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ORD-ORPP&E

COVID-19 (SARS-CoV-2) Research Specimens

Frequently Asked Questions

These FAQs are based on the CDC guidance released March 31, 2020 located at:

https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html#guidance

1. What is the difference between BSL-1, 2 and 3 laboratories?[1]

	BSL-1	BSL-2 Use all BSL-1 precautions plus:	BSL-3 Use all BSL-2 precautions plus:
Lab practice	Standard microbiological practices are followed. Work can be performed on an open lab bench or table, and surfaces are decontaminated after use No eating, drinking, or cosmetic use is permitted. Persons must wash their hands after working with material and before leaving the lab, or use an alcohol-based hand sanitizer	Access to the laboratory is restricted when work is being conducted. All work with infectious materials that can form aerosols or splashes are performed within a biological safety cabinet (BSC).	Laboratorians are under medical surveillance and might receive immunizations for microbes they work with. All work with infectious materials must be performed within an appropriate BSC Access to the laboratory is always restricted and controlled.
Personal Protective Equipment (PPE)	Lab coats, gloves, eye protection and face protection are worn as needed	Appropriate personal protective equipment (PPE) is worn, including lab coats and gloves. Eye protection and face shields can also be worn, as needed.	Appropriate PPE must be worn, and respirators might be required.

[1] See Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition, for a complete listing of practices, primary barriers/safety equipment and facilities (secondary barriers) by BSL level.
Accessible at: https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF

Facility	A sink must be available for hand washing. The lab should have doors to separate the working space with the rest of the facility.	The laboratory has self-closing doors. A sink and eyewash are readily available. An autoclave or an alternative method of decontamination is available for proper disposals.	A hands-free sink and eyewash are available near the exit. Exhaust air cannot be recirculated, and the laboratory must have sustained directional airflow by drawing air into the laboratory from clean areas towards potentially contaminated areas. Entrance to the lab is through two sets of self-closing and locking doors.

2. 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. CDC has SARs-CoV-2 guidance/FAQ on this: **https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html**

3. If my protocol requires me to collect specimens from either persons under investigation (PUI) or COVID+ subjects, what personal protective equipment (PPE) do I need to wear?

There is no difference in what healthcare professionals need as PPE from what a researcher needs as PPE when interacting with either a PUI or COVID+ patient/subject. See CDC guidance. https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html#adhere

4. What is the current recommended PPE for interacting with PUI or COVID+ patients/subjects?

- **Respirator or Facemask**
  - Put on a respirator or facemask (e.g., surgical mask, procedure mask), if a respirator is not available) before entry into the patient room or care area. NOTE: A face mask (also called a surgical mask, procedure mask, or other similar terms) should not be confused with PPE for a worker; the mask acts to contain potentially infectious respiratory secretions at the source (i.e., the person's nose and mouth).
- **Eye Protection**
  - Put on eye protection (i.e., goggles or a disposable face shield that covers the front and sides of the face) upon entry to the patient room or care area. Personal eyeglasses and contact lenses are NOT considered adequate eye protection. Note: A face shield may be

worn over goggles to protect exposed areas of the face but should not be worn as a primary form of eye protection
    - Remove eye protection before leaving the patient room or care area.
    - Reusable eye protection (e.g., goggles) must be cleaned and disinfected according to manufacturer's reprocessing instructions prior to re-use. Disposable eye protection should be discarded after use.
- **Gloves**
    - Put on clean, non-sterile gloves (that fit snuggly over the gown cuff)upon entry into the patient room or care area.
        - Change gloves if they become torn or heavily contaminated.
    - Remove and discard gloves when leaving the patient room or care area, and immediately perform hand hygiene.
- **Gowns**
    - Put on a clean isolation gown (preferably with fluid-resistant properties) upon entry into the patient room or area. Change the gown if it becomes soiled. Remove and discard the gown in a dedicated container for waste or linen before leaving the patient room or care area. Disposable gowns should be discarded after use. Cloth gowns should be laundered after each use.

5. If my protocol requires me to collect a nasopharyngeal swab, what precautions should I take?

You should wear an N-95 or higher-level respirator, e.g., a powered air purifying respirator (PAPR) with high-efficiency particulate arrestance (HEPA) filter, R/P95, N/R/P99, or N/R/P100 filtering facepiece respirator; an air-purifying elastomeric (e.g., half-face or full-face) respirator with appropriate filters or cartridges (or facemask if a respirator is not available), eye protection, gloves, and a gown. Face shields may also be worn on top of a respirator to prevent bulk contamination of the respirator. Those present should be limited to only those essential for patient care and procedure support. Visitors should not be present for the procedure. Visitors should not be present for specimen collection. Specimen collection should be performed in a normal examination room with the door closed. Clean and disinfect procedure room surfaces promptly.

6. What is an aerosol generating procedure (AGP)?

Both clinical and laboratory procedures can result in aerosol generation. A procedure that is likely to induce coughing (e.g., sputum induction, open suctioning of airways) is such a clinical procedure. These should be performed cautiously and avoided if possible. See #14 below for a list of common laboratory procedures that can generate aerosols.

