Centers for Disease Control and Prevention

Coronavirus Disease 2019 (COVID-19)

Frequently Asked Questions about Biosafety and COVID-19

Specimen Handling

Q: How should the laboratory perform a risk assessment to identify and mitigate risks?

A: Risk assessments and mitigation are dependent on the procedures to be performed, identification of the hazards involved in the process and/or procedures, the competency level of the personnel who perform the procedures, the laboratory equipment and facility, and the resources available. Risk assessments should try to identify what could go wrong, and how the laboratory will mitigate those risks.

For additional information, refer to the following:

- Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)
- Risk Assessment Best Practices
- World Health Organization Laboratory Biosafety Manual, 3rd

Q: Are certified Class II biological safety cabinets (BSCs) required to process specimens? Should laboratory staff put procedures in place to minimize personnel exposure if there is no certified Class II BSC?

A: Personnel should perform manipulation of clinical specimens from suspected COVID-19 persons under investigation (PUI), including routine clinical chemistry and hematology testing, inside a certified Class II BSC. Personnel should wear appropriate personal protective equipment (PPE): closed buttoned laboratory coat or gown, gloves, and eye protection at a minimum. If no certified Class II BSC is available, or if instrumentation (e.g., centrifuges, automated extraction equipment) cannot be used inside a BSC, use extra precautions to provide a barrier between the specimen and personnel, such as a mask or respirator plus other physical barriers (e.g., splash shield).

For additional information, refer to the following:

- CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)

Q: What biosafety level is recommended for handling clinical specimens from suspected COVID-19 PUIs?

A: In clinical laboratories, personnel handling respiratory specimens, whole blood, serum, plasma, and urine specimens should use Standard Precautions at BSL-2. Conduct work using intact, full-length genomic RNA at BSL-2 (BMBL 6th ed.– prepublication). Personnel should perform site- and activity-specific risk assessments to determine if enhanced biosafety precautions are warranted based on situational needs.

For additional information, refer to the following:

- CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

Q: What disinfectant should personnel use to decontaminate work surfaces?

A: Personnel should use products with EPA-registered hospital disinfectants with label claims to be effective against other respiratory pathogens, such as seasonal influenza and other human coronaviruses. Follow manufacturer's recommendations for use – dilution (i.e., concentration), contact time, and care in handling.

For additional information, refer to the following:

- Interim Infection Prevention and Control Recommendations for Patients with Confirmed 2019 Novel Coronavirus (2019-nCoV) or Persons Under Investigation for 2019-nCoV in Healthcare Settings
- CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
- Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)

Q: How should specimens be stored?

A: Store specimens at 2-8°C for up to 72 hours after collection. If a delay occurs in extraction, store specimens at -70°C or lower. Store extracted nucleic acid at -70°C or lower.

For additional information, refer to the following:

- Interim Infection Prevention and Control Recommendations for Patients with Confirmed 2019 Novel Coronavirus (2019-nCoV) or Persons Under Investigation for 2019-nCoV in Healthcare Settings
- CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel

Q: How should personnel remove biohazardous waste from the laboratory or testing area for decontamination and disposal? Does an autoclave need to be available in the facility?

A: For waste associated with testing clinical specimens from suspected COVID-19 PUIs, personnel should follow standard procedures associated with other respiratory pathogens, such as seasonal influenza and other human coronaviruses. Biohazardous waste containers should be leakproof and closed prior to removal from the laboratory for decontamination. If there is no autoclave onsite, then pack waste in accordance with institutional policy and procedures.

For additional information, refer to the following:

- Biosafety in Microbiological and Biomedical Laboratories (BMBL) (5th edition)

Q: How should staff members transport clinical specimens from suspected COVID-19 PUIs within a facility?

A: Staff members should adhere to standard procedures associated with other respiratory pathogens, such as seasonal influenza and other human coronaviruses when they transport specimens within a facility. Personnel should perform site- and activity-specific risk assessments to determine if enhanced biosafety precautions are warranted based on situational needs.

For additional information, refer to the following:

- Infection prevention and control during health care when novel coronavirus (nCoV) infection is suspected
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)

Specimen Packaging and Shipping

Q: Do people packing specimens for transport need to be trained and competent?

