

INTERIM BIOSAFETY GUIDELINES FOR LABORATORIES

**FOR PERSONNEL, HANDLING SAMPLES OR
MATERIALS ASSOCIATED WITH THE 2019 NOVEL
CORONAVIRUS (2019-nCoV)**



Ministry of Health and Indigenous Medical Services, Sri Lanka

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1. General Guidelines for working with potentially infectious materials

- Laboratory workers should wear appropriate personal protective equipment (PPE) which includes disposable gloves, laboratory coat/gown, eye protection and a respirator (N95 or similar) when handling potentially infectious specimens.
- Any procedure with the potential to generate fine-particulate aerosols (e.g., vortexing or sonication of specimens in an open tube) should be performed in a Class II Bio Safety Cabinet (BSC).
- Appropriate physical containment devices (e.g., centrifuge safety buckets; sealed rotors) should be used for centrifugation. The rotors and buckets should be loaded and unloaded in a BSC.
- Perform any procedures outside a BSC in a manner that minimizes the risk of exposure to an inadvertent sample release

2. Bio safety risk assessment for clinical/lab procedures for 2019-nCoV

Table 1 - Bio safety risk assessment for clinical/lab procedures for 2019-nCoV

Procedure	What could go wrong or hazard?	Overall risk
Sample collection	<ul style="list-style-type: none">• Aerosol exposure during sample processing• Eye splash during sample processing• Infectious culture material spill	<ul style="list-style-type: none">• High• Medium• Medium/High
Sample reception	<ul style="list-style-type: none">• Leaking sample•	<ul style="list-style-type: none">• High•
RT-PCR	<ul style="list-style-type: none">• Aerosol exposure during NA extraction	<ul style="list-style-type: none">• Medium

3. Biosafety risk mitigation for clinical procedures for 2019-nCoV

Table 2 - Biosafety risk mitigation for clinical procedures for 2019-nCoV

Procedure	Risk mitigation	Residual risk
<ul style="list-style-type: none"> • Sample collection 	<ul style="list-style-type: none"> • Standard PPE + Respirator • GMPP • Validated waste management 	<ul style="list-style-type: none"> • Low
Procedure	Risk mitigation	Residual risk
<ul style="list-style-type: none"> • Sample reception • RT-PCR for 2019-nCoV • 	<ul style="list-style-type: none"> • Work in BSC • Standard PPE + Respirator • GMPP • Validated waste management 	<ul style="list-style-type: none"> • Low

- BSC – Biosafety cabinet –Class 11
- PPE – Personal Protective Equipment
- GMPP – Good Microbiological Practices and Procedure

4. Recommended Personal Protective Equipment (PPE)

- N95 mask / Respirators (NIOSH-certified N95).
- Eye/facial protection (i.e. goggles or a face shield)
- A clean, non-sterile, long-sleeved fluid-resistant gown with tight cuffs. If gowns are not fluid resistant, a waterproof apron should be used for procedures where it is expected that fluid might penetrate the gown
- Apron (when performing additional procedures)
- Gloves

5. Sequence for donning personal protective equipment (PPE)

1. Gown

- Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back
- Fasten in back of neck and waist



2. Mask or respirator

- Secure ties or elastic bands at middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin
- Always check the seal/fitness after wearing N95 mask. Be aware that the presence of facial hair (e.g. beard) may prevent a proper respirator fit for the wearer.



- Check for any leakages- Cup both hands over the respirator and inhale and exhale sharply to check for any leaks around the nose. If any leaks are found readjust the nosepiece and repeat the leak test.



3. Goggles or face shield

- Place over face and eyes and adjust to fit

4. Gloves

- Extend to cover wrist of isolation gown

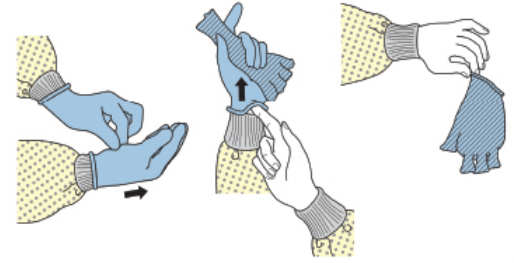


Figure 1 - Sequence for donning personal protective equipment

6. Safe doffing of personal protective equipment (PPE)

1. Gloves

- Outside of gloves are contaminated
If your hands get contaminated during glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove
- Hold removed glove in gloved hand
Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove
- Discard gloves in a yellow bag



2. Goggles or face shield

- Outside of goggles or face shield are contaminated.
If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band and without touching the front of the goggles or face shield. If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a yellow bag.