7. If my protocol requires an aerosol generating procedure, are there different precautions?

Both clinical and laboratory procedures can result in aerosol generation.

For clinical procedures, you should wear an N95 or higher-level respirator, eye protection, gloves, and a gown. You should limit the number of personnel in the room during the procedure. Those present should be limited to only those essential for patient care and procedure support. Visitors should not be present for the procedure. AGPs should ideally take place in an airborne infection isolation room (AIIR). Clean and disinfect all procedure room surfaces promptly.

For laboratory procedures, , you should wear an N95 or higher-level respirator, eye protection, gloves, and a gown. You should limit the number of personnel in the room during the procedure. All work with infectious materials that can form aerosols or splashes are performed within a biological safety cabinet (BSC). NOTE: Per CDC guidance, 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.

https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html

8. What constitutes an Airborne Infection Isolation Room (AIIR)?

AIIRs are single-patient rooms at negative pressure relative to the surrounding areas, and with a minimum of 6 air changes per hour (12 air changes per hour are recommended for new construction or renovation). Air from these rooms should be exhausted directly to the outside or be filtered through a high-efficiency particulate air (HEPA) filter directly before recirculation. Room doors should be kept closed except when entering or leaving the room, and entry and exit should be minimized. Facilities should monitor and document the proper negative-pressure function of these rooms.

9. What disinfectants have been approved for use against COVID-19?

Please see this EPA list: https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

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

Routine diagnostic testing of patient specimens, such as the following activities, can be handled in a BSL-2 laboratory using Standard Precautions: *Note: any manipulations of potentially infectious samples that have the potential to generate aerosols (see #14 below) should be performed in a biological safety cabinet.*

- 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

NOTE: A site-specific risk assessment should be performed to determine if enhanced biosafety precautions, such as those consistent with BSL-3, are warranted based on situational needs (e.g. high testing volumes), including when:

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

11. How should specimens be stored?

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

12. 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.

13. 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.

14. 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. Standard precautions also include safe waste management as well as cleaning and disinfection of surfaces and equipment.

15. What laboratory 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, sub-culturing blood culture bottles, spilling specimens, and cleaning up spills.

16. 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.

17. 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 https://www.who.int/ihr/publications/WHO-WHE-CPI-2019.20/en/

18. 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 (sufficient to absorb the volume of liquid in the primary container).

3. A rigid outer packaging to protect the specimens during shipment.

19. What is a Category B substance?

Infectious substances are subclassified as Category B when they contain biological agents capable of causing infection in humans or animals, but NOT meeting the criteria for Category A; that is, the consequences of an infection are not considered severely disabling or life-threatening. See WHO guidance for more details. https://apps.who.int/iris/bitstream/handle/10665/325884/WHO-WHE-CPI-2019.20-eng.pdf?ua=1

20. At what temperature should specimens be shipped?

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.

21. If I have additional questions about shipping specimens, where can I find information?

For labeling and specific shipping instructions see CDC guidance:
https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html

22. If I am doing COVID-19 virus isolation work, what type of laboratory must I be in?

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.

23. If I am doing a project with my University affiliate, may I walk the specimens over or put the packaged COVID-19 biospecimens in my car and drive them over to the affiliate?

No. Specimens must be handled in accordance with standard transfer methods between the institutions, as you would with a clinical specimen.

24. What should I do in case of a biological spill or exposure during my research study?

Prior to initiating research with coronavirus, you should prepare a biological spill kit. Laboratories engaged in research with **any** infectious agents should have a spill kit that contains, at a minimum, the following:

- Disposable absorbent material (e.g., paper towels and absorbent pads/granules)
- EPA approved disinfectant such as 70% ethanol or 10% household bleach. *Note: bleach should be made fresh periodically.* For comprehensive a list of EPA registered disinfectants that can be used for coronavirus, see:
  https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2
- Biohazard bags (autoclavable)
- Disposable broom & dustpan, small brush with handle
- Tongs/forceps
- PPE (e.g., gloves, gown/coverall, safety glasses, face shield, shoe or boot covers, respirator (for instances when spill occurred outside biosafety cabinet)) – change regularly to ensure integrity of materials
- Laminated clean-up procedure card

You should also consult your local facility safety staff and policies for advice and guidance. All biological spills, regardless of scale or exposure potential need to be reported to the Lab Supervisor or Principal

Investigator (PI). All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

In general, small spills that result in minimal contamination of the work area can be safe managed by laboratory staff. Laboratory personnel can clean up small quantities of known material if they are familiar with the associated hazards, have appropriate personal protective equipment, and are trained in spill-cleanup procedures. Spills involving large volumes of infectious material or that result in significant contamination of the laboratory will likely need to be addressed in conjunction with facility safety staff. Additionally, biological spills outside of primary containment (i.e., a biological safety cabinet) raise additional concerns including pathogen aerosolization, the potential splash of mucous membranes during spill/spill cleanup, how far the contamination spread, etc. Biological spills outside biological safety cabinets can generate aerosols that can be dispersed in the air throughout the laboratory.

