

Research with COVID-19 samples or SARS-CoV-2 virus requires Institutional Biosafety Committee (IBC) approval prior to start of work. Outlined here are the appropriate biosafety levels based on the sample type and proposed work practices.

Sample Collection

Collection of samples from suspected or confirmed COVID-19 patients must be performed following all required Infection Control Procedures established for UCSD Medical Centers.

- Stool, whole blood, serum, urine, etc.
- Rapid respiratory testing performed at the point of care (no nucleic acid isolation)
- Swab samples
- Air samples from point of care areas
- Sewage samples

Primary Barriers and Personal Protective Equipment (PPE)

- PPE: Gown, gloves, surgical mask or N95, eye protection, face shield

Transportation

Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.

If transporting outside of the facility, complete Shipping training and contact Outbound Shipping outboundshipping@ucsd.edu

Clinical Trials

COVID-19 clinical trials involving the following will require approval by the IBC prior to start of work:

- Recombinant or synthetic nucleic acids
- Patient samples processed in a research lab

BSL-2 facility & work practices

The following materials or procedures are examples that require BSL-2 facility and work practices:

- Fixed specimens or samples
 - Inactivation methods should be validated and described in the BUA protocol
- Staining and microscopic analysis of fixed smears
- Examination of bacterial cultures
- Molecular analysis of extracted nucleic acid preparations
- Using automated instruments and analyzers (if aerosol containment is a feature) FACS—fixed samples
- Performing electron microscopic studies with glutaraldehyde-fixed grids
- Work with synthetically generated SARS-CoV-2 nucleic acids which lack a means of cellular entry.

Laboratory Practices and Technique

- Good (Standard) Microbiological Practices
- Access to the laboratory is restricted when work is being conducted
- All procedures in which infectious aerosols or splashes may be created are conducted in Class II Type A1 or A2 Biosafety Cabinets (BSCs) or other physical containment equipment.
- Use safety cups whenever possible to avoid exposure to aerosols.

Primary & Secondary Barriers and PPE

- PPE: single gloves, gown/lab coat, eye protection
- BSCs, if available, are properly maintained and certified
- Mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory
- A method for decontaminating all laboratory wastes should be available in the facility. Surface decontamination at every step using EPA List N disinfectants and contact times.

Administrative Controls

- Completion of Aerosol Transmissible Disease Training through UC Learning Center
- Laboratory personnel have lab-specific training in handling pathogenic agents
- Mandatory reporting of laboratory exposures to occupational health
- Maintain social distancing when in the laboratory as defined in Research Reduction Plans
- All waste is collected and disposed as biohazardous waste

BSL-2 facility with BSL-3 work practices

The following materials or procedures are examples that require BSL-2 facility and BSL-3 work practices:

- Aliquoting and/or diluting specimens
- Inoculating bacterial or mycological culture media for culture of organisms other than SARS-CoV-2.
- Performing diagnostic tests that do not involve propagation of viral agents in vitro or in vivo
- Nucleic acid extraction procedures involving potentially infected specimens (human or animal).
- precipitation or membrane filtration
- Preparation and chemical- or heat-fixing of smears for microscopic analysis
- Respiratory samples and secretions
- FACS—non-fixed samples
- Inactivated virus lysate
- Work with ANY sample where procedure may produce an aerosol
- Work with SARS-CoV-2 recombinant nucleic acids in host-vector systems (e.g. in viral vectors or prokaryotic models).

Laboratory Practices and Technique

- Follow all BSL-2 requirements
- All work with samples must occur within a BSC or in equipment where sample is in sealed container. All exceptions must be approved by the IBC prior to start of work.
- Use screw cap tubes and replace glass with plastics
- When working in the BSC, minimize removal of hands from cabinet and remove/dispose outer glove before removing hands
- Disinfect pipettes before disposal using 10% bleach prior to disposal as biohazard waste

Primary & Secondary Barriers and PPE

- PPE: double gloves, lab coat, eye protection with side shields.
- All samples are opened inside the BSC in case of spills/leakage.
- Surface decontamination at every step using EPA List N disinfectants and contact times.

Administrative Controls

- Centrifuge blood specimens in safety cups or sealed rotor, loaded and unloaded in a BSC
- All waste is collected and disposed as biohazard waste

BSL-3

- Virus isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens
- High Speed Cell Sorting
- Inactivation by validated methods before transfer of inactivated samples outside BSL-3

Institutional Oversight

UCSD IBC and High Containment Laboratory Oversight Committee (HCLOC) must approve research prior to start of work in a BSL-3 facility.

BSL-3 Facility

Due to the increase in requests to conduct work in the BSL-3 facility, the campus established a BSL-3 Core to support the campus SARS-CoV-2/COVID-19 research. Contact ehsbio@ucsd.edu for additional information.

Transfer of samples outside BSL-3

Refer to your BUA for specific requirements for transferring samples out of the BSL-3. Contact ehsbio@ucsd.edu for additional information.