

Institutional Biological Safety Committee

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

Last Update: April 2020

These guidelines are based on the CDC Interim Laboratory Biosafety Guidelines with guidance from WHO and ABSA (The Association of Biosafety and Biosecurity - International). They will be updated as new details are provided.

All work involving SARS-CoV-2 (COVID-19) related materials, including any human-derived materials which may potentially be infected with SARS-CoV-2, requires IBC approval. The IBC will review and assess the proposed work. Some projects may also require IRB approval.

All labs should perform a site-specific and activity-specific risk assessment to identify and mitigate risks.

HIGHLIGHTS

- Projects involving isolated SARS-CoV-2 (e.g. isolation, culturing, assays) must be conducted within the UC BSL3 Facility.
- Projects involving SARS-CoV-2 (COVID-19) patient samples must be conducted within a BSL2 Facility adopting BSL3 practices (BSL2+).
- Projects involving only inactivated SARS-CoV-2 (COVID-19) related samples must be conducted within a BSL2 Facility adopting BSL2 practices.

BIOSAFETY LEVEL 2

TYPE of PROCEDURES

- Use of automated instruments and analyzers (excluding sorting and flow cytometry of unfixed cells and instrumentation that would generate aerosols not in a closed system such as sonicators and homogenizers)
- Staining and microscopic analysis of fixed smears
- Examination of bacterial cultures from patient samples
- Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
- Molecular analysis of extracted nucleic acid preparations
- Use of inactivated specimens, such as specimens in nucleic acid or protein extraction buffer
- Electron microscopic studies with glutaraldehyde-fixed grids
- Storage of samples
- Final packaging of specimens to diagnostic laboratory for additional testing
- FACS analysis– fixed samples

LABORATORY PRACTICES and TECHNIQUES

- Good (Standard) Microbiological Practices ([BMBL 5th edition](#))
- Access to the laboratory is restricted when work is being conducted; signage indicating that work is in progress must be posted on lab doors
- All procedures in which aerosols or splashes may be created are conducted in a biosafety cabinet (BSC) or other physical containment equipment; all samples opened in biosafety cabinet
- Centrifuge: Use of safety cups and sealed rotors to avoid exposures to aerosols
- Decontamination of all work surfaces before, during and after work ([EPA List N](#))
- Treat biohazard waste (autoclave or add bleach to 10% final concentration) before disposal in biohazard waste barrels.

ENGINEERING CONTROLS and PPE

- Facility must be equipped with a sink and eyewash station
- Class II Type A2 BSC – certified and properly maintained
- Inward flow of air (negative pressure room) without circulation to spaces outside of the laboratory
- **PPE:** Gloves, gown/lab coat (preferably fluid resistant with knit cuffs), face shield or surgical mask plus goggles

ADMINISTRATIVE CONTROLS

- Review of the electronic Manual (eManual) on [Personal Protective Equipment](#) (PPE)
- Review of the eManual on [Aerosol Exposure Control](#)
- Review of the Biosafety [Spill Clean-Up](#) procedures
- [BSC training](#) completion
- [Blood Borne Pathogen \(BBP\) training](#) completion
- [Report](#) all laboratory incidents
- Review symptoms of COVID-19

BIOSAFETY LEVEL 2 with BIOSAFETY LEVEL 3 PRACTICES (BSL2+)

TYPE of PROCEDURES

- Aliquoting and/or diluting samples
- Inoculating patient samples into bacterial or mycological culture media
- Acquisition of flow cytometry using unfixed samples (not sorting)
- Performing diagnostic tests that do not involve propagation of viral agents *in vitro* or *in vivo*
- Nucleic acid or protein extraction procedures involving potentially infected specimens
- Preparation and chemical or heat fixing of smears for microscopic analysis
- Work with any potentially infected sample that may generate an aerosol (should be in a contained system)
- Inactivated viral culture lysate
- Respiratory samples and secretions (collection and testing)

LABORATORY PRACTICES AND TECHNIQUES

- Good (Standard) Microbiological Practices ([BMBL 5th edition](#))
- Access to the laboratory is restricted when work is being conducted; signage indicating work in progress
- All procedures conducted in a biosafety cabinet (BSC) or other physical containment equipment
- Use of respiratory protection (N95) and plexi-glass shield, if unable to open samples in a BSC or for all work with respiratory secretions
- Centrifuge: Use of safety cups and sealed rotors to avoid exposures to aerosols
- Decontamination of all work surfaces before, during and after work ([EPA List N](#))

ENGINEERING CONTROLS and PPE

- Facility must be equipped with a sink and eyewash station
- Class II Type A2 BSC – certified and properly maintained
- Inward flow of air (negative pressure room) without circulation to spaces outside of the laboratory
- A procedure for decontaminating wastes (autoclave before disposal in biohazard trash receptacles)
- **PPE:** Double gloves, face mask respirator (e.g. N95), gown/lab coat (fluid resistant preferable with knit cuffs), goggle or face mask

ADMINISTRATIVE CONTROLS

- Review of the electronic Manual (eManual) on [Personal Protective Equipment](#) (PPE)
- Review of the eManual on [Aerosol Exposure Control](#)
- Review of the Biosafety [Spill Clean-Up](#) procedures
- [BSC training](#) completion
- [Blood Borne Pathogen \(BBP\) training](#) completion
- [Report](#) all laboratory incidents
- Review symptoms of COVID-19
- Respirator Compliance: Medical Respiratory Clearance, Fit-testing and Respirator training

IOSAFETY LEVEL 3

TYPE of PROCEDURES

- Experiments involving SARS-CoV-2 (e.g. viral isolation, culturing, plaque assays)
- High speed cell sorting

LABORATORY PRACTICES AND TECHNIQUES

- Good (Standard) Microbiological Practices (Follow BSL3 practices and procedures according to CDC [BMBL 5th edition](#))
- Work must be conducted in a BSL3 facility
- All procedures involving the manipulation of infectious materials must be conducted within a certified biosafety cabinet (BSC)

ENGINEERING CONTROLS and PPE

- Facility must be equipped with a sink and eyewash station
- Facility exhaust system must have HEPA filtration
- Biosafety cabinet (BSC) is required for work
- Decontamination of all work surfaces before, during and after work ([EPA List N](#))
- Autoclave waste before disposal
- **PPE:** Double gloves, body suit, shoe covers, respirator (i.e. PAPR)

ADMINISTRATIVE CONTROLS

- Review of the electronic Manual (eManual) on [Personal Protective Equipment](#) (PPE)
- Review of the eManual on [Aerosol Exposure Control](#)
- Review of the Biosafety [Spill Clean-Up](#) procedures
- [BSC training](#) completion
- [Blood Borne Pathogen \(BBP\) training](#) completion
- [Report](#) all laboratory incidents
- Review symptoms of COVID-19
- Respirator Compliance: Medical Respiratory Clearance, Fit-testing and Respirator training
- Review BSL3 SOPs
- BSL3 Facility Hands-on training

REFERENCES / RESOURCES

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>

<https://absa.org/covid19toolbox/>

<https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF>

<https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF>

[https://www.who.int/publications-detail/laboratory-biosafety-guidance-related-to-coronavirus-disease-2019-\(covid-19\)](https://www.who.int/publications-detail/laboratory-biosafety-guidance-related-to-coronavirus-disease-2019-(covid-19))

<https://therapak.com/our-services/drug-development-kitting-services/biological-substance-shipping-systems/>

<https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>