The first rule of a spill response is: **DON'T MAKE IT WORSE**

In other words, don't panic, remain calm, and think through your next steps. Do not take any actions that will spread contamination beyond the immediate area of the spill. For example, spills on the floor can easily be spread to other areas through contamination of shoes. Spills frequently create a potential for biological exposures; however, if you are wearing appropriate PPE, your likelihood of an exposure will be reduced.

General recommendations for any biological spill response include:

1. Notify others working in the area of the hazard.
2. **If this is a large spill or if you have sustained significant contamination to your PPE or shoes, take no additional action; ask someone to notify facility safety staff and wait for assistance to arrive.**
3. If the spill is small (e.g., a few milliliters and confined to the benchtop or biological safety cabinet) and your PPE was not contaminated, retrieve the spill kit.
4. If any broken glass is present use forceps or tongs to place pieces into a disposable, puncture resistant biohazard container.
5. Cover the spill area with absorbent materials.
6. Apply disinfectant* onto the absorbent material to saturate the contaminated area and wait appropriate contact time. **Sufficient contact time is critical for the disinfection process**; follow manufacturers recommendations for contact time. *Note: the presence of organic material (e.g. sputum) can slow the disinfection process, and thus contact time may need to be increased in spills containing organic material.*
7. Carefully remove disinfectant saturated absorbent material and place into the biohazard bag for disposal.
8. Repeat steps 5, 6, & 7 one time.
9. When the spill is addressed, remove and properly dispose of PPE.
10. Wash your hands with soap and water immediately.
11. Notify facility safety staff, occupational/employee health**, and the SRS of the incident.
12. Restock the kit for next use. (See kit contents list on reverse side of card)

*For infectious agents, such as coronavirus, that are easily aerosolized, carefully pouring the disinfectant over the area is preferable to use of a spray bottle.

**Remember that although spills create a risk of exposure, appropriate use of proper PPE is your best defense in the event of an unexpected incident. However, it is still important to alert facility occupational/employee health of the incident as they may recommend testing/monitoring in accordance with established medical guidelines.

25. What if I have an unprotected exposure? What should I do?

If you have an unprotected exposure (i.e., not wearing recommended PPE, or exposure despite PPE) to a confirmed or possible COVID-19 patient or specimen, contact your supervisor or occupational health immediately. Follow any local policies that are in place for exposures, Because a cough or sneeze from a known or suspected positive COVID-19 patient could result in contamination of your skin, clothing, and/or PPE; use caution not to spread contamination to other individual, to surfaces, or to other areas; if possible have a person who was not impacted notify facility safety and occupation health and wait for assistance.

26. What is the difference between a surgical mask and N95 respirator?

A **surgical mask** is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. These are often referred to as face masks, although not all face masks are regulated as surgical masks. Note that the edges of the mask are not designed to form a seal around the nose and mouth.

An **N95 respirator** is a respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles. Note that the edges of the respirator are designed to form a seal around the nose and mouth. Surgical N95 Respirators are commonly used in healthcare settings and are a subset of N95 Filtering Facepiece Respirators (FFRs), often referred to as N95s.

See CDC infographic https://www.cdc.gov/niosh/npptl/pdfs/UnderstandDifferenceInfographic-508.pdf

27. Can an N95 respirator be re-used?

Yes. If reuse of N95 respirators is permitted at your laboratory or medical facility, respiratory protection program administrators should ensure adherence to administrative and engineering controls to limit potential N95 respirator surface contamination (e.g., use of barriers to prevent droplet spray contamination) and consider additional training and/or reminders (e.g., posters) for staff to reinforce the need to minimize unnecessary contact with the respirator surface, strict adherence to hand hygiene practices, and proper PPE donning and doffing technique, including physical inspection and performing a user seal check.(16) Healthcare facilities should develop clearly written procedures to advise staff to take the following steps to reduce contact transmission:

- Discard N95 respirators following use during aerosol generating procedures.
- Discard N95 respirators contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.

- Discard N95 respirators following close contact with any patient co-infected with an infectious disease requiring contact precautions.
- Consider use of a cleanable face shield (preferred3) over an N95 respirator and/or other steps (e.g., masking patients, use of engineering controls), when feasible to reduce surface contamination of the respirator.
- Hang used respirators in a designated storage area or keep them in a clean, breathable container such as a paper bag between uses. To minimize potential cross-contamination, store respirators so that they do not touch each other and the person using the respirator is clearly identified. Storage containers should be disposed of or cleaned regularly.
- Clean hands with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the respirator (if necessary, for comfort or to maintain fit).
- Avoid touching the inside of the respirator. If inadvertent contact is made with the inside of the respirator, discard the respirator and perform hand hygiene as described above.
- Use a pair of clean (non-sterile) gloves when donning a used N95 respirator and performing a user seal check. Discard gloves after the N95 respirator is donned and any adjustments are made to ensure the respirator is sitting comfortably on your face with a good seal.

28. How do I remove my PPE to prevent possible contamination?

The order to remove is gloves, goggles or face shield, gown, mask or respirator. See the CDC guidance https://www.cdc.gov/hai/pdfs/ppe/PPE-Sequence.pdf