



Guidance for Working with Human Specimens

Work with all human specimens must be conducted according to the appropriate containment and work practices. Handling human samples collected during the COVID-19 pandemic requires additional considerations. Upper and lower respiratory system specimens, such as nasopharyngeal and oropharyngeal samples, sputum, mucus, and lung tissues present an increased risk of exposure to SARS-CoV-2. Stool samples may also contain the virus. Blood and non-respiratory tissues/cells pose a lower risk than the upper and lower respiratory system specimens.

Any work that is expected to involve human samples from COVID-19+ patients, from COVID-19 persons under investigation (PUIs), or work using SARS-CoV-2 infection models (*in vivo* and *in vitro*) must have:

1. IBC review/approval (if laboratory research)
2. IACUC and/or COMIRB review/approval (if applicable)
3. BSL3 Oversight approval (if BSL3 resources are requested or required by the nature of the research)
4. Have appropriate PPE (including respiratory protection) for the duration of the study
5. Steering and Allocation Committee for the COVID-19 Bio-Repository approval to obtain patient specimens (if applicable)

CDC guidance for laboratories: <https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html>

Requirement for laboratory researchers with known SARS-CoV-2 (+) or potential SARS-CoV-2 (+) materials:

1. Enrollment in Occupational Health Program with updated information including working with SARS-CoV-2 materials (hospital employees notify Employee Health)
2. Daily symptom/fever watch

What can be done at the different biosafety levels:

Major considerations: viral load, potential for aerosol creation

BSL2: Aerosol producing procedures performed in a Biological Safety Cabinet (BSC), strict adherence to CDC best practices for BSC work (Appendix A, [Biosafety in Microbiological and Biomedical Laboratories](#))

Biological material, examples:

- Unfixed human specimens, not including respiratory samples, GI samples, or feces
- Respiratory system samples, GI samples, or feces tested and confirmed to be SARS-CoV-2 negative
- Inactivated virus: if IBC approved inactivation method (should be a validated method with published data)
- Coronavirus strains categorized as risk group 2,
- cDNA of SARS-CoV-2 viral genes
- Nucleic acids extracted with a method that is validated to inactivate the SARS-CoV-2
- Antibody neutralization assays (no live virus)



BSL2+: All biological materials are handled in a BSC, regardless of the potential for aerosol production

Biological material, examples:

- Unfixed human respiratory samples, i.e., nasopharyngeal and oropharyngeal samples, sputum, mucus, and lung tissues (unless patient has screened negative for SARS-CoV-2)
- Human GI tissue samples and feces

Guidance on containment for specific procedures can be discussed with the [Division of Biosafety](#).

Deviations from these guidelines must be approved by the IBC and Biosafety Officer.

Researchers can apply to the Bio-Repository Core Facility to obtain patient samples.

Steering and Allocation Committee reviews these requests,

Apply through Redcap, <https://redcap.ucdenver.edu/surveys/?s=ALDKDYDPT7>

Guidance chart for working with human samples during the COVID-19 Pandemic

	BSL-1	BSL-2	BSL-2+	BSL-3
Healthy patients screened and tested (-) for COVID-19				
Upper and lower respiratory samples (nasal, lung, sputum)		✓		
Human blood, plasma, PBMC		✓		
Human non-respiratory tissues/cells/fluids		✓		
Human GI tissues and feces		✓		
Unscreened patients, reasonably considered				
Upper and lower respiratory samples (nasal, lung, sputum)			✓	
Human blood, plasma, PBMC		✓		
Human non-respiratory tissues/cells/fluids		✓		
Human GI tissues and feces			✓	
Suspected COVID-19 (+) patients				
Upper and lower respiratory samples (nasal, lung, sputum)			✓	
Human blood, plasma, PBMC		✓		
Human non-respiratory tissues/cells/fluids		✓		
Human GI tissues and feces			✓	
Confirmed COVID-19 (+) patients				
Upper and lower respiratory samples (nasal, lung, sputum)			✓	
Human blood, plasma, PBMC		✓		
Human non-respiratory tissues/cells/fluids		✓		
Human GI tissues and feces			✓	
SARS-CoV-2 culture and propagation				✓

*Patient COVID-19 vaccination status does not affect this decision matrix

**Deviations from this decision matrix must be approved by the IBC and Biosafety Officer



References

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