



Environmental Health and Safety, Biological Safety Program

Guidance Document

Title: Laboratory Research Involving SARS-CoV-2

Section: Biological Safety

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This guidance document outlines safety requirements for UTHealth Houston laboratories that wish to conduct research with SARS-CoV-2, specimens from patients with suspected and/or confirmed COVID-19, and wastewater screening for SARS-CoV-2 RNA.

Summary

Any work that is expected to involve human samples from COVID-19+ patients, from COVID-19 persons under investigation (PUIs), wastewater expecting to contain SARS-CoV-2, or work using SARS-CoV-2 infection models (*in vivo* and *in vitro*) must be reviewed and approved by the UTHealth Houston Institutional Biosafety Committee (IBC).

The IBC will help to perform a risk assessment and may require enhanced BSL-2 practices (BSL-2+) for work to be safely conducted in a BSL-2 laboratory facility.

At the present time, SARS-CoV-2 best meets the definition of a risk group 3 (RG3) biological agent and Institutional Biosafety Committees (IBCs) should consider the agent to be RG3 as a starting point in their risk assessment when reviewing research subject to the *NIH Guidelines*.

References for laboratory safety measures to be utilized are as follows:

The Centers for Disease Control and Prevention (CDC) [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 \(COVID-19\)](#) (updated 12/2021)

The World Health Organization (WHO) [Laboratory biosafety guidance related to novel coronavirus \(2019-nCoV\)](#) (March 2024)

The American Biological Safety Association International (ABSA) has published a helpful document titled "Considerations for Handling SARS-CoV-2 Samples" https://absa.org/wp-content/uploads/2020/03/ABSA2020_Covid-19-dr3.pdf (updated 5/25/2022)

The Centers for Disease Control and Prevention (CDC) [Wastewater Surveillance](#) (May 2024)

What kind of work is currently allowed?

Activities	Assigned Biosafety Level
<p>Research Activities with Known or Likely Infected Specimens from Humans or Animal Models</p> <ul style="list-style-type: none"> • Molecular analysis of already extracted nucleic acid preparations • Analysis of specimens¹ that have been inactivated by a method approved by the UHealth IBC • Final packaging of specimens¹ already in a sealed, decontaminated primary container for transport to collaborating laboratories for additional analysis³ • Pathologic/Microscopic examination of fixed specimens¹ (formalin-fixed tissues or glutaraldehyde-fixed grids) • Routine staining and microscopic analysis of fixed smears • Routine examination of bacterial and mycotic cultures • Routine antibody or antigen tests • Use of automated instruments and analyzers with aerosol capture features 	BSL-2 ⁴
<p>Research Activities with Known or Likely Infected Specimens from Humans or Animal Models²</p> <ul style="list-style-type: none"> • Processing, aliquoting or preparing specimens¹ for research use and storage • Preparation of chemical- or heat-fixed specimens for microscopic analysis • Nucleic acid extraction of specimens¹ for molecular analysis • Preparation of non-inactivated specimens for other laboratory assessments • Performing diagnostic tests (that do not involve activities with the potential to propagate virus) • Inoculating bacterial or mycological media 	BSL-2 + (Enhanced) ⁵
<ul style="list-style-type: none"> • Concentration of SARS-CoV-2 from wastewater which requires bio-aerosol generating processes 	
<ul style="list-style-type: none"> • Storage and laboratory work with seed stocks, working stocks or specimens¹ with the intent to grow or use live virus • Viral Isolation, characterization and/or expansion • Use of live SARS-CoV-2 virus in functional assays • Live cell sorting with intact virus • Use of live SARS-CoV-2 virus in animal 	BSL-3 / ABSL-3 ⁶

¹ Specimens are defined as, but not limited to, blood, serum, plasma, tissues, feces, urine, sputum, mucosal swabs or washes/secretions collected from any species

² Specimens known or likely infected with active infection (within 10 days of symptom onset); if samples do not meet this requirement, BSL-2 practices must be used.

³ Specimens from suspected or confirmed cases should be transported as UN3373, “Biological Substance, Category B”

⁴ BSL-2 practices and facility according to the Biosafety in Microbiology and Biomedical Laboratories, 6th Edition, June 2020;

- PPE: laboratory coat, eye protection (face shield, goggles, safety glasses, splash guard), single pair of gloves

⁵ BSL-2 + (Enhanced) includes BSL-2 with the addition of the following:

- Any procedure with the potential to generated aerosols or droplets (e.g. flipping open snap-cap tubes, pipetting, vortexing, cell sorting, ELISA plate washing) should be performed in a certified Class II Biological Safety Cabinet (BSC).
- If a BSC is unavailable for aerosol or droplet generating procedures, a combination of PPE (lab coat, gloves and mucous membrane and respiratory protection such as an N95 respirator with a face shield, safety glasses or goggles) along with equipment (e.g. splash guards, sealed centrifuge rotors and/or gasketed cups) must be implemented.

