SARS-CoV-2 (COVID-19) Research Laboratory Safety Guidance

Please note that all procedures will be subject to IBC review and approval. The IBC will set the finalized biosafety level based on their risk assessment.

Research Activities with Known or Likely COVID-19 Infected Specimens from Humans or Animal Models	Assigned Biosafety Level	Contact for Questions, Approvals & Access to Appropriate Laboratory Facilities

• Storage and laboratory work with seed stocks, working stocks or specimens[1] with the intent to grow or use live virus at Rutgers.
  • Virus isolation, characterization and/or expansion
  • Viral cultures or isolates should be transported as Category A, UN2814, "infectious substance, affecting humans" [2]
• Use of live non-attenuated SARS-CoV-2 virus in functional assays:
  • Plaque/Focus Forming Unit assays
  • Serologic virus capture/binding assays
  • Therapeutic MIC assays
  • Live cell sorting with intact virus
• Use of live non-attenuated SARS-CoV-2 virus in animal
	BSL-3/ABSL-3[3]	**David Alland, MD**
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• Processing, aliquoting or preparing specimens[1] for research use and storage • Preparation of chemical- or heat-fixed specimens[1] for microscopy and other laboratory procedures utilizing a validated and approved inactivation method[7] • Nucleic acid extraction of specimens[1] for molecular analysis • Performing diagnostic tests (e.g. serology) that do not involve activities with the potential to propagate virus • Inoculating bacterial or mycological culture media	**BSL-2 *with* enhancements[4,5]**	**Rutgers Environmental Health and Safety (REHS)** biosafety@rutgers.edu Phone: 848-445-2550
• Molecular analysis of already extracted nucleic acid preparations • Analysis of specimens[1] that have undergone an appropriate inactivation method[7] • Final packaging of specimens[1] already in a sealed, decontaminated primary container for transport to collaborating laboratories for additional analyses • Specimens from suspected or confirmed cases should be transported as UN3373, "Biological Substance, Category B • Pathologic/microscopic examination of chemical- or heat-fixed specimens[1] (e.g. formalin-fixed tissues or glutaraldehyde-fixed grids) • Routine staining and microscopic analysis of fixed smears • Routine examination of bacterial and mycotic cultures • Research with full length viral genome[6]	**BSL-2[4]**	**Rutgers Environmental Health and Safety (REHS)** biosafety@rutgers.edu Phone: 848-445-2550

[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.

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[2] Import permits are required for any importation into the US, and some strains require import permits for shipments within the US. Contact REHS with questions at biosafety@rutgers.edu. Export requests must be approved by RU Export Control (rp627@ored.rutgers.edu) and REHS (biosafety@rutgers.edu). Persons shipping must be current with IATA training.

[3] Animal Biosafety Level-3 (ABSL-3). For more information regarding performing COVID-19 research in BSL-3/ABSL-3, please visit the following link: http://njms.rutgers.edu/research/CCRP2/REHSGuidelines.cfm

[4]All work assigned as "BSL2" or "BSL2 with enhancement" will be performed inside a certified BSC, unless otherwise approved by the IBC.

- Laboratories that work with COVID-19+ specimens as well as SARS-CoV-2 rDNA must do the work in separate certified biosafety cabinets.

[5] Required Enhancements to standard BSL2:

- Isolated room location, with limited staff entry, reviewed by REHS and approved by the IBC.
- BSC will be decontaminated with an EPA approved disinfectant for coronavirus. Alcohols will not be used as the sole disinfectant for cleaning or disinfection of surfaces or waste. BSL3 work practices are required (e.g. chemical disinfection in cabinet before autoclaving).
- Personnel will wear a closed front gown, face shield and double pair of gloves. If closed front gowns are not available, designated lab coats must be worn. Coversleeves are recommended.
- Centrifugation of specimens must be performed using sealed centrifuge rotors or safety cups.
- The use of sharps, Pasteur pipets included, should be eliminated wherever possible.

[6]Work must be in designated location, without concomitant work with tissue culture or in vitro translation assays. Contact REHS for additional guidance.

[7]Notes on SARS-CoV-2 Inactivation:

- Inactivation of SARS-CoV-2 is dependent on many variables including the sample matrix. For example, inactivation of virus stock or cell supernatant is generally easier than inactivation of virus in samples with high protein content such as whole blood or serum/plasma.
- The Rutgers IBC will approve inactivation methods on a case-by-case basis for each IBC protocol and has approved many proposed chemical and physical inactivation methods based on literature and/or lab-generated validation data. In addition, the IBC has approved the following SARS-CoV-2 heat inactivation method for serum/plasma:
    - **Serum/plasma from Rutgers and affiliated hospitals/clinics** – researchers may heat treat ≤0.5 mL serum/plasma samples to 56C for a minimum of 60 minutes and subsequently handle those samples as inactivated using BSL2 precautions (instead of BSL2 enhanced). Larger volumes would need to be either divided into smaller aliquots equal to or less than 0.5 mL, or need to undergo quality control testing in the lab by a method approved by the IBC (e.g., plaque assays, temperature probes, etc.).
    - **Serum/plasma from commercial vendors and outside institutions** – the IBC will continue to review claims of heat inactivation of these materials on a case-by-case basis. If the vendor/institution can provide sufficient, batch-specific or lot-specific evidence of heat inactivation (e.g., plaque assay data), then quality control testing would not be needed in order to use the material under BSL2 (non-enhanced) conditions. Alternatively, the lab could use the heat treatment method above on samples sold or supplied as “inactivated”.
- New inactivation data for SARS-CoV-2 is being published regularly. Investigators can propose inactivation methods in their IBC protocols and are encouraged to review the REHS shared folder with inactivation data found here: https://rutgers.box.com/s/2gbkuegdioz7fj8xraf7fifdleoznlfe
- Contact REHS (biosafety@rutgers.edu) for additional guidance or questions regarding inactivation.