Interim Guidelines for Biosafety and COVID-19

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

Updated May 11, 2020

Summary of Recent Changes

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 Biosafety 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. Standard Precautions include hand hygiene and the use of personal protective equipment (PPE), such as laboratory coats or gowns, gloves, and eye protection.

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

Routine Viral Testing

Routine viral 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

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 public health 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 to Generate Droplets or Aerosols

For procedures with a high likelihood to generate aerosols or droplets, use 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, such as wastewater/sewage surveillance testing, not 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

Virus isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens should only be conducted in a Biosafety Level 3 (BSL-3) laboratory using BSL-3 practices. Site- and activity-specific biosafety risk assessments should be performed to determine if additional biosafety precautions are warranted based on situational needs.

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 . Personnel must be trained to pack and ship according to the regulations and in a manner that corresponds to their function-specific responsibilities.

Resources

- CDC Laboratory Biosafety Frequently Asked Questions
- EPA List N: Disinfectants for Use Against SARS-CoV-2
- Saf-T-Pak Packaging Checklist, see Category B
- 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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