Coronavirus Disease 2019 (COVID-19)

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

Updated Aug. 11, 2020 Print

Summary of Recent Changes

Revisions made on August 7, 2020 include:

- Standard Precautions

Revisions made on July 16, 2020 include:

- Added DOT resources to Specimen Packing and Shipping and Resource section

Revisions made on July 13, 2020 to update:

- Language for virus isolation

Revisions made on June 3, 2020 include:

- Added anatomic pathology guidance for COVID-19
- Updated Point-of-Care testing guidance for COVID-19

Revisions made on May 11, 2020 include recommendations for:

- Point-of-Care testing guidance for COVID-19

Until more information becomes available, precautions should be taken in handling specimens that are suspected or confirmed for SARS-CoV-2. Timely communication between clinical and laboratory staff is essential to minimize the risk incurred in handling specimens from patients with possible SARS-CoV-2 infection. Such specimens should be labeled accordingly, and the laboratory should be alerted to ensure proper specimen

handling. General and specific biosafety guidelines for handling SARS-CoV-2 specimens are provided below. For additional information on handling SARS-CoV-2 specimens, refer to the Laboratory Frequently Asked Questions.

General Guidance

All laboratories should perform a site-specific and activity-specific risk assessment to identify and mitigate risks. 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
- The resources available

Follow Standard Precautions when handling clinical specimens, all of which may contain potentially infectious materials.

Follow routine laboratory practices and procedures for decontamination of work surfaces and management of laboratory waste.

Routine Diagnostic Testing

Routine diagnostic testing of specimens, such as the following activities, can be handled in a BSL-2 laboratory using Standard Precautions:

- Using automated instruments and analyzers
- Processing initial samples
- 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
- Performing electron microscopic studies with glutaraldehyde-fixed grids

Anatomic Pathology

The practice of anatomic pathology plays a critical role in determining accurate disease diagnoses by studying organ tissues and fluids. Anatomic pathology includes **surgical pathology, histotechnology, cytology, and autopsy.**

Risks associated with surgical pathology and some cytology procedures occur during the manipulation of fresh tissue and body fluids from patients who may have an unknown or known infectious disease, such as COVID-19. Risks are increased in the surgical grossing room during manual specimen handling, tissue dissection, and the preparation of frozen sections of tissue using a cryostat. These procedures can result in percutaneous exposures from punctures or cuts; droplet or aerosol exposures from splashes of blood and body fluids; and exposures from surfaces contaminated with the virus.

Clinical as well as non-clinical support staff need to be aware of these risks and provided with effective mitigation procedures. See Laboratory Frequently Asked Questions for more information.

For information on **autopsies**, see Collection and Submission of Postmortem Specimens from Deceased Persons with Known or Suspected COVID-19

Note: This guidance does **not** apply to clinical pathology, which involves laboratory testing on patient specimens, such as blood, body fluids, stool and urine. Clinical pathology uses different procedures and workflows than those used in anatomic pathology, and therefore the risks and mitigation controls needed to protect personnel are different. At a minimum, all personnel—whether practicing anatomic or clinical pathology—should follow Standard Precautions when handling patient tissues and specimens.

Decentralized and Point-of-Care Testing

Point-of-Care (POC) tests are intended to supplement laboratory testing, making testing available to communities and populations that cannot readily access laboratory testing, and bolstering testing to quickly address emerging outbreaks. Examples of potential uses for POC instruments for COVID-19 diagnostic purposes include:

- Deployment to rural hospitals or other critical care sites that lack widely available testing.
- Use at public health department testing sites that perform CLIA-waived testing for other purposes.
- Deployment to long-term care facilities or correctional institutions.
- Rapid deployment to aid in the investigation of a newly identified case cluster.
- Placement in laboratories to test high-priority specimens that require a rapid result.

Regulatory requirements and necessary CLIA documentation need to be considered when deploying instruments to these settings if they are not currently performing other POC testing. 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, such as a long-term care facility. The temporary COVID-19 testing site is only permitted to perform waived tests, consistent with the laboratory's existing certificate, and must be under the direction of the existing lab director.