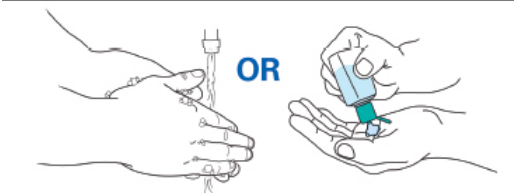


Figure 2 - Safe doffing of personal protective equipment (PPE)

3. Gown

- Gown front and sleeves are contaminated. If your hands get contaminated during gown removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Unfasten gown ties, taking care that sleeves don't contact your body when reaching for ties
- Pull gown away from neck and shoulders, touching inside of gown only
- Turn gown inside out
Fold or roll into a bundle and discard in a yellow bag

4. Mask or respirator

- Front of mask/respirator is contaminated DO NOT TOUCH. If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a yellow bag

7. The currently available diagnostic method in Sri Lanka

Real-time Reverse Transcription (RT)-PCR assay to detect 2019-nCoV RNA.

Virus isolation in cell culture and initial characterization of viral agents recovered in cultures of 2019-nCoV specimens are **NOT** recommended at this time, except at a BSL3 facility.

8. Specimens for diagnosing 2019-nCoV

- Respiratory materials including nasopharyngeal or oropharyngeal swabs in Viral Transport Medium (VTM).
- Use a sterile, leak-proof, screw-cap container with VTM for sputum.
- Endotracheal aspirate or bronchoalveolar lavage in patients with more severe respiratory disease. Send in VTM.
- Tissue from biopsies or autopsy including those from the lungs in VTM

All specimens should be triple packaged

NB: Collection of the samples should be done with **CAUTION** and all samples regarded as **potentially infectious** with regard to **strict adherence to Infection Prevention and Control guidelines**.

9. Infection prevention measures during sample collection for 2019-nCoV diagnosis

- Ensure that Health Care workers (HCWs) who collect specimens follow the standard and additional precautions and use the recommended PPE
- Perform procedures in an adequately ventilated room:
- Limit the number of persons present in the room to the minimum required for the sample collection
- Wear recommended PPE
- Follow the steps of donning and doffing PPE
- Perform hand hygiene before and after contact with the patient and his or her surroundings and after PPE removal.

10. Specifics for the transport of samples to the laboratory

- Ensure that personnel who transport specimens are trained in safe handling practices and spill decontamination procedures.
- Follow the requirements in the national or international regulations for the transport of dangerous goods (infectious substances) as applicable.
- Deliver all specimens by hand whenever possible. State the full name, age, **travel history, clinical symptoms and the type of specimen** of the suspected case clearly on the accompanying request form.
- Send all samples on ice (4°C).
- Notify the laboratory as soon as possible that the specimen is being transported.
- PPE is not necessary for people who transport specimens in the triple package.

11. Packing and Shipping

Basic triple packaging system: The system consists of three layers as follows.

1. Primary receptacle- This should be a watertight, leak-proof receptacle containing the specimen and properly labeled. The receptacle should be wrapped in enough absorbent material to absorb all fluid in case of breakage. For disposal purposes please choose a suitable **plastic** container as a primary receptacle.
2. Secondary receptacle- This should be a durable, watertight, leak-proof receptacle to enclose and protect the primary receptacle(s). Several wrapped primary receptacles for the same laboratory test may be placed in one secondary receptacle. Enough additional absorbent material must be used to cushion multiple primary receptacles.
3. Outer package - This is the container in which the secondary receptacle is placed. This is the outer most package that protects it and its contents from outside influences such as physical damage and water while in transit.

