Frequently Asked Questions about Biosafety and COVID-19

Updated June 5, 2020

Specimen Handling

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

All laboratories should perform a site-specific and activity-specific risk assessment to identify and mitigate risks and determine if enhanced biosafety precautions are warranted based on situational needs, such as high testing volumes, and the likelihood to generate infectious droplets and aerosols. Risk assessments and mitigation measures are dependent on the procedures 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.

The risk assessment should identify all potential scenarios of a particular activity that could produce a negative outcome. The risk assessment should prioritize those potential negative outcomes, or risks, based on an evaluation of the likelihood and consequences of each of those identified risks. The risk assessment should determine the most appropriate control measures, and how the system will measure the effectiveness of those control measures.

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

Are certified Class II biological safety cabinets (BSCs) required to process suspected or confirmed SARS-CoV-2 specimens? Should laboratory staff put procedures in place to minimize personnel exposure if there is no certified Class II BSC?

For procedures with a high likelihood to generate aerosols or droplets, use either a certified Class II Type A1 or A2 BSC or additional precautions to provide a barrier between the specimen and personnel. Examples of these additional precautions include personal protective equipment (PPE), such as a surgical mask or face shield, or other physical barriers, like a splash shield; centrifuge safety cups; and sealed centrifuge rotors to reduce the risk of exposure to laboratory personnel.

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)

How should point-of-care testing (POCT) be conducted outside a traditional laboratory?

For viral testing of specimens conducted outside of a traditional clinical laboratory, such as rapid respiratory testing, use Standard Precautions to provide a barrier between the specimen and personnel during specimen manipulation.

For additional information, refer to:

- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

If laboratory personnel collect blood or respiratory specimens directly from suspected or confirmed COVID-19 patients, what PPE should they wear?

If laboratory personnel have direct contact with suspected or confirmed COVID-19 patients, they should follow recommended PPE for health care providers while in the presence of these patients.

For additional information, refer to:

- Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings
- OSHA 29 CFR 1910.1030 Bloodborne Pathogens Standard

What is the recommended biosafety level for handling suspected or confirmed SARS-CoV-2 patient specimens?

Routine viral testing of patient specimens, such as the following activities, can be handled in a BSL-2 laboratory using Standard Precautions:
• Using automated instruments and analyzers
• Staining and microscopic analysis of fixed smears
• Examination of bacterial cultures
• Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
• Molecular analysis of extracted nucleic acid preparations
• Final packaging of specimens for transport to diagnostic laboratories for additional testing. Specimens should already be in a sealed, decontaminated primary container
• Using inactivated specimens, such as specimens in nucleic acid extraction buffer
• Electron microscopic studies with glutaraldehyde-fixed grids

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)
- OSHA 29 CFR 1910.1030 Bloodborne Pathogens Standard

What disinfectant should personnel use to decontaminate work surfaces?

Decontaminate work surfaces and equipment with appropriate disinfectants. Use EPA-registered hospital disinfectants with label claims to be effective against SARS-CoV-2 . Follow manufacturer's recommendations for use, such as dilution, contact time, and safe handling.

How should specimens be stored?

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

For additional information, refer to the following:

- Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings
- CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel

How should laboratory personnel remove biohazardous waste from the laboratory or testing area for decontamination and disposal?

Handle laboratory waste from testing suspected or confirmed COVID-19 patient specimens as all other biohazardous waste in the laboratory. Currently, there is no evidence to suggest that this laboratory waste needs additional packaging or disinfection procedures.

For additional information, refer to the following:

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

How should personnel transport suspected or confirmed SARS CoV-2 specimens within a facility?

Personnel 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:

- 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).pdf

What are Standard Precautions?

Standard Precautions are based on the principle that all blood, body fluids, secretions, nonintact skin, mucous membranes, and excretions (except sweat) may contain transmissible infectious agents. Standard Precautions include hand hygiene and the use of personal protective equipment (PPE) such as laboratory coats or gowns, gloves, and eye protection.

For additional information, refer to the following:

- 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- CDC Isolation Precautions

What are infectious aerosols and droplets?

Aerosols and droplets containing particles that are <100 µm in diameter are not visible to the naked eye. Laboratory workers may not be aware that such particles can be generated during many laboratory procedures and that these particles could be inhaled or could cross-contaminate work surfaces, materials, and equipment.

Infectious aerosols are small liquid or solid particles suspended in the air that contain infectious agents. They can disperse throughout the laboratory and remain infective over time and distance. These particles are of a size that may be inhaled into the lower respiratory tract (<5 µm in diameter). Examples of organisms transmitted by aerosols include spores of Aspergillus spp., Mycobacterium tuberculosis, rubeola virus (measles), and varicella-zoster virus (chickenpox).

Droplets traditionally are defined as larger infectious particles (>5 µm in diameter) that rapidly fall out of the air, contaminating gloves, the immediate work area, and the mucous membranes of the persons performing the procedure.

Examples of infectious agents that are transmitted via the droplet route include Bordetella pertussis, influenza viruses, adenovirus, Mycoplasma pneumoniae, SARS-associated coronavirus (SARS-CoV), group A streptococcus, and Neisseria meningitidis.

