NIDDK Central Repository (NIDDK-CR) – Resources for Research (R4R)

COVID-19 Guidelines and FAQs

1. **Do COVID-19 positive specimens represent a different sort of biohazard and do they need to be stored separately? How does the NIDDK Biorepository currently handle potentially HIV-infected specimens; for example, is BSL2 or BSL3 required? Do COVID-19 requirements depend on specimen type?**

   There is still much to learn about COVID-19 and there are some concerns with the potential for airborne transmission with some types of COVID-19 specimens or under a specific set of scenarios, which represents a challenge not typical for the vast majority of incoming frozen clinical specimens handled at the NIDDK Central Repository. Following the available guidance, our contracted support staff at Precision for Medicine, treats COVID-19 specimens like any other infectious pathogen, including HIV, using universal precautions and BSL-2 level requirements. Currently they are receiving, processing, storing, and distributing a variety of COVID-19 specimen types in support of their government and commercial clients. As part of these efforts additional precautions have been implemented:

   - **Enhanced procedures for handling and disinfecting incoming thawed COVID-19 specimens**. These procedures have been introduced to ensure the safety of the Biorepository team and to mitigate the potential of airborne exposure to COVID-19 virus particles in the event that specimens arrived out of frozen condition and arrived thawed. These enhanced procedures were developed following guidance from the Biosafety in Microbiological and Biomedical Laboratories (BMBL), Centers for Disease Control and Prevention (CDC)/World Health Organization (WHO) guidance and following best practices.
   - **Specific COVID-19 vial level identifiers**. Currently, known COVID-19 specimens have been given specific identifiers in our specimen management software (Biological Specimen Inventory -BSI) to indicate that they are COVID-19 specimens, and if applicable, of international origin. These designations assist in the identification of suspected and confirmed COVID-19 specimens and assist with the maintenance of regulatory compliance.

2. **What are the current, or proposed, protocols for COVID-19 related safety procedures in terms of Biorepository staff and specimen handling for future COVID-19-related incoming collections?**

   As always, we observe universal precautions when handling all clinical specimens, following well-established processes and procedures for working with infectious material including infectious pathogens. We have developed SOPs (Standard Operating Procedures) on Biobanking and Specimen Handling of COVID-19 Specimens and for Processing Incoming Frozen Specimens. These procedures have been developed following guidance from the Biosafety in Microbiological and Biomedical Laboratories (BMBL), Centers for Disease Control and Prevention (CDC)/World Health Organization (WHO) guidance and following best practices. In addition, we are providing supplemental training for all Biorepository technicians who are handling COVID-19 specimens. This supplemental training standardizes the processes for safely receiving, accessioning, and handling COVID-19 positive and suspected specimens.

3. **Does the Biorepository recommend requiring COVID-19 testing on incoming specimens? What are the recommendations on how to handle these potential biohazardous biospecimens?**

   At this time the NIDDK Biorepository does not recommend that non-COVID-19 study specimens be tested before shipment. The Biorepository considers all incoming clinical materials potentially hazardous, and staff are trained to handle them accordingly using appropriate PPE and procedures that were developed for safe handling of infectious pathogens. We recognize this is an evolving situation and will provide additional guidance regarding COVID-19 testing of incoming specimens as needed and it becomes available.

   For incoming COVID-19 specimens, the Biorepository is working under the assumption that specimens being supplied to us are collected and packaged in accord to CDC's special guidance to help reduce contamination of shipping materials.

   The Biorepository takes additional precautions during the receiving process to mitigate risks and is committed to working closely with the study teams, early and often, to better align shipping and packing processes to ensure the safety of our staff.

   All sites shipping COVID-19 specimens to the NIDDK Biorepository must prepare and package specimens following the Required Shipping Guidelines, that include:

   a. Pack and ship suspected and confirmed SARS-CoV-2 patient specimens, cultures, or isolates as UN 3373 Biological Substance, Category B, in accordance with the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations. (https://www.iata.org/contentassets/b08040a138dc4442a4f066e6fb99fe2a/dgr-62-en-pi650.pdf) and following Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19) (https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html)

      Other Helpful links:

      - Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
      - Collection and Submission of Postmortem Specimens from Deceased Persons with Confirmed or Suspected COVID-19 https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html
      - Laboratory biosafety guidance related to coronavirus disease (COVID-19): Interim guidance, 28 January 2021 https://www.who.int/publications/i/item/WHO-WPE-GIH-2021.1
      - Guidance for laboratories shipping specimens to WHO reference laboratories that provide confirmatory testing for COVID-19 virus https://www.who.int/publications/i/item/guidance-for-laboratories-shipping-specimens-to-who-reference-laboratories-that-provide-confirmatory-testing-for-covid-19-virus
      - Biosafety for Specimen Handling https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety.html

4. **Does the Biorepository require advance notice from sites when shipping COVID-19 related specimens? What information should shipping sites provide to the Biorepository prior to shipping COVID-19 related specimens?**

   It is imperative that the Biorepository receives advanced notice as to when shipments might be arriving. This is particularly important when the Biorepository may be receiving both COVID-19 and non-COVID-19 specimens from the same originating site.