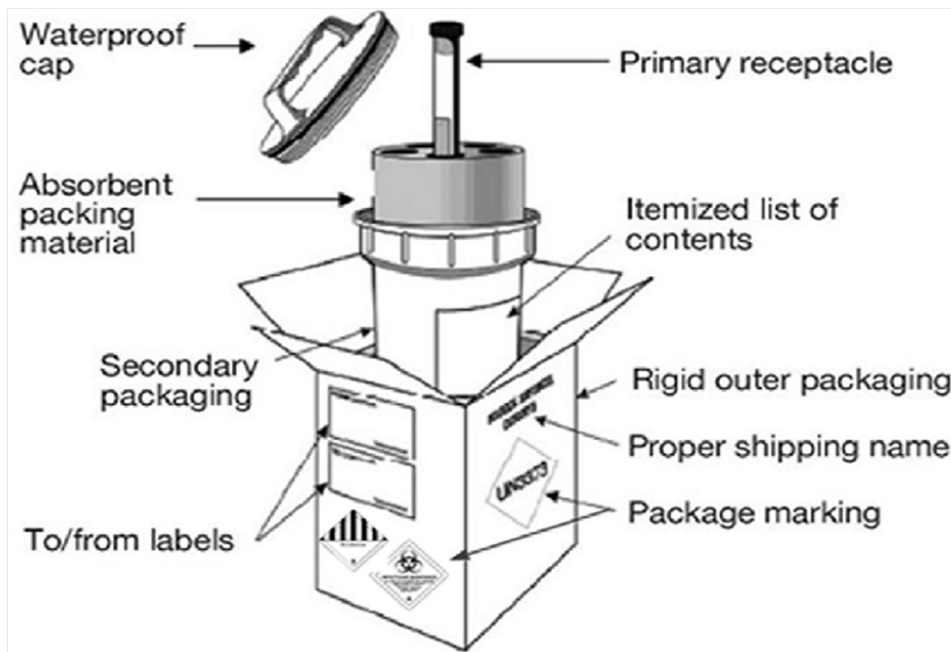


Figure 3 - Basic triple packaging system

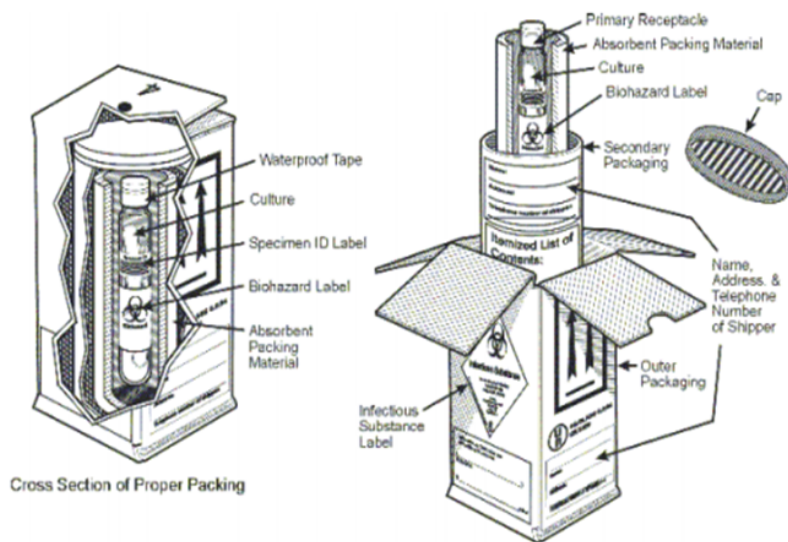


Figure 4 – Packaging and Labeling of Infectious Substances

- **Size of the triple package** – As this is opened inside a biosafety cabinet (BSC) this should be small enough to be accommodated in a BSC.
- The specimen container should be properly labelled.
- Specimen data forms, letters and other types of information that identify or describe the patient, specimen and the receiver should be taped to the outside of the secondary receptacle.
- All tests should have a duly signed separate request form/s.
- Packaging, shipping, and transport of specimens from confirmed or suspected cases of 2019-nCoV infection must follow the current edition of the International Air Transport Association (IATA) Dangerous Goods
- Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential 2019-nCoV specimens.
- Novel coronavirus specimens should follow the UN Model Regulations, and any other applicable regulations depending on the mode of transport being used.
- More information may be found in the WHO Guidance on regulations for the Transport of Infectious Substances 2019-2020 (Applicable as from 1 January 2019).
- A summary on transport of infectious substances can also be found in Toolbox 4 of the Managing epidemics handbook.

