



StageBio

StageBio is the leading provider of preclinical necropsy, histology, pathology and specimen archiving services for the biopharmaceutical, medical device and contract research industries.

Services

Necropsy

Histology

Pathology

Archival

Overview

StageBio offers a full suite of services for preclinical and translational research and development, including everything from study protocol development through to materials archival. Based on the applicable specialty area and expertise required for your project, services are performed at one of our research sites. Expedited options are often available to meet your critical deadlines.

stagebio.com

Services

Necropsy

- Prosector services performed at your site
- Supervision by experienced board-certified veterinary pathologists, at your site
- Domestic and international services performed, in compliance with FDA, USDA and AAHA guidelines
- Technical expertise in a variety of species
- Quality data recording as per client standards

Histology

- US FDA-compliant laboratories (21 CFR 58), including Quality Assurance Unit and Standard Operating Procedures (SOPs)
- Established methods for tissue preservation and integrity, including paraffin, plastic and frozen tissue embedding
- Quality-controlled slide production including all standard stains and extensive specialty staining capabilities

Pathology

- Microscopic evaluation by one of 25+ board-certified veterinary pathologists
- Clear, professional pathology reports
- Accommodation of client-specific report format requirements
- Experience with an extensive list of animal models and specialty areas
- Multiple pathology data recording options, including but not limited to, our validated electronic commercial systems and direct data entry into a client's electronic system
- High-quality microscopic imaging services

Archival

- Vaults monitored 24/7 via NIST-calibrated data loggers
- FM-200 fire suppression systems
- Ultra-low temperature, frozen and refrigerated materials storage
- Sample returned within 24 hours
- Certified incineration services
- Courier options available for hand-delivered critical shipments

Necropsy Services

We have a team of trained prosectors, prepared to travel to your site, to provide necropsy services. We also offer necropsy supervision by our highly trained board-certified veterinary pathologists. Our team is trained in necropsy techniques on the following species:



MOUSE



RAT



FERRET



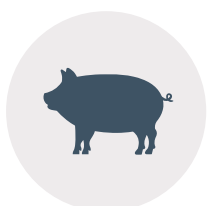
GUINEA PIG



CAT



GOAT



PIG



RABBIT



DOG



NON-HUMAN
PRIMATE



SHEEP

Histology Services

From trimming to slide staining, we offer standard and specialty histology services based on our clients' needs. In addition, we will partner with you to provide pathology and method development consultations to ensure appropriate fulfillment of client study objectives.

Trimming

- Standard trimming
- Study-specific trimming, per protocol
- Specialty trimming with pathologist oversight

Processing

- Bone decalcification

Embedding

- Standard and oversized paraffin blocks
- Plastic (Spurr resin, methyl methacrylate, glycol methacrylate)
- Optimal Cutting Temperature (OCT) compound for frozen sectioning

Slide Sectioning

- Paraffin and plastic microtomy

- Cryotomy: standard and thick (up to 50 microns from fixed tissue) frozen sectioning
- Ground sectioning from plastic-embedded samples
- Laser microtomy: precise, contact-free cutting of plastic-embedded histological samples

Staining

- Standard and special stains available
- Expert immunohistochemical and immunofluorescent techniques

Quality Control

- 100% block to slide match
- Quality review of staining
- Quality control of paperwork

Pathology Services

Our pathology services are tailored to each study. We understand that evaluation and interpretation requirements vary based on scope and purpose of work, and we apply high-quality standards to each scientific approach. In addition to slide evaluation, our board-certified veterinary pathology team can assist with protocol development, advise on unique investigative approaches, and consult on method development for specialized investigations and techniques. Areas of expertise include:

Clinical Pathology

- Data interpretation for clinical chemistry, hematology, coagulation, urinalysis, blood gas, and other plasma, serum, whole blood, or body fluid parameters as requested
- Qualitative cytology evaluation
- Integrated clinical and anatomic pathology reports

Molecular Pathology

- Tissue cross-reactivity (TCR)
- Immunohistochemistry (IHC)
- Immunofluorescence (IF)
- In situ hybridization (ISH)
- Fluorescent in situ hybridization (FISH)
- Single and multiplex labeling (chromogenic and fluorescent)

Image Analysis

- Digital radiography
- Micro CT imaging and analysis
- High-resolution slide scanning
- Computerized image analysis (morphometry)
- Image segmentation and object counts
- Image data mining
- Stereologic analysis

Neuropathology

- Direct delivery: intrathecal, intracerebroventricular, intraparenchymal including intrastriatal, and intrahippocampal
- In-dwelling catheter administration
- Adeno-associated vectors
- Deep brain stimulation
- Nerve stimulation and cryoablations
- Evaluation of specialty neuroscience tissue processing investigations
- Juvenile neurotoxicity studies

Medical Device

- Orthopedic
- Cardiovascular
- Wound healing
- Subcutaneous/Intramuscular implants
- Ocular
- Gastrointestinal
- Bioresorbable implants
- ISO 10993-6 tests for local effects after implantation
- ISO 10993-11 tests for systemic toxicity

Routine Pathology

- Toxicologic pathology
- Carcinogenicity (conventional and genetically modified test systems)
- Animal models of disease
- Developmental and reproductive toxicology
- Regenerative medicine
- Infectious diseases and biowarfare
- Target animal safety

Pathology Services, Continued

Regulatory Compliance

Our team has extensive experience working professionally with domestic (FDA, EPA) and international (OECD, NMPA) regulatory authorities, and will consult with regulators regarding questions that may arise at any stage of a study.