   It is helpful for our staff to understand downstream specimen utilization, this is particularly true for COVID-19 related specimens. This assists the Biorepository prepare and provide appropriate services. Things to consider:

   a. Will any processing such as aliquoting be required to be performed by the Biorepository? Or are these primarily for receipt, storage, and distribution?

   b. What are the vial types? This will help us to ascertain if there is anything new or different from current NIH institutes' studies?

   c. Do you envision these specimens coming from existing sites or new sites?

   d. For sites shipping vials, will the outside of vials and packages be cleaned/disinfected? Please refer to recommendations in FAQ- 3

   e. For active studies with internal and ancillary support, what is the expected turnaround time for when the study will need the vials to be shipped back out of the NIDDK Biorepository?

   f. Are we expecting any international shipments (receiving or shipping)?

5. **Is the NIDDK Biorepository able to ship COVID-19 related specimens internationally? Are there any requirements to ship COVID-19 related specimens within the United States and internationally?**

   The NIDDK-contracted Biorepository, Precision for Medicine, is currently receiving COVID-19 related material from multiple sites worldwide in support of NIAID-funded studies. When shipping to and from international sites, per CDC guidelines, a permit is required. Our Biorepository has an active import permit which may be amended to add additional labs. Any study desiring to import material containing SARS-CoV-2, or receive a transfer of previously imported material containing SARS-CoV-2 within the United States, is required to obtain a CDC Import Permit. Following CDC guidelines, the NIDDK Biorepository will require permits when:

   a. Importing isolates or cultures of SARS-CoV-2

   b. Importing infectious substances (such as blood, bodily fluids, tissues) that are reasonably expected to contain SARS-CoV-2

   c. Importing nucleic acids capable of producing SARS-CoV-2; for example, full-length genomic RNA extracted from SARS-CoV-2

   d. Subsequent transfers of previously imported material containing SARS-CoV-2 within the United States

At the present time, permits are NOT required for the following activities:

a. Specimens or isolates/cultures of SARS-CoV-2 within the United States or its territories that were not generated from imported material

b. Nucleic acids encoding partial sections or fragments of SARS-CoV-2 incapable of producing infectious virus (such as partial or degraded SARS-CoV-2 genomic RNA)

c. Diagnostic specimens not known or suspected of containing SARS-CoV-2

As a reminder, the regulatory landscape is rapidly evolving, and it is important that the end-user regularly check with the CDC Import Permit site to ensure they comply with CDC regulations. For additional up to date information visit the CDC Import Permit Program (IPP) e-tool page at https://www.cdc.gov/cpr/ipp/etool.htm.

6. Do investigators need to factor in COVID-19 testing as an additional cost to specimen preparation?

At this time, the Biorepository does not require that non-COVID-19 study incoming specimens be tested before being accepted into the Biorepository. Likewise, it does not test specimens for SARS-CoV-2 before shipping out to investigators. This is in alignment with ongoing protocols dictating the handling of HIV and other infectious pathogens. If there were a requirement for testing of incoming or outgoing samples, this will be the responsibility of the collecting or receiving sites.

Additional Resources Relevant to Biorepositories and COVID-19:

- Vaught J. Biobanking during COVID-19 pandemic. Biopreservation and Biobanking 2020, vol 18(3). DOI:10.1089/bio.2020.29069.jiv https://pubmed.ncbi.nlm.nih.gov/32297797/
- Abdalhamid B, Bilder CR, McCutchen EL, Hinrichs SH, Koepsell SA, Iwen PC. Assessment of Specimen Pooling to Conserve SARS CoV-2 Testing Resources. Am J Clin Pathol. 2020;153(6):715-718. doi:10.1093/ajcp/aqaa064 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7188150/
- Radbel J, Jagpal S, Roy J, et al. Detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARSCoV-2) Is Comparable in Clinical Samples Preserved in Saline or Viral Transport Medium. J Mol Diagn. 2020;22(7):871-875. doi:10.1016/j.jmoldx.2020.04.209 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7219422/
- ISBER - Comments on "Responsible Data Sharing to Respond to the COVID-19 Pandemic: Ethical and Legal Considerations (v 2.0): The Perspective of the Regulatory and Ethics Work Stream of the Global Alliance for Genomics and Health." https://cdn.ymaws.com/www.isber.org/resource/resmgr/docs/Comments_on_GA4GH_Respons ibl.pdf
- COVID-19 - ISBER: https://www.isber.org/page/covid-19
- ASCP - Laboratories on the Front Lines: Battling COVID-19. https://www.ascp.org/content/get-involved/institute-of-science-technology-policy/coronavirus- 2019-(covid-19)-resources/battling-covid-19