12. Specimen transport to Medical Research Institute, Colombo

Hospital staff should strictly adhere to the following instructions for specimen transport to Medical Research Institute for the confirmation of virus or any other special bacterial or fungal diagnosis in suspected patients with 2019-nCoV.

- Inform the Director / Head of Laboratory before sending the specimens.
- Label the specimens with appropriate tests required and patient details.
- Separate the tests according to specialized fields such as virology, bacteriology and mycology etc.
- All specimens should be triple packaged.

- Depending on the test requested packaging should be done separately to distribute to different laboratories.
- All tests should have a duly signed separate request form/s.
- A notation should be made in the request form to identify the specimen as biohazardous. If available, biohazardous labelling is ideal.
- The counter or any laboratory at the Medical Research Institute unable to sort out samples in the triple package. Therefore, if different laboratory tests are needed, different sets of triple packaged specimens should be sent to MRI to distribute to the appropriate laboratory. Once the triple package is removed by the laboratory staff all irrelevant specimens will be discarded. MRI will not be responsible for lost samples.
- Transport of samples should be according to Category B transportation regulations.
- Specimens should be hand delivered to the counter at the Medical Research Institute directly from the hospital by trained personnel.

13. Specifics for bio safety practices in the laboratory

- Ensure that health laboratories adhere to appropriate biosafety practices.
- Any testing on clinical specimens from suspected or confirmed patient should be performed in appropriately equipped laboratories by staff trained in the relevant technical and safety procedures.
- It is recommended that all manipulations in laboratory settings of samples originating from suspected or confirmed cases of 2019-nCoV can be conducted according to WHO/CDC recommendations
- National guideline on the laboratory biosafety should be followed in all circumstances.
- Also, for general information on laboratory biosafety guidelines, refer WHO Laboratory Biosafety Manual, 3rd edition (8) and 4th Edition.

A. The following activities may be performed in BSL-2 facilities using standard BSL-2 work practices:

- Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
- Molecular analysis of extracted nucleic acid preparations
- Electron microscopic studies with glutaraldehyde-fixed grids
- Routine examination of bacterial and mycotic cultures
- Routine staining and microscopic analysis of fixed smears
- Final packaging of specimens for transport to diagnostic laboratories for additional testing. Specimens should already be in a sealed, decontaminated primary container.
- Inactivated specimens (e.g., specimens in nucleic acid extraction buffer)

B. The following activities involving manipulation of potentially infected specimens should be performed as above and, in a Class II, BSC:

- Aliquoting and/or diluting specimens
- Inoculating bacterial or mycological culture media
- Performing diagnostic tests that do not involve propagation of viral agents in vitro or in vivo
- Nucleic acid extraction procedures involving potentially infected specimens
- Preparation and chemical- or heat-fixing of smears for microscopic analysis

14. Clinical Laboratory Testing

Clinical laboratories performing routine **haematology, urinalysis, and clinical chemistry studies, and microbiology laboratories** performing diagnostic tests on serum, blood, or urine specimens can be done in BSL2 laboratory wearing recommended PPE. All staff should follow standard laboratory practices, including Standard Precautions, when handling potential 2019-nCoV specimens.

