

COVID-19 DATA/SPECIMEN (DS) STEWARDSHIP COMMITTEE

FREQUENTLY ASKED QUESTIONS (FAQ)

****PLEASE CHECK ROUTINELY THE FAQ SINCE CONDITIONS MAY CHANGE AS THE PANDEMIC EVOLVES OVER TIME ****

Updated: April 1, 2020

- **What type of COVID-19 data and/or specimens are available?**

The Department of Pathology and Laboratory Medicine Biorepository is managing specimens obtained from COVID-19 patients. These are all residual clinical specimens and include: heparinized plasma, EDTA whole blood, nasopharyngeal swab specimens stored in universal transport media. There may be some bronchoalveolar lavage (BAL), tracheal aspirate, and serum specimens. Data will also be banked under a School of Medicine sponsored institutional review board (IRB) approved protocol and be accessible for investigators requesting access.

- **How much and what conditions are samples stored at?**

The clinical samples are divided up into 1.0 mL aliquots. Typically, one clinical sample provides 1.0 to 1.5 mL plasma. Clinical samples will usually be collected at least once for each day for the patient. Plasma samples stored at -70°C. From this population, COVID-19 positive patients typically only have one to three nasopharyngeal swab samples available. These are saved in universal transport media and then frozen at -70°C. Residual whole blood samples preserved in EDTA are stored at refrigerated temperatures (2-5°C). Other samples may be available upon request, however, is contingent on what is ordered for routine care and feasible during the COVID-19 response.

- **What is the Pathology and Laboratory Medicine Biorepository?**

The Department of Pathology and Laboratory Medicine operates a College of American Pathologists (CAP) accredited biorepository. Having the CAP accreditation allows specimens from the biorepository to be held to the highest standards recognized by the Federal government and allows specimens to be used for patient care. All refrigerator and freezers are monitored in the hospital. Such biorepositories are inspected every two years by CAP, just like clinical laboratories. Being part of the Department of Pathology and Laboratory Medicine enables these banked specimens to have access to the latest diagnostic tests and results used for everyday patient care.

- **Does it cost to access samples and the paired data?**

The Department of Pathology and Laboratory Medicine does not sell samples or their paired data. Fees are only for staff time to obtain, process, and release data and specimens, as well as storage fees. Samples that do not come with any data or other processing is usually \$27/sample. Groups

are limited to requests of 20 samples at a time (can request more than once). Additional fees for processing and data for the samples may apply.

- **What are the requirements for obtaining and conducting research on COVID-19 samples?**

COVID-19 positive patient samples are classified as biosafety level (BSL) – 2. However, culturing of the virus requires BSL-3 facility. To conduct research for these samples, you must have Pathology Clinical Research Oversight Committee approval, and received approval by the COVID-19 DS committee. Investigators must also have a current Institutional Review Board (IRB) approved protocol and have appropriate laboratory facilities and biological use authorizations (BUA) to support the proposed research.

- **Can I get COVID-19 samples outside of those banked by the clinical laboratory (i.e., prospectively collected specimens)?**

Since COVID-19 patients, at this time, are under droplet isolation, it is difficult to obtain additional samples. Nursing staff and other healthcare providers are operating under strict personal protective equipment conditions and therefore additional samples are not feasible to obtain.

- **Can I get peripheral blood mononuclear cells (PBMC) from COVID-19 patients?**

Peripheral blood mononuclear cells are not routinely used for patient care, therefore non-exists in the biobank. Collection of PBMCs is relatively time sensitive, and therefore must be collected prospectively and processed quickly. Due to isolation precautions for COVID-19 patients, it may be unfeasible to collect these samples at this time outside of defined clinical trials that have been approved by the COVID-19 data/specimen stewardship (DS) committee.

- **How do I access COVID-19 data and/or specimens?**

Provide a brief protocol or description of your study. This submission will be reviewed by CROC and forwarded to the COVID-19 data/specimen stewardship (DS) committee for review and scoring.

Next, submit the compiled application via the Department of Pathology and Laboratory Medicine Clinical Research Oversight Committee (CROC) using the online intake form: <https://ctscassist.ucdmc.ucdavis.edu/ctscassist/surveys/?s=TFTKKYMTFM>

- **What do I do if I am proposing a quality project for the hospital?**

Same as other studies. Please go through the CROC website, but also indicate this is a hospital quality project.

- **How do I access COVID-19 data only?**

The UC Davis School of Medicine is establishing a data repository which will also be tied to the specimen biobank. Once the repository is established, investigators can submit formal requests to access this database.

- **Given access to data and specimens may limited, how does the School of Medicine plan to prioritize study requests and clinical trials?**

The UC Davis School of Medicine has established the COVID-19 Data/Specimen Stewardship (DS) Committee to review requests. Review criteria are published online.