DEPARTMENT OF PATHOLOGY & LABORATORY MEDICINE

FREQUENTLY ASKED QUESTIONS (FAQ) FOR RESEARCH SPECIMEN TESTING AT UCDMC

Who do I contact to perform testing at UCD Health?

The Clinical Research Oversight Committee (CROC) reviews requests for all research services for Pathology and Laboratory Medicine (i.e. basic, clinical, and quality) requiring Pathology and Laboratory Medicine services. Requests should be made by filling out the Pathology Intake Form and providing the required documentation specified on the form.

What can be tested through the UCD Health Clinical Laboratory?

Tests available at the UCD Health Clinical Laboratory can be obtained from The Testing Directory Please note, certain tests are restricted to clinical use only and require prior Pathology approval for research. The list of restricted tests can be found here https://health.ucdavis.edu/pathology/research/index.html

How much does it cost?

The latest Epic cost query tool is used to determine the pricing for each test. Note that test prices may vary based on the type of study (clinical, industry, or applied research): https://ctsc-prod.ucdmc.ucdavis.edu/ucdrc/epiccer/2019unified/epicRCosts.aspx?

I already have an IRB approved study, what should I do?

Please contact the Pathology Clinical Research Oversight Committee (CROC) as soon as possible by filling out the <u>Pathology Intake Form</u>. Specimen testing cannot occur until Pathology provides approval. It is the investigators responsibility to ensure the IRB protocol is current.

How will I receive my results?

Specimens that are not tied to a specific patient on the UCD Health Electronic Medical Record System will be reported on paper and/or as scanned copies. We currently do not offer data reporting on electronic spreadsheets (e.g., Excel).

Can I send any type of sample?

Certain specimen types and storage conditions are not appropriate for testing. Please review test collection and storage requirements at www.testmenu.com/ucdavis. Specimen containers should also be similar to what is routinely tested at UCD Health. However non-standard specimen collection devices may be accepted on a case-by-case basis and may require the investigator to aliquot the samples themselves into appropriate tubes.

How long does it take for testing to be completed?

Testing turnaround time for research studies is dependent on the type of test. Typically, one-week turnaround time is requested, however certain other tests may take longer.

Scheduling of when you can perform research testing will need to be coordinated with the CROC coordinators to avoid impact on routine testing for patient care.

How are quality improvement / quality assurance studies reviewed by CROC?

Quality studies are handled in the same fashion as any other project. The Department of Pathology and Laboratory Medicine is supportive of quality research, however, studies must be evaluated to ensure they do not impact routine care. Additionally, requests for new tests or workflows as part of the quality project must also be approved by the Hospital Test Utilization Review Committee.

• Can I use the Clinical Laboratory's centrifuge (or other instrument)?

Unfortunately, all Clinical Laboratory space and instruments can only be accessed by approved Department of Pathology and Laboratory Medicine personnel. This is for security, HIPAA, and compliance reasons. If certain resources are needed, please submit your study proposal for CROC review since some services may be available for a fee.

• Can I store and/or process samples in the Clinical Laboratory?

The UCD Health Clinical Laboratory does not currently offer short-term or long-term specimen storage for clinical laboratory tests. (For questions about Biorepository specimen storage services please see Biorepository Shared Resources.)

How can I get samples from the Clinical Laboratory?

Specimens can be made available for studies that have been approved by the Pathology Clinical Research Oversight Committee and UC Davis Institutional Review Board. The process to obtain samples must be discussed early to avoid study delays since certain specimens may require additional staff time to collect.

• Can I request a new test to be performed for a research study?

All new tests must be approved by the Department of Pathology and Laboratory Medicine as well as the UCD Health Test Utilization Committee. This process may require extensive review that exceeds normal turnaround times for research studies. We recommend studies consider alternative tests or laboratories that may perform this testing. However, any send out laboratory tests must still be approved by Pathology and Laboratory Medicine.

Do blood draw only studies (i.e., no testing is performed) need to come through the laboratory?

Even though testing is not performed, blood collection alone must also be reviewed by the Pathology Clinical Research Oversight Committee. Please complete the <u>Pathology Intake</u> <u>Form</u> for submission.

• Can the UCD Health Laboratory perform animal or non-biological testing?

Animal specimens are evaluated on a case-by-case basis, however, all mouse and rat samples are not accepted. Mice and rat specimens can be tested by the Comparative Pathology Laboratory on the main UC Davis campus. Non-human primate specimens must be approved

through the California National Primate Research Center and the Pathology Clinical Research Oversight Committee. Non-biological specimens are also treated on a case-by-case basis, and are typically not approved for testing.

Why are some tests "restricted"?

Certain tests require extensive manual processing which would impact patient care or require substantial resources and would make research testing cost-prohibitive for the institution. Restricted tests require significant justification for approval including assurances that the test volumes would not impact the clinical laboratory workflow. The clinical laboratory reserves the right to discontinue these services at any point based on patient care demands.