Laboratories should consider the following when using POC instruments for SARS-CoV-2 diagnostic purpose:

- Use the instrument in a location associated with 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 the risk of exposures.
- 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 prior to 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. Following the manufacturer's recommendations for use, such as dilution, contact time, and safe handling.

For additional information, refer to:

- SARS-CoV-2 (COVID-19) Fact Sheet: Guidance – Proposed Use of Point-of-Care (POC) Testing Platforms for SARS-CoV-2 (COVID-19)
- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories
- Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)

Procedures with a High Likelihood of Generating Droplets or Aerosols

Procedures with a high likelihood of generating aerosols or droplets, should be done using either a certified Class II Biological Safety Cabinet (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.

Site- and activity-specific biosafety risk assessments should be performed to determine if additional biosafety precautions are warranted based on situational needs, such as high testing volumes, and the likelihood to generate infectious droplets and aerosols.

Environmental Specimen Testing

Procedures that concentrate viruses, such as precipitation or membrane filtration, can be performed in a BSL-2 laboratory with unidirectional airflow and BSL-3 precautions, including respiratory protection and a designated area for donning and doffing PPE. The donning and doffing space should not be in the workspace. Work should be performed in a certified Class II BSC.

This guidance is intended for only those laboratories that perform virus concentration procedures, including wastewater/sewage surveillance testing, and not for public health or clinical diagnostic laboratories that handle COVID-19 clinical specimens or laboratories that perform culture and isolation of SARS-CoV-2. Site- and activity-specific biosafety risk assessments should be performed to determine if additional biosafety precautions are warranted based on situational needs, such as high testing volumes or large volumes, and the likelihood to generate infectious droplets and aerosols.

Virus Isolation

CDC recommends virus isolation in cell culture, and initial characterization of viral agents recovered in cultures of novel SARS-CoV-2 should be conducted in a Biosafety Level 3 (BSL-3) laboratory using BSL-3 practices. To determine appropriate biosafety mitigation measures, laboratories should perform an activity-specific biosafety risk assessment that evaluates laboratory facilities, personnel and training, practices and techniques, safety equipment, and risk mitigation measures. Biosafety professionals, laboratory management, and scientific and safety experts should be involved in the risk assessment process.

For more information on risk assessments:

- Biosafety in Microbiological and Biomedical Laboratories 5th Edition
- Association of Public Health Laboratories Risk Assessment Best Practices

SARS-CoV-2 Viral Culturing at CDC

Decontamination

Decontaminate work surfaces and equipment with appropriate disinfectants by using an EPA-approved disinfectant for SARS-CoV-2 . Following the manufacturer's recommendations for use, such as dilution, contact time, and safe handling.

Laboratory Waste Management

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 any additional packaging or disinfection procedures

Specimen Packing and Shipping

Pack and ship suspected and 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 and U.S. Department of Transportation's (DOT) Transporting Infectious Substances Safely . Personnel must be trained to pack and ship according to the regulations and in a manner that corresponds to their function-specific responsibilities.

Resources

- Longhorn PrimeStore Molecular Transport Medium Fact Sheet [2 pages]
- CDC Laboratory Frequently Asked Questions
- EPA List N: Disinfectants for Use Against SARS-CoV-2
- Saf-T-Pak Packaging Checklist, see Category B
- Guide to Packaging Category B Diagnostic Samples
- IATA 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 cold pack (CDC) – 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).
  - When using dry ice (CDC) – 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).
- CDC Schematic for packaging, UN 3373 Category B
- WHO Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)
- APHL Risk Assessment Best Practices
- WHO Laboratory Biosafety Manual, 3rd
- WHO Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV)-World Health Organization
- CDC 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- CDC Isolation Precautions
- SARS-CoV-2 (COVID-19) Fact Sheet: Guidance – Proposed Use of Point-of-Care (POC) Testing Platforms for SARS-CoV-2 (COVID-19)
- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories

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