Specimen Transport & Biosafety for Clinical Laboratories

Updated July 1, 2021

What's Changed: Updated to align with recent CDC recommendations including biological risk assessment and added guidance for anatomic pathology section.

Collection & Transport of Respiratory Specimens for Testing for SARS-CoV-2

Collection of Clinical Specimen by Direct Care Colleagues:

- For providers/colleagues collecting respiratory specimens or within 6 feet of patients suspected to be infected with SARS-CoV-2, maintain proper infection control and use recommended personal protective equipment (PPE) – see PPE Guidebook.
- For providers/colleagues who are handling specimens, but are not directly involved in collection and not working within 6 feet of the patient, follow Standard Precautions.
  - See System Guide on Testing for SARS-CoV-2 (Lab Diagnosis of COVID-19) for details on appropriate types of specimens. Most commonly these are clinical specimens from the respiratory tract; e.g. nasopharyngeal (NP) and oropharyngeal (OP) swabs, nasal mid-turbinate (NMT) swabs, tracheal and lower respiratory tract aspirates, bronchoalveolar lavage (BAL) specimens, and sputum.
  - Once collected using appropriate PPE, place specimen in a specimen bag with a biohazard symbol and place this bagged specimen into a second specimen bag.

Site-and Activity-Specific Biological Risk Assessment

Refer to existing biological risk assessment documents and/or policy for specimens submitted for testing of SARS-CoV-2. If sufficient biosafety information/instruction is included for handling and processing of these specimens, no additional risk assessment is necessary - with the exception of process and method of transport of specimens to the Clinical Laboratory. Site-specific and activity-specific risk assessments are aimed at identifying and mitigating risks. Risk assessments and mitigation measures are dependent on:

- The procedures performed
- Identification of the hazards involved in the process and procedures
- The competency level of the personnel who perform the procedures
- The laboratory equipment and facility
- The resources available

See also CDC’s framework for a biological risk assessment; Biological Risk Assessment: General Considerations for Laboratories (cdc.gov)

Use of Pneumatic Tube System (PTS) for Transport of Respiratory Specimens to Central Receiving in Clinical Laboratory:

Where available, PTS is an efficient method for timely transport of clinical specimens to the Laboratory for testing. This is especially so for a large campus as well as for specimens collected after-hours as manual transport to the Laboratory requires dedicated time by colleagues to
accomplish. Further this manual process may impact timeliness of getting the specimen processed and results back to the patient’s care team.

NOTE:
Refer and use existing ministry policies and procedures for details on which types of specimens are appropriate for transport through the PTS as well as procedure for response to spills inside the PTS.

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

As recommended by CDC, the Clinical Laboratory leaders and others in the ministry must perform a risk assessment prior to using the PTS for respiratory specimens collected from patients for testing for SARS-CoV-2. A Risk Assessment Template is included with this Guide – see Appendix. If risk assessment determines use of PTS adheres with the ministry’s overall biosafety program and policies, transport of respiratory specimens via the PTS is permitted.

- A risk assessment for other types of specimens from patients with suspected or confirmed COVID-19, such as blood, urine, and feces, is not required. In these cases, follow standard ministry policies.

Receiving and Processing Specimens in the Clinical Laboratory:

Follow Standard Precautions when handling clinical specimens, all of which may contain potentially infectious materials. Standard Precautions include hand hygiene and the use of specific personal protective equipment (PPE) determined by the potential for exposure to blood, body fluids and infectious material. PPE, such as laboratory coats or gowns, gloves, eye protection, or a disposable mask and face shield, can help protect the skin and mucous membranes of the eyes, nose and mouth.

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

- Initial processing of specimens
- 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
- Performing electron microscopic studies with glutaraldehyde-fixed grids
- Performing routine antibody or antigen detection tests

Procedures with a High Likelihood of Generating Droplets or Aerosols
- These include working with specimens that might involve centrifugation, pipetting, vortexing, mixing, shaking, sonicating, etc.
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 and additional PPE such as N95 respirator or disposable procedure mask and eye protection.

Decontamination

- Decontaminate work surfaces and equipment with appropriate disinfectants by using an EPA-registered disinfectant that is effective against SARS-CoV-2 or similar lipid enveloped viruses. Follow the disinfectant manufacturer’s instructions 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 – follow standard, established waste management practices and policies.

Specimen Packing and Shipping for External Transport

- 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.

Decentralized and Point-of-Care (POC) 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.

Regulatory requirements and necessary CLIA documentation must 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. Locations providing POC testing are only permitted to perform waived tests, consistent with the laboratory’s existing certificate, and must be under the direction of the existing lab director.

Locations performing this testing should use 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.

Anatomic Pathology
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 laboratory and support staff need to be aware of these risks and provided effective mitigation procedures. For information on autopsies, see also: COVID-19 Guidance Postmortem Specimens | CDC

Note: Anatomic pathology uses different procedures and workflows than those used in clinical pathology, and therefore the risks and mitigation controls needed to protect personnel may be different. At a minimum, all personnel—whether practicing anatomic or clinical pathology should follow Standard Precautions when handling clinical specimens, including hand hygiene and the use of PPE, such as laboratory coats or gowns, gloves, eye protection or a disposable mask and face shield, to help protect the skin and mucous membranes of the eyes, nose and mouth.

References:

APPENDIX. Risk Assessment Template for Use of PTS for Transport of Respiratory Specimens

Examples of factors/experience to consider for RA process and documentation:

- Have there been any incidents involving accidental spill/release of respiratory specimens transported through the PTS?
  - If so, review aspects as to extent of spill for lessons learned, response and procedure for decontamination of PTS after spills.
  - For any incidents was there possible exposure of colleagues to areas inside that PTS that might have been contaminated?
- Is current exclusion to use PTS for respiratory specimens having an impact on timeliness of processing?
- Are there any barriers involving use of manual transport of respiratory specimens to the Lab?

1. Identify the issue.
2. Develop arguments that support the proposed process or issue.
3. Develop arguments that oppose the proposed process or issue.
4. Evaluate both arguments.
5. Reach a conclusion.
6. Document the process.
7. Monitor and reassess the conclusion

Date of assessment: _______________________
Location of risk: __________________________
Evaluator(s): __________________________________________

Step 1: What is being evaluated?
________________________________________________________________________________

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Step 4: Evaluate both arguments:
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Step 5: Reach a conclusion:
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________________________________________________________________________________
________________________________________________________________________________
Step 6: Submit assessment:
Submitted to: ______________________________
Date: ______________________________

Step 7: Monitor conclusion: Date to review risk for any changes:
________________________________________________________________________________

Is a re-evaluation needed? ___ Yes ___ No If yes, indicate often should this be re-evaluated:
Re-evaluated By:
________________________________________________________________________________

Submitted By: ______________________________
Date: ______________________________