Peer Review & Pathology Working Groups

We offer comprehensive peer review services performed by experienced pathologists who are able to organize, chair, and participate in Pathology Working Groups to resolve challenging pathology issues.

Expert Capabilities

Our team of board-certified pathologists has a wide range of special preclinical expertise including, but not limited to:

- Biomarker development
- Bone, joint, and musculoskeletal pathology
- Cell and gene therapy
- Clinical pathology
- Cosmetic fillers and other resorbable materials
- Dental pathology
- Dermal pathology
- Endocrine pathology
- Experimental animal models
- FDA animal rule studies
- Immunopathology
- Inhalation Exposure
- Cardiovascular pathology
- Mammary gland pathology
- Medical device pathology
- Molecular pathology
- Neuropathology
- Novel investigational techniques
- Oncology, immune oncology
- Ocular pathology
- Otic pathology
- Rare diseases
- Reproductive pathology (male and female)
- Renal pathology
- Small molecules
- Vaccines and biologics

Our pathologists are experienced in the evaluation of a wide variety of animal species, from routine and unique rodent models to rabbits, dogs, cats, minipigs, domestic pigs, non-human primates, livestock, and birds.

Quality Reporting

We subscribe to commercial preclinical data capture systems, as well as customized neuropathology and digital pathology software, allowing us to provide high quality reports with clear interpretation of results.

Photomicrographs may be embedded into pathology reports or provided as separate files to fulfill clients' needs. Pathology data can be prepared for SEND submission, and all reports include a regulatory compliance statement identifying the standards applied during study conduct.



Our archival services facilitate long-term storage solutions for multiple types of specimen and research material, in vaults which are monitored 24/7 via NIST-calibrated data loggers.

- FM-200 fire suppression systems
- Ultra-low temperature, frozen and refrigerated
- Wet tissues
- Blocks
- Microscope slides
- Information such as paper raw data, digital media, X-ray, etc.
- Test articles/retained samples
- Study materials returned within 24 hours
- Worldwide courier services
- Carrier logistics to include international customs
- Temperature-controlled/monitored shipping
- Certified, witnessed incineration
- On-site shipment preparation at your facility to include inventory, packaging, and shipping
- Hand-delivered critical shipments

Site Descriptions

MARYLAND

Cumberland, MD

Our Cumberland facility offers immunohistochemical and immunofluorescence staining, including exploratory antibody development and veterinary diagnostics. This location is BSL-2 compliant, and offers full human tissue panel tissue cross-reactivity (TCR) services from our internal frozen tissue bank.

Frederick, MD

Our Frederick facility consists of our neurohistology laboratory and is the center of our neuropathology expertise. Paraffin, frozen and osmication fixation are performed at this site, in addition to thick frozen sectioning and ultra-thin sectioning of plastic resin.

Thurmont, MD

Our Thurmont facility provides medical device histopathology, image analysis, morphometry and investigative pathology. Paraffin, frozen and plastic histology are performed at this site, in addition to specialty staining, whole slide scanning and micro CT imaging.

MASSACHUSETTS

Marlborough, MA

Our Marlborough facility performs immunohistochemical staining, immunofluorescence staining, whole slide scanning, morphometric analysis, and investigative pathology. This site offers a broad range of routine and advanced staining techniques for both frozen and formalin-fixed paraffin-embedded tissues. This site is Biosafety Level 2 (BSL-2) laboratory that can accommodate frozen or fresh non-human primate and human tissues and cell lines.

OHIO

Mason, OH

Our Mason facility performs standard and specialized paraffin tissue processing of normal and specimens. This site also accommodates glycol methacrylate plastic embedding, special staining techniques, gross photography and microscopic slide scanning.

VIRGINIA

Maurertown, VA

Our Maurertown facility is the central location for our archival services, housing 250,000 cubic feet of ambient, refrigerated, and frozen storage. Our secure building contains state-of-the-art fire and burglar alarm systems, in addition to remote temperature monitoring, 24-hour video surveillance and an electrical back-up generator.

Mount Jackson, VA

Our Mount Jackson facility is the home base for our company, housing our corporate headquarters, our largest paraffin histology laboratory, and additional archiving space. Many standard toxicology and paraffin histology studies are accommodated at this site.

GERMANY

Freiburg

Our Freiburg, Germany facility expands our preclinical and clinical laboratory resources and offers a complete range of GLP-compliant services, from necropsy and histological processing to pathological evaluation of tissue samples with expertise in immunohistochemistry, cryoprocessing, fixed tissue preparation, ISH, tissue cross-reactivity (TCR) studies, and in vivo toxicology studies.