- Specimens must be stored in a location that is dedicated specifically for SARS-CoV-2 samples and only accessible by trained laboratory personnel. For example, storage could be dedicated to an entire freezer only for these specimens, or a dedicated box/shelf could be identified within a freezer. All laboratories are required to maintain an inventory* of all SARS-CoV-2 specimens. At minimum, this should include:
 - when specimens are received
 - logging specimens in and out of storage
 - when specimens are destroyed/inactivated.
- PPE: laboratory coat or disposable gown, eye protection, surgical mask (with exception above), double pair of gloves
- Specialized training for donning and doffing PPE with the Biological Safety Program

⁶ BSL-3 and ABSL-3 practices and facility according to the Biosafety in Microbiology and Biomedical Laboratories, 6th Edition, June 2020

- PPE: Disposable, impervious gown or Tyvek coverall, eye protection, respiratory protection, double pair of gloves, shoe covers
- Specialized training for the facility prior to access with the Biological Safety Program

All principal investigators must provide an SOP for the safe handling of SARS-CoV-2 specimens. This should describe how specimens are collected, processed, and stored. Describe all techniques and manipulations planned. This should also include personal protective equipment (PPE) to be used and emergency response procedures such as how spills outside of containment will be handled.

Decontaminate work surfaces and equipment with appropriate disinfectants by using an EPA-registered N List disinfectant.

Laboratory waste generated during processing and testing should be discarded as biohazardous waste.

It is mandatory to report any symptoms and any laboratory exposure to Occupational Health.

Laboratory Responsibilities

IBC Protocol: All principal investigators are required to submit a *Protocol for the Use of Biological Agents* to the IBC (via the [online protocol system](#)) for any work outlined above inclusive of a new protocol or an amendment to an existing protocol if the work described is similar in scope. *Note:* the online protocol system is only accessible through the UTHealth Houston network or VPN.

Risk Assessment: All principal investigators are required to perform a site-specific and activity-specific risk assessment to identify and mitigate risks associated with work with SARS-CoV-2 specimens. Risk assessments and mitigation measures depend on:

1. Procedures performed
2. Identification of hazards with the procedures
3. Competency level of personnel
4. Laboratory equipment and facility
5. Resources

Biosafety levels for currently available SARS-CoV-2 materials

[BEI](#) and [ATCC](#) have repositories for many research materials related to COVID-19. This table lists the currently available products and the biosafety level required for work with the material.

Product Type	Description	Biosafety Level	Source
Virus	SARS-CoV-2 isolates	BSL-3	BEI
Nucleic Acid	SARS-CoV-2 genomic RNA	BSL-2	BEI or ATCC
	Quantitative synthetic RNA from SARS-CoV-2	BSL-1	BEI or ATCC
	Quantitative PCR (qPCR) from inactivated SARS-CoV-2	BSL-1	BEI or ATCC
Inactivated Virus	SARS-CoV-2 isolate – heat inactivated	BSL-2*	BEI or ATCC
	SARS-CoV-2 isolate – gamma-irradiated inactivated	BSL-2*	BEI
Serum/Plasma	Pooled non-human primate (NHP) convalescent serum	BSL-2	BEI
Plasmid	Vector containing SARS-CoV-2 spike glycoprotein gene	BSL-1	BEI
Protein	Spike protein from SARS-CoV-2	BSL-1	BEI
Human samples	Human patient samples (blood, nasal fluids, nasal swabs, bronchoalveolar lavage fluid, etc.)	BSL-2	COVID-19+ patients/PUIs
Wastewater	Wastewater for screening for COVID-19	BSL-2 +; BSL-2 if inactivated	Municipal Treatment Plants

*BEI indicates BSL-1 for inactivated virus samples, however, these agents must still obtain IBC approval and the IBC may require BSL-2/ABSL-2 for use at UTHealth

What am I working with?	Biosafety Level	Animal Biosafety Level*	IBC Approval required
Spike protein SARS-CoV-2	BSL-1	ABSL-1	No
Plasmid expressing spike protein of SARS-CoV-2	BSL-1	ABSL-1	Maybe
Heat inactivated SARS-CoV-2	BSL-2	ABSL-2	Yes
SARS-CoV-2 genomic RNA	BSL-2	ABSL-2/3	Yes
SARS-CoV-2 virus – <i>in vitro</i> culture/propagation of virus	BSL-3		Yes
SARS-CoV-2 virus – animal infection model		ABSL-3	Yes
Patient specimens – no viral propagation	BSL-2 or BSL-2+	ABSL-3	Yes
Patient specimens – viral propagation	BSL-3	ABSL-3	Yes
Surrogate coronavirus strains from ATCC (e.g., HCoV-OC43, HCoV-229E)	BSL-2	ABSL-2	Yes

*Animal biosafety level may be changed based on species

For further information, please contact the EHS Biological Safety Program at (713) 500-8170.

This policy has been reviewed and approved by the Institutional Biosafety Committee.