A: Personnel should be trained in the proper safety, packing, and shipping regulations for UN 3373 Biological Substance, Category B when sending when sending clinical specimens from suspected COVID-19 PUIs. Personnel should be trained in a manner that corresponds to their function-specific responsibilities.

For additional information, refer to the following:

- Guidance on regulations for the transport of infectious substances 2019 – 2020

Q: What specific packaging should personnel use when shipping clinical specimens from suspected COVID-19 PUIs?

A: Follow shipping regulations for UN 3373 Biological Substances, Category B:

1. A leakproof primary container.
2. A rigid, leakproof, watertight secondary packaging with absorbent material.
3. A rigid outer packaging to protect the specimens during shipment.

For additional information, refer to the following:

- IATA Dangerous Goods Regulations Packaging Instruction 650
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)

Q: At what temperature should specimens be shipped?

A: Specimens should be shipped at 2-8°C with ice packs. If the specimen is frozen, ship overnight on dry ice. The primary receptacle and the secondary packaging should maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures which could result if refrigeration were lost. Packages containing dry ice should be designed and constructed so as to prevent the buildup of pressure and to allow the release of gas that could rupture the packaging.

For additional information, refer to the following:

- CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

Q: What information is required on the outer package for shipment of specimens with ice packs?

A: Ensure the outer package has been properly marked and labeled with the following:

1. Hazard labeled with UN Identification Number already on label – UN 3373
2. Biological Substance, Category B
3. Shipper's name, address, and phone number
4. Receiver's name, address, and phone number
5. Name and phone number of a responsible person is optional if it is on the airway bill.

For additional information, refer to the following:

- Guidance on regulations for the transport of infectious substances 2019 – 2020

Q: What information is required on the outer packages for shipment of specimens with dry ice?

A: Ensure the outer package has been properly marked and labeled with the following:

1. Hazard labeled with UN Identification Number already on label – UN 3373
2. Biological Substance, Category B
3. Hazard Labeled with UN Identification Number- UN 1845
4. Dry Ice along with the net weight (kg) of the dry ice
5. Shipper's name and address
6. Receiver's name and address
7. Name and phone number of a responsible person.

For additional information, refer to the following:

- Guidance on regulations for the transport of infectious substances 2019 – 2020
- IATA Dangerous Goods Regulations Packaging Instruction 650

Q: What information is required on an overpack if used for specimen shipment?

A: The overpack should be marked in accordance with the packing instructions required for the outer package:

1. Hazard labeled with UN Identification Number already on the label – UN 3373
2. Biological Substance, Category B
3. Shipper's name, address, and phone number
4. Receiver's name, address, and phone number
5. Package Orientation Label
6. Marked with the word "Overpack"
7. Name and phone number of a responsible person is optional if it is on the airway bill

For additional information, refer to the following:

- IATA Dangerous Goods Regulations Packaging Instruction 650
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

Q: Is a shipper's declaration required? What documentation is required for shipment? What if specimens are shipped on dry ice?

A: A shipper's declaration is not required for UN 3373 Biological Substances, Category B shipped samples. If an Air Waybill is used, the "Nature and Quantity of Goods" box should show "UN 3373 Biological Substance, Category B" along with the number of packages. If specimens are shipped on dry ice, include UN 1845, Dry Ice, 9, along with the net weight of the dry ice. See IATA PI 650 for additional information.

For additional information, refer to the following:

- Guidance on regulations for the transport of infectious substances 2019 – 2020
- IATA Dangerous Goods Regulations Packaging Instruction 650

Q: Is a Responsible Person required on the shipping paperwork?

A: Yes, a Responsible Person should be listed on the air waybill or Shipper's Declaration (if applicable).

For additional information, refer to the following:

- Guidance on regulations for the transport of infectious substances 2019 – 2020
- IATA Dangerous Goods Regulations Packaging Instruction 650

Q: Once packaging of the samples is complete should staff members decontaminate the work area?

A: Staff members should use products with EPA-registered emerging viral pathogens claims for SARS-CoV-2 or human coronaviruses for decontaminating hard non-porous surfaces. Follow manufacturer's recommendations for use, dilution (i.e., concentration), contact time, and care in handling.

For additional information, refer to the following:

- Interim Infection Prevention and Control Recommendations for Patients with Confirmed 2019 Novel Coronavirus (2019-nCoV) or Persons Under Investigation for 2019-nCoV in Healthcare Settings

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