

UNMC SARS-CoV-2 (COVID-19) Research Laboratory Biosafety Guidelines¹

Assigned Biosafety Level	Research Activities with Known or Likely Infected Specimens from Humans or Animal Models	Key Biosafety Elements
BSL-3/ABSL-3	<ul style="list-style-type: none"> • Storage and laboratory work with seed stocks, working stocks, or specimens² with the intent to grow or use live virus at UNMC. <ul style="list-style-type: none"> - Virus isolation, characterization, and/or expansion • Use of live SARS-CoV-2 virus in functional assays: <ul style="list-style-type: none"> - Plaque/Focus Forming Unit assays - Serologic virus capture/binding assays - Therapeutic MIC assays • Use of live SARS-CoV-2 virus in animals 	<p style="text-align: center;">Restricted activity.</p> <ul style="list-style-type: none"> • Contact a Biosafety Officer for additional information • The BSL-3/ABSL-3 Facility Director must assess and approve PI and personnel access to the facility, BSL-3 training, and proposed projects • SARS-CoV-2 is considered a Risk Group 3 pathogen⁴
BSL-2	<ul style="list-style-type: none"> • Processing, aliquoting, or preparing specimens² for research use and storage • Preparation of chemical- or heat-fixed specimens² for microscopic analysis • Nucleic acid extraction of specimens² for molecular analysis • Preparation of inactivated specimens for other laboratory assessments. • Performing diagnostic tests with respiratory samples that <u>do not</u> involve activities with the potential to propagate the virus • Inoculating bacterial or mycological culture media • Work with inactivated viral lysate • Molecular analysis of already extracted nucleic acid preparations • Analysis of specimens² that have been inactivated by a method approved by UNMC Institutional Biosafety Committee (IBC) • Pathologic/microscopic examination of fixed specimens² (e.g., formalin-fixed tissues or glutaraldehyde-fixed grids) • FACS – fixed cells/samples • Serological analysis of serum or plasma or urinalysis 	<ul style="list-style-type: none"> • Must have an approved IBC protocol¹ detailing the materials handled, procedures performed, aerosol-generating procedures, location of work, waste handling procedures, and personnel involved • The laboratory space must meet BSL2 requirements as determined by an inspection UNMC BSL2 Laboratory Inspection Checklist • Wear PPE as determined by a detailed risk assessment • Good (Standard) Microbiological Practices • Conduct all procedures with the potential to generate aerosols in a BSC • Do not use sharps (unless absolutely necessary) • Restricted access to the lab and samples • Use centrifuge safety cups whenever possible • Ensure personnel have completed biosafety training • PI/lab supervisor must document their proficiency at working under BSL-2 conditions
<p>Shipping and Transport: Patient specimens from suspected or confirmed cases should be transported as UN3373, “Biological Substance Category B”.</p> <p>Viral cultures or propagated isolates may be classified as Category B. However, certain variants may be subject to Category A based on factors considered such as circulation of the variant in the population of the areas the material are to be transported from and to.³ WHO Working definitions and primary actions for SARS-CoV-2 variants</p>		
<p>¹ All research-related activities involving SARS-CoV2 must be covered by an IBC protocol.</p> <p>² Specimens are defined as, but not limited to, blood, tissues, feces, sputum, mucosal swabs, or washes/secretions collected from any species.</p> <p>³ For assistance with required import and export regulations, please contact the Export Control Office.</p> <p>⁴ The NIH recommends that IBCs consider SARS-CoV-2 a RG3 pathogen as a starting point for risk assessments and biocontainment</p>		
<p>Resources: WHO Laboratory biosafety guidance related to SARS-CoV-2 (COVID-19)</p> <p>CDC’s Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19</p> <p>CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, 6th ed.</p>		<p style="text-align: center;">Questions about Laboratory Biosafety? Email: UNMC Biosafety</p> <p style="text-align: center;">UNMC Vice Chancellor for Research Institutional Biosafety Committee</p>