

# GLP HISTOPATHOLOGY AND MORPHOMETRY

## Supporting the Research Continuum, from Pilot to Regulatory Submission

Histology is a critical endpoint for the evaluation of medical devices, drugs, biologics and biomaterials. Our histopathology facility and ACVP-boarded pathologists provide flexible support and active collaboration for all facets of sample processing, staining, imaging and analysis, pairing it with expert interpretation and reporting.

### Expert Pathologist Assessment

CBSET can support your next study with industry-experienced, board-certified veterinary pathologists co-located with an integrated scientific team, to inform your regulatory and scientific endpoints with confidence.

- Written reports (GLP and non-GLP)
- Scoring paradigms and quantitative analysis
- Morphometry and electron microscopy

### Staining Paradigms Selected to Elucidate Disease, Injury or Toxic Effect in Tissue

**Primary staining** provides rapid, low-cost visualization of any tissue type for robust qualitative assessments of histological changes.

Common primary stain paradigms include:

**Cytology** – e.g., Wright-Giemsa

#### Histology

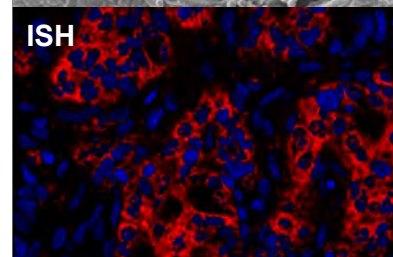
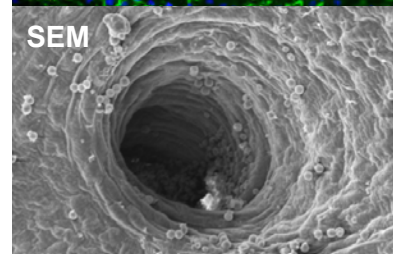
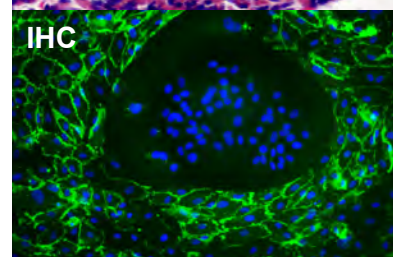
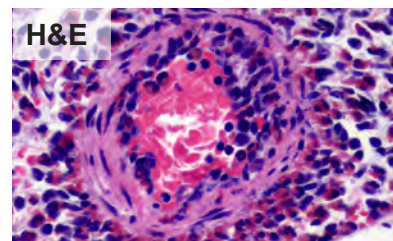
- Fibrosis/ repair – e.g., Masson's trichrome
- Bone/ collagen – e.g., von Kossa, Goldner's trichrome, safranin O
- Vascular – e.g., Movat's pentachrome, van Gieson elastin

**Secondary staining (IHC, IFA, ISH)** is used for pinpoint contrast and quantitative analysis.

**Immunohistochemistry (IHC)** and **Immunofluorescence (IFA)** use antibodies targeting cellular biomarkers, coupled to chromogenic enzymes or fluorophores, for improved dynamic range and sensitivity. **In Situ Hybridization (ISH)** detects expression of RNA in sections via oligonucleotide hybridization to target RNA sequences.

Common secondary stain paradigms include:

- Neurologic – e.g., neurofilament (NF), tyrosine hydroxylase (TH), calcitonin gene related peptide (CGRP)
- Connective tissue/vascular – e.g., collagen I, collagen III, von Willebrand factor, actin
- Inflammation – e.g., CD3, CD79a, C18, CD68
- Cell death and proliferation – e.g., TUNEL, proliferating cell nuclear antigen (PCNA)
- Gene expression (custom oligonucleotide probes directed to mRNA targets)



## ABOUT CBSET

CBSET is a state-of-the-art biomedical research institute located in Lexington MA.

Our mission is to advance biomedical research, through innovative, high-quality services. We combine top-tier research with operational expertise. Since our inception, CBSET has continued to develop technical and scientific acumen through collaborative projects in the medical device, pharmaceutical and academic communities. Our 40,000 square foot, GLP-compliant, AAALAC-accredited facility includes vivaria, procedure rooms, catheterization / imaging labs, surgical and necropsy suites, histopathology, SEM, and a range of other technologies.

## Why CBSET?

- **Credibility.** We are recognized as unbiased experts, bringing independent credibility to your regulatory filings.
- **Culture.** Our culture is science rather than commerce; we welcome unprecedented models and creative collaboration.
- **Mission.** As a 501(C3), non-profit corporation, our motivation is to enable your success; your product is our mission.
- **Integrated resource.** Our multidisciplinary team includes board-certified veterinary, quality, biological and quantitative sciences expertise, as well as board-certified pathologists – all in one facility.

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## Slide Processing

- Tissue trimming and fixation
- Paraffin and plastic resin processing
- Embedding, sectioning and staining
- Microtomy and EXAKT micro-grinding

## Tissue Biomarker Analysis

- Method development
- Secondary probe strategies for optimized signal detection and amplification
- A wide range of fluorophores, or fluorophore-conjugated secondary antibodies
- Multiplexing for simultaneous visualization of multiple markers
- Quantitative analysis/ scoring of localization and intensity of signals

## CBSET's Comprehensive Histopathology Suite

