

Guidelines for Research Biospecimens During the COVID-19 Pandemic

As the spread of COVID-19 continues, the UCD community is encouraged to take precautions when working with biospecimens obtained for research. The Clinical and Translational Science Center (CTSC) is providing the following guidance for all activities related to the handling, processing, and storage of biospecimens. The information below is based on the recommendations from global, federal, and state entities. These guidelines will be updated as new details are provided. The recommendations below should be followed with all research biospecimens.

Biospecimen Handling

General guidance: No additional handling precautions are recommended for biospecimens collected during the COVID-19 outbreak from non-COVID-19 infected patients or from patients not under investigation (non-PUIs). Universal Precautions remain the best practice for infection control from all biospecimens.

COVID-19 patients/PUI guidance: When handling and processing biospecimens from COVID-19 patients or patients under investigation (PUIs), we strongly recommend adherence to the recently issued CDC guidelines ([cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html](https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html)). Reiterated below are important guidelines aligned to those provided by the CDC and adapted for UCD research laboratories:

- When collecting biospecimens from COVID-19 patients/PUIs, all personnel should follow current infection control precautions related to personal protective equipment (PPE) to minimize risk of transmission to self and others.
- All specimen containers (vacutainers, cups, test tubes, conical tubes, vials, etc.) that may contain SARS-CoV-2 should be opened and processed within a certified Class II Biological Safety Cabinet (i.e. tissue culture biosafety cabinet with HEPA filter).
- Following collections, biospecimens from COVID-19 patients/PUIs should be taken directly to a BSL-2 laboratory and not stored and/or opened at workstations (such as cubicles, desks, etc.).
- All faculty and laboratory managers must ensure their personnel are using aseptic techniques when processing specimens. This includes disinfection of all surfaces and equipment using 10% bleach solutions (0.5% sodium hypochlorite), both inside and outside of the biosafety cabinet.
- All waste must be disposed of as biohazardous waste as with any BSL-2 type material.
- Use of dedicated, HEPA-filtered incubators for tissue culture growth of any biospecimens from PUIs is recommended.

All biospecimen types procured from COVID-19 patients/PUIs are to be managed in only Biosafety Level 2 (BSL-2) or higher laboratories. This includes sampling of nasopharyngeal swabs, saliva, urine, blood, feces, and tissue. Early studies out of China, do indicate that COVID-19's viral RNA has been found in saliva, feces, and blood.[1] [2]

Please note: if working with live viral cultures of SARS-CoV-2, a BSL-3 laboratory facility and further consultation with UCD's EHS is required. Recommendations from the UK ([link](#)) published March 13, 2020.

Biospecimen Storage

General guidance: No additional storage requirements are recommended for biospecimens collected during the COVID-19 outbreak from non-COVID-19 infected patients or from PUIs.

COVID-19 PUI/confirmed case guidance: Because the COVID-19 viral load may persist following archival and/or cryopreservation of biospecimens for future use, researchers are encouraged to work with the Health System personnel to reconcile any potential samples containing COVID-19 against the list of cases. If identified, those biospecimens may be submitted for laboratory testing to confirm the presence of COVID-19. Further guidance on the use of samples testing positive for COVID-19 will follow. Testing of solid tissue procured from suspected patients can be confirmed using CDC's testing guidance for post-mortem tissue: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html>

Biospecimen Shipping

Shipping of suspected or confirmed COVID-19 specimens is still considered Class B, UN 3373. See CDC guidance on shipping of specimens: <https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html>

Exposure Control

Follow UCD's protocols for management of pathogen exposure for all individuals working with biospecimens (<https://safetyservices.ucdavis.edu/article/bloodborne-pathogen-exposure-control-plan>).

In the event you are exposed (inhalation, ingestion, injury, or contact with mucosal surface) to any biospecimens, you must follow UCD's policy on seeking medical care and reporting.