PCR/Serology/Clinical chemistry/Hematology:

- Personnel protection: Gloves, Long-sleeved gown, Eye protection, Respiratory protection (N95 type)
- Primary containment: Biological safety cabinet type Class 11 A2 when processing specimens
- Secondary containment: BSL2 laboratory
- Staff training: Good microbiological practices and procedures and demonstrated competence

15. Decontamination and disposal of waste

- After specimens are processed, decontaminate work surfaces with 0.1% hypochlorite. Contact time is at least 10 minutes. Alcohol (e.g. isopropyl 70%, ethyl alcohol 60%) can be used to wipe down surfaces where the use of bleach is not suitable, e.g. metal.
- Equipment should be disinfected according to manufacturer's instructions with appropriate disinfectants. 70% alcohol can also be used for equipment surfaces.
- For spillages use 1% hypochlorite. Contact time is at least 10 minutes.
- All disposable waste should be autoclaved and incinerated. If incinerator is available within the premises waste could be directly sent for incineration.

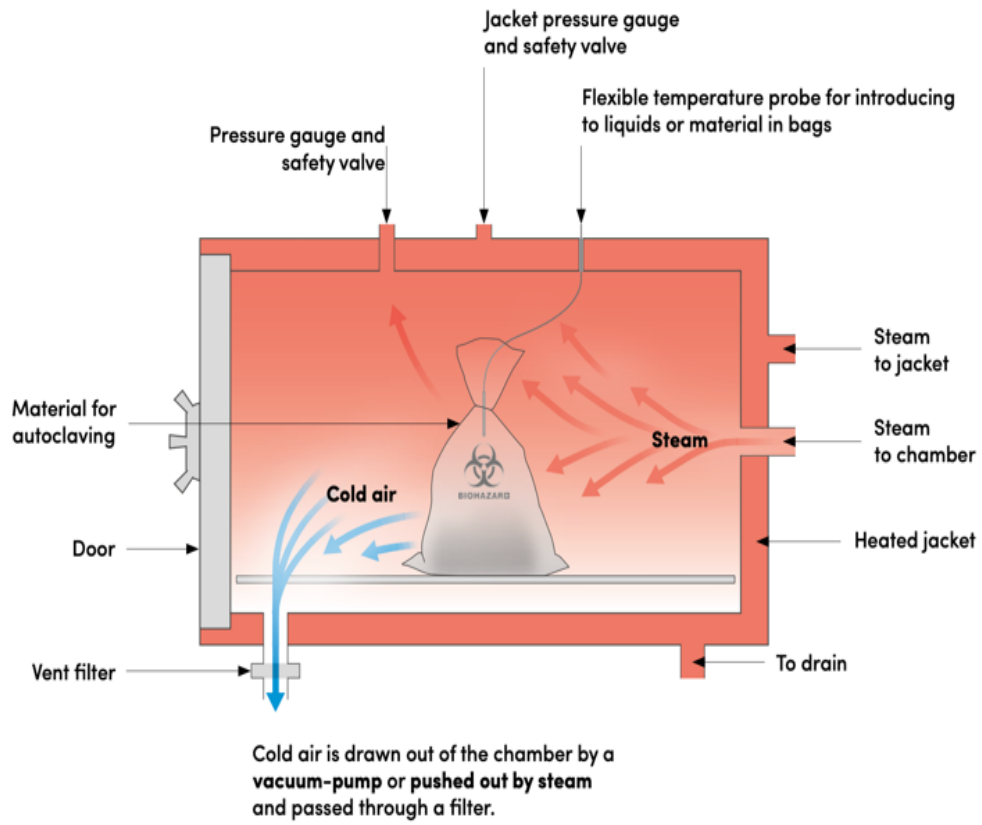


Figure 5 - Decontamination and disposal of waste

16. References

- https://www.who.int/csr/sars/biosafety2003_04_25/en/. and other guidance
- <https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html>
- <https://www.who.int/docs/default-source/coronaviruse/20200114-interim-laboratory-guidance-version.pdf>
- <https://www.nea.gov.sg/our-services/public-cleanliness/environmental-cleaning-guidelines/guidelines-for-environmental-cleaning-and-disinfection>
- [https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-\(ncov\)-infection-is-suspected-20200125](https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-(ncov)-infection-is-suspected-20200125)
- https://www.who.int/csr/disease/coronavirus_infections/Biosafety_InterimRecommendations_NovelCoronavirus2012_31Oct12.pdf?ua=1
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV) February 2, 2020