For additional information, refer to the following:

- WHO Laboratory Biosafety Manual, 3rd
- 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- CDC Isolation Precautions

What procedures can generate aerosols and droplets?

Many routine laboratory procedures can potentially generate aerosols and droplets that are often undetectable. The following laboratory procedures have been associated with the generation of infectious aerosols and droplets: centrifugation, pipetting, vortexing, mixing, shaking, sonicating, removing caps, decanting liquids, preparing smears, flaming slides, aliquoting and loading specimens, loading syringes, manipulating needles, syringes or sharps, aspirating and transferring blood and body fluids, subculturing blood culture bottles, spilling specimens, and cleaning up spills.

For additional information, refer to the following:

- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories
- Biosafety in Microbiological and Biomedical Laboratories, 5th Ed.
- Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)

Can the pneumatic tube system be used to transport patient specimens from suspected or confirmed COVID-19 patients?

It depends on the type of specimen being transported:

- CDC recommends that respiratory specimens from patients with suspected or confirmed COVID-19 should not be transported through pneumatic tubes. At this time, this recommendation only applies to suspected or confirmed COVID-19 respiratory specimens. Examples of respiratory specimens include nasopharyngeal (NP) and oropharyngeal (OP) swabs, nasal mid-turbinate (NMT) swabs, tracheal and lower respiratory tract aspirates, bronchoalveolar lavage (BAL) specimens, and sputum.
- Based on currently available data, other types of specimens, such as blood, urine, and feces, are still acceptable to transport through pneumatic tubes.

Facilities should ensure that all personnel who transport specimens via pneumatic tubes are trained in safe handling practices, specimen management, and spill decontamination procedures.

Each facility should also evaluate its risks and determine the most appropriate biosafety measures and practices to implement.

For additional information, refer to the following:

- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories MMWR, Supplement / Vol. 61 January 6, 2012

How should decentralized and point-of-care (POC) testing for COVID-19 diagnostic purposes be conducted outside of a traditional laboratory?

Testing sites that operate a POC diagnostic instrument must have a current Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate. During the COVID-19 public health emergency, the Centers for Medicare & Medicaid Services (CMS) will permit a laboratory to extend its existing Certificate of Waiver to operate a temporary COVID-19 testing site in an off-site location (e.g., long-term care or correctional facilities). The temporary COVID-19 testing site is only permitted to perform waived tests, consistent with the laboratory's existing CLIA certificate, and must be under the direction of the existing laboratory director.

Laboratories should consider the following when using POC instruments for COVID-19 diagnostic purposes:

- Use the instrument in a location that has a current CLIA certificate.
- Perform a site-specific and activity-specific risk assessment to identify and mitigate safety risks.
- Train staff on the proper use of the instrument and ways to minimize their risk of exposure.
- Follow Standard Precautions when handling clinical specimens, including hand hygiene and the use of PPE, such as laboratory coats or gowns, gloves, and eye protection. If needed, additional precautions can be used, such as a surgical mask or face shield, or other physical barriers, such as a splash shield to work behind.
- When using patient swabs, minimize contamination of the swab stick and wrapper by widely opening the wrapper before placing the swab back into the wrapper.
- Change gloves after adding patient specimens to the instrument.
- Decontaminate the instrument after each run by using an EPA-approved disinfectant for SARS-CoV-2 and following the manufacturer's recommendations for use, including dilution, contact time, and safe handling.

For additional information, refer to:

- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- Fact Sheet: Guidance – Proposed Use of Point-of-Care (POC) Testing Platforms for SARS-CoV-2 (COVID-19)

Specimen Packing and Shipping

Do people packing patient specimens, isolates or cultures for transport need to be trained and competent?

For transporting patient specimens, cultures or isolates, personnel must be trained in the proper safety, packing, and shipping regulations for Division 6.2, UN 3373 Biological Substance, Category B in accordance with the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations (DGR). 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

What specific packaging should personnel use when shipping suspected or confirmed SARS-CoV-2 patient specimens, isolates or cultures?

Pack and ship suspected or confirmed SARS-CoV-2 patient specimens, cultures or isolates as UN 3373 Biological Substance, Category B, in accordance with the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations (DGR) :

1. A leakproof primary container.
2. A 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)

At what temperature should specimens be shipped?

Specimens should be shipped at 2-8oC 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)

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
    - Dangerous Goods Documentation
    - Click on "Infectious substances" and there is an option to download the packing instructions.
- Labels for UN 3373
    - When using cold pack – Include the name and telephone number of the person who will be available during normal business hours who knows the content of the shipment (can be someone at CDC). Place the label on one side of the box and cover the label completely with clear tape (do not tape just the edges of the label).
- Schematic for packaging, UN 3373 Category B

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

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
    - Packing Instructions 650 for UN 3373
    - Click on "Infectious substances" and there is an option to download the packing instructions.
- Labels for UN 3373
    - When using dry ice – Include the name and telephone number of the person who will be available during normal business hours who knows the content of the shipment (can be someone at CDC). Place the label on one side of the box and cover the label completely with clear tape (do not tape just the edges of the label).
- Schematic for packaging, UN 3373 Category B

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

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)

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

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

Is a Responsible Person required on the shipping paperwork?