Health Campus employees (faculty, staff, students):

- 1) Immediately report exposure to your department
- 2) If directed by your department, also report exposure using the Incident Reporting Employee Exposure online portal ([link](#))
- 3) While asymptomatic, researchers and staff may continue to work, following UC Davis Health directives on [Management of Patients and Healthcare Personnel](#)
- 4) Additional guidance can be found on the UC Davis Health [COVID-19: Information and Resources for Employees](#) intranet page or by calling the UC Davis Health COVID-19 dedicated employee hotline at 916-284-6402

Main Campus:

Employees (faculty and staff):

- 1) Go home directly
- 2) Fill out online worker compensation paperwork ([link](#)) via UC Davis Safety Services
- 3) Call the Occupational Health Clinic at 530-752-6051 to report your exposure
- 4) Employee will self-quarantine for 14 days and complete a symptom log

Students:

- 1) Go home directly
- 2) Call the Student Health Clinic at 530-752-6559 to report your exposure
- 3) Students will self-quarantine for 14 days and complete a symptom log

In the event of a biospecimen spill or leak onto a surface, follow UCD's Bloodborne Pathogen's Exposure Plan and immediately contact EH&S at 530-752-1493.

Lab Guidance

- [COVID-19: safe handling and processing for samples in laboratories](#) (GOV.UK)
- [Novel coronavirus \(2019-nCoV\) technical guidance: laboratory testing for 2019-nCoV in humans](#) (WHO)
- [Interim guidelines for collecting, handling, and testing clinical specimens from patients under investigation \(PUIs\) for coronavirus disease 2019 \(COVID-19\)](#) (CDC)
- [Interim laboratory biosafety guidelines for handling and processing specimens associated with coronavirus disease 2019 \(COVID-19\)](#) (CDC)
- [Laboratory guidelines for detection and diagnosis of the novel coronavirus \(2019-nCoV\) infection](#) (PAHO)
- [COVID-19: guidance for sampling and for diagnostic laboratories](#) (PHE)
- [Policy for diagnostics testing in laboratories certified to perform high complexity testing under CLIA prior to Emergency Use Authorization for coronavirus disease-2019 during the Public Health Emergency](#) (FDA)
- [Information for laboratories COVID-19 requests for diagnostic panels and virus](#) (CDC)
- [Disease commodity package - novel coronavirus \(nCoV\)](#) (WHO)

Diagnostics

- [CDC tests for COVID-19](#) (CDC)
- [Real time RT-PCR panel for detection of 2019-novel coronavirus](#) (CDC)
- [2019-novel coronavirus \(2019-nCoV\) real-time rRT-PCR panel primers and probes](#) (CDC)
- [Diagnostic testing for 2019-nCoV](#) (Johns Hopkins fact sheet, Jan 28, 2020)
- [Coronavirus \(COVID-19\) update: FDA issues new policy to help expedite availability of diagnostics](#) (FDA news release, Feb 29, 2020)
- [FDA's actions in response to 2019 novel coronavirus at home and abroad](#) (FDA statement, Feb 14, 2020)
- [Shipping of CDC 2019 novel coronavirus diagnostic test kits begins](#) (CDC news release, Feb 6, 2020)
- [HHS seeks abstract submissions for 2019-nCoV diagnostics development](#) (US HHS news release, Feb 5, 2020)
- [Coronavirus disease \(COVID-19\) R&D](#) (WHO)
- [2019 novel coronavirus Emergency Use Authorization/a](#) (FDA)
- [FDA takes significant step in coronavirus response efforts, issues Emergency Use Authorization for the first 2019 novel coronavirus diagnostic](#) (FDA news release, Feb 4, 2020)
- [FDA announces key actions to advance development of novel coronavirus medical countermeasures](#) (FDA news release, Jan 27, 2020)

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[1] Wei Zhang, Rong-Hui Du, Bei Li, Xiao-Shuang Zheng, Xing-Lou Yang, Ben Hu, Yan-Yi Wang, Geng-Fu Xiao, Bing Yan, Zheng-Li Shi & Peng Zhou (2020) Molecular and serological investigation of 2019-nCoV infected patients: implication of multiple shedding routes, *Emerging Microbes & Infections*, 9:1, 386-389.

[2] Yong Zhang, Cao Chen, Shuangli Zhu, Chang Shu, Dongyan Wang, Jingdong Song, et al. Isolation of 2019-nCoV from a Stool Specimen of a Laboratory-Confirmed Case of the Coronavirus Disease 2019 (COVID-19)[J]. *China CDC Weekly*, 2020, 2(8): 123-124.