



End-to-End Histopathology and Precision Medicine Services for Global Clinical Trials



AcelaBio (US) Inc. is a commercial state-of-the-art research laboratory delivering histopathology and precision medicine services for global clinical trials. Our accredited facility, located in San Diego, California, is built on deep expertise in clinical and precision medicine research and our scientific and operational experts are dedicated to delivering reliable, high-quality data.

Our mission is to bring people, technology, and science together in a state-of-the-art histopathology laboratory that delivers accurate and consistent data to enhance our understanding of disease mechanisms and support development of safe and effective therapy for patients.

Areas of expertise:

- Gastrointestinal Diseases (including but not limited to: IBD, NASH, EGID, CeD)
- Oncology
- Dermatology

Services

We provide end-to-end histopathology and precision medicine services “from sample-to-score” for clinical trials and clinical research:



Accessioning

Cross-referencing of sample identifiers with shipping manifest or requisition form.

Confirmation of completeness of sample-associated meta-data.

Registration of sample in laboratory information system.



Processing

Fully automated process to dehydrate, clear and infiltrate the tissue.



Embedding

Embedding of processed tissue into a wax block.

Ensuring that tissue is oriented in a correct way for downstream microtomy.



Sectioning

Microtomy with sectioning of wax block to cut sections of typically 4 µm thickness.

Tissue sections are subsequently placed on positively charged glass slides.



Antibody Optimization and Validation

Process of characterizing and validating antibodies for the identification of biomarker targets.

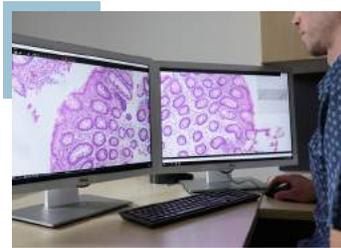
Testing out different dilutions, buffers, and reaction kits.



Whole Slide Imaging Scanning

Digital pathology using 510(k) approved scanner to scan whole glass slides at 40X.

Digitized slides can then be transferred to image management system for pathologist review.



Pathology Review

Support assay development as it relates to ensuring staining pattern is correct.

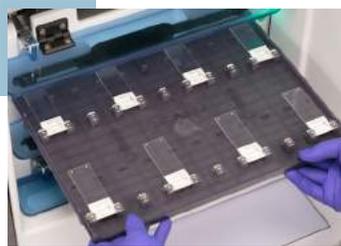
Identification and annotation of tissue areas, structures and cells to support development of algorithms for quantitative digital image analysis.

Review of clinical cases which may include disease activity scoring and diagnosis.



Data Management

Delivery of consistent data & imagery through automated laboratory information systems.

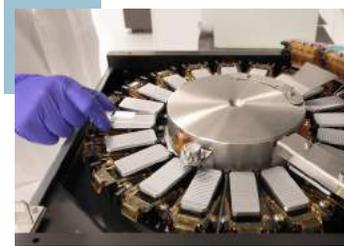


Hematoxylin & Eosin

Automated staining of tissue on glass slide with hematoxylin and eosin.

Hematoxylin stains cell nuclei a purplish blue.

Eosin stains the extracellular matrix and cytoplasm pink.



Special Stains

Automated special staining of tissue on glass slide, such as with Masson Trichrome.



Immunostaining

Automated staining with antibodies linked to chromogens to identify a certain target.

Single or multiplex chromogenic immunohistochemistry.



Assay Development

Development of new staining protocol, typically using immunohistochemistry.

Starting point can be a known target, an antibody, or an in vitro diagnostic (IVD).



Sample Logistics

Preparation and shipment of blocks and slides to national and international locations.



Storage & Archiving

Semi-automated archival system of blocks and slides in temperature & humidity-controlled environment.



Consulting

Implementation of histopathology services in multicenter global clinical trials.

Selection of biomarker targets based on mechanism of action and technical capabilities.



Project Management

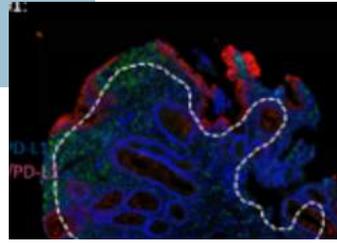
Operational experts ensure projects are delivered on time within budget.





In Situ Hybridization (ISH)

Use of specific probes to identify target gene transcripts in tissue using RNAScope.



Digital Image Analysis

Quantitative digital image analysis using machine learning and AI techniques.

Custom algorithm development with oversight of expert pathologists.

Generate quantitative, reproducible data on whole slide images or specific regions of interest.

*For Research Use Only (Not for Use in Diagnostic Procedures).



RNA Extraction

Extraction of whole RNA from formalin fixed paraffin embedded (FFPE) tissue blocks or sections.

Allows for downstream bulk RNAseq and generation of insights at the gene transcript level.

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Spatial Transcriptomics

Mapping of the whole transcriptome with morphological context using 10X Genomics Visium.

Ability to analyze existing formalin fixed paraffin embedded (FFPE) tissue blocks or sections.

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Bioinformatics

Leverage existing pipelines for RNAseq data analysis including primary analysis, QC, differential gene expression analysis and pathway analysis.

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Clinical Trial Support

AcelaBio works in partnership with Alimentiv, a leading full-service niche CRO specialized in gastroenterology, to provide an end-to-end clinical study management solution that ranges from early trial design to full execution of a clinical trial.

*For GI Services Only.



Watch our video lab tour at www.ancelabio.com or schedule a visit to our facility.

Accreditations

We deliver robust quality assurance and quality control at every stage and adherence to U.S. State, Federal, and International standards and regulations. AcelaBio is compliant with:

- Good Clinical Laboratory Practice (GCLP)
- Good Clinical Practice (GCP)
- FDA 21 CFR Part 11

AcelaBio has the following accreditations / certifications:

- CDPH Clinical and Public Health Laboratory License Q3 2021
- CMS/CLIA Certificate of Registration Q3 2021
- College of American Pathologists (CAP)



**AcelaBio can fulfill your
histopathology & precision
medicine needs.**