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

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

Decontaminate work surfaces and equipment with appropriate disinfectants. Use EPA-registered hospital disinfectants with label claims to be effective against SARS-CoV-2. Follow manufacturer's recommendations for use, such as dilution, contact time, and safe handling.

For additional information, refer to the following:

- Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus 2019 (COVID-19) in Healthcare Settings
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

Anatomic Pathology

What are the anatomic pathology best practices to prevent COVID-19 exposure while performing procedures and processing specimens?

Manual processing of fresh unfixed specimens, including frozen sections, should be conducted in a manner that provides a barrier between the specimen and personnel during specimen manipulation. In addition, protect the mucous membranes of the eyes, nose, and mouth during procedures that are likely to generate **splashes, sprays, droplets, and aerosols.** Examples of these barriers include:

- Performing tissue dissection in a certified Class II A1 or A2 biological safety cabinet (BSC) if available
- Working behind a splash shield
- Using combinations of PPE, such as:
  - surgical mask with attached eye shield
  - surgical mask and goggles
  - mask and a face shield that fully cover the front and sides of the face
  - double gloves or mesh cut-resistant gloves
  - surgical scrubs, shoe covers, full gown, plastic apron, and hair covering
  - N95 respirators or powered air-purifying respirators (PAPRs) (the use of respiratory protection requires fit testing and appropriate training)

What precautions should clinical and non-clinical support staff take when handling specimen containers that may be contaminated with blood and body fluids?

All laboratories should perform a site- and activity-specific risk assessment and follow Standard Precautions when handling specimen containers and paper requisitions that could have been contaminated by tissue and fluid specimens. This risk assessment may suggest use of some of these mitigation strategies:

- Use face shields and/or work behind a splash guard whenever possible.
- Store human specimens in closed containers that can be decontaminated before moving them to a secure area.

Place specimen containers in closed and clearly labeled plastic bins until pick-up and disposal according to your institutional waste management policies.

What are the biosafety recommendations for performing frozen sectioning on confirmed and suspected COVID-19 patient specimens?

Avoid frozen sectioning from confirmed COVID-19 patients whenever possible. Talk with the relevant clinical and surgical teams about the clinical necessity and benefit of frozen sectioning and consider appropriate alternatives for suspected and confirmed COVID-19 cases. When frozen sectioning is unavoidable, the following are recommended, if possible:

- Receive specimens in an area apart from administrative staff
- Consider using a cryostat that has a downdraft and other safety features.
- Use cryostats in a closed room that has inward directional (negative) airflow vented directly to the outside or recirculated through a HEPA filter to avoid contaminating the rest of the surgical pathology suite.
- Provide grossing rooms with inward directional air flow.
- Reduce the number of operators to a minimum.
- Wear appropriate PPE, including but not limited to:
  - Fluid-resistant disposable double gloves and gown,
  - Fluid-resistant disposable apron,
  - Eye protection (face shield or goggles), and
  - N95 respirator or fluid-resistant surgical mask.
- Do not use freezing sprays; they are not recommended by the manufacturers of cryostat instrumentation.
- Wear cut-resistant, stainless steel mesh gloves during disassembly, cleaning, and disinfection of microtome knives.
- Collect accumulated instrument shavings and discard them as biohazardous waste.
- Follow local standard decontamination procedures of the cryostat and other surfaces. Ultraviolet lights are not a substitute for terminal cleaning of the instrument.

For additional information, refer to the following:

- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories

What chemical treatments inactivate SARS-CoV-2 in tissues during histopathology processing?

Human tissues submitted for permanent pathologic examination typically undergo several processing steps with chemicals that have been shown to inactivate coronaviruses:

- Studies with SARS-CoV-1 and MERS-CoV have shown that virus inactivation for these coronaviruses occurs in a time-dependent fashion with both formalin fixation and temperatures of 56°C or above.
- Alcohol at 70% concentration or higher has been shown to inactivate the virus and tissue processing typically includes a series of alcohol dehydration steps that use 70% to 100% alcohol prior to paraffin embedding.
- In addition, the final step of applying a glass or plastic coverslip to the slide provides an additional barrier between the personnel and the tissue.

For additional information, refer to the following:

Inactivation of the coronavirus that induces severe acute respiratory syndrome, SARS-CoV

Inactivation and safety testing of Middle East Respiratory Syndrome Coronavirus

Practical Guide to Specimen Handling in Surgical Pathology

Coronavirus disinfection in histopathology

NSH-COVID-19: Novel Coronavirus Resources

Does a grossing station that draws air and fumes toward the rear of the unit offer the same protection as a biosafety cabinet?

No. Grossing stations pull formalin fumes away from the person who is doing the dissecting. In general, grossing stations are not as effective as biosafety cabinets at protecting the user from exposure to biological agents.

For additional resources related to biological safety cabinets, refer to:

- Fundamentals of Working Safely in a Biological Safety Cabinet provides free training CEU
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition Section III_ Biological Safety Cabinets (page 292).

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