoV-2/COVID-19 virus by **1 April 2022**, unless advised otherwise by the Biosafety Branch, MOH.
5. Will comply with all other relevant regulatory requirements, including material or waste disposal.

Signature of Declarant

Name:

Designation:

Date: