



Preclinical Research Services

Preclinical Research Device Testing Services

Sinclair Research Center has supported the medical device industry with customized surgical studies for many years, establishing a reputation for technical expertise, regular communication, on-time reporting and high value. We now further support the device industry with a full range of **ISO 10993 Part 1** biocompatibility studies with this same high level of service. We now provide Toxicology, PK and Safety Testing in one facility for drugs, **medical devices and drug/device combination products**.

Representative capabilities include:

Sensitization Testing (Part 10)

- ☞ Guinea Pig Maximization
- ☞ Guinea Pig Repeated Patch (Buehler)

Irritation (Part 10)

- ☞ Intracutaneous Reactivity
- ☞ Primary Skin Irritation
- ☞ Ophthalmic studies
 - *ISO 9394 Testing*

Systemic Toxicity (Part 11)

- ☞ Acute, Subchronic and Chronic Toxicity:
 - *Dermal*
 - *Ocular*
 - *Soft and Hard Tissue*

Implantation (Part 6)

- ☞ Intramuscular
- ☞ Subcutaneous
- ☞ Intraperitoneal
- ☞ Spinal (and other orthopedic sites)
- ☞ Ocular
- ☞ Osteoinduction/Osteoconduction

TK/PK (Part 16)

- ☞ Rodent
- ☞ Large Animal (including NHP)

Genotoxicity* (Part 3)

- ☞ Bacterial Mutagenicity
- ☞ Mouse Lymphoma
- ☞ Chromosomal Aberration

Hemocompatibility (Part 4)

- ☞ Thromboresistance Test (multiple species)
- ☞ Compliment Activation*
- ☞ Coagulation Studies*
- ☞ Platelet and Leukocyte Counts*
- ☞ Hemolysis*

Cytotoxicity* (Part 5)

- ☞ Agarose Overlay
- ☞ MEM Elution
- ☞ Direct Contact
- ☞ Growth Inhibition
- ☞ Extract Colony Assay

Risk Assessment (Part 18)

- ☞ Expert consulting available
- ☞ Clinical Chemistries
- ☞ Necropsy Facilities

Supporting Capabilities

- ☞ Hematology (5 part differential)
- ☞ Histology/Pathology
- ☞ Animal models Joint/Cartilage Models
- ☞ Studies in 15 species including NHP and Miniature Swine

***In-Vitro Testing Services provided by Nelson Laboratories, Inc.**

Sinclair Research Center is a GLP Compliant, USDA licensed and AALAC approved research facility.