

ISO 9001:2000  
FDA REGISTERED  
ISO 17025

# BIOCOMPATIBILITY TEST SERVICES

Nelson Laboratories, Inc. is an independent testing laboratory that supports many industries, including the medical device, pharmaceutical, and nutraceutical industries.

This segment sheet is designed to provide you with a better understanding of how Nelson Laboratories can assist you with your test service needs. To receive a full capabilities list or for a price quote, please contact the Nelson Sales Department at [sales@nelsonlabs.com](mailto:sales@nelsonlabs.com).



## CAPABILITIES

**Cytotoxicity Testing** – ISO 10993-5, USP 87 (*in vitro*) – Cytotoxicity, a rapid, standardized test, is a very sensitive and inexpensive way to determine whether your materials contain significant quantities of harmful extractables and what their effect may have on cellular components.

*Available Testing Services:* Agar Overlay (USP, ISO), MEM Elution (USP, ISO), and Direct Contact.

**Hemocompatibility Testing** – ISO 10993-4 (*in vitro* & *in vivo*) – This group of tests determines the compatibility of devices designed for direct or indirect contact with circulating blood.

*Available Testing Services:* Hemolysis test, ASTM or NIH (Extract method & Direct Contact), Complement Activation, Coagulation studies, Dog Thrombogenicity, Partial Thrombogenicity Test, and Prothrombin Test.

**Sensitization Testing** – ISO 10993-10 (*in vivo*) – Sensitization or hypersensitivity tests look for adverse reactions in animals by exposing the animal to the material or by taking extracts from the device or materials and injecting and/or topically applying them to the animal. Sensitization reactions appear as redness and swelling as the material or extract interacts with the animal's immune system.

*Available Testing Services:* Murine Local Lymph Node Assay (LLNA), Guinea Pig Maximization, and Guinea Pig Repeated Patch (Buehler).

**Irritation Testing** – ISO 10993-10 (*in vivo*) – These tests evaluate the reaction to a single, repeated or continual exposure from device materials that may produce irritation. This is different from sensitization in that there is no involvement of an immunological mechanism.

*Available Testing Services:* Intracutaneous (USP, ISO), Primary Skin Irritation, Ocular Irritation, and Mucosal Irritation (Oral, Vaginal, Bladder).

**Systemic Toxicity Testing** – ISO 10993-11 (*in vivo*) – Systemic toxicity (acute) tests evaluate the potential adverse effects of medical devices on the body's organs and tissues which are remote from the site of contact. There are four categories: acute (24 hours), subacute (14 to 28 days) subchronic (90 days or 10 percent of an animal's life span), and chronic (anything longer).

*Available Testing Services:* Acute Systemic Toxicity (USP, ISO) and Pyrogen – Materials Mediated (USP, ISO).

**Genotoxicity Testing** – ISO 10993-3 (*in vitro* & *in vivo*) – Genotoxicity tests using bacterial or mammalian cells to determine gene mutations, changes in chromosome structure and number, or other gene toxicities caused by medical devices, materials, or their extracts.

*Available Testing Services:* Mouse Lymphoma, Chromosomal Aberration, AMES Mutagenicity, and Mouse Micronucleus.

**Implantation Testing** – ISO 10993-6 (*in vivo*) – Implantation testing determines the local pathological effects of an implanted device on the surrounding tissue. A representative sample is implanted directly into the animal and the tissue is evaluated at both the macroscopic and microscopic levels.

*Available Testing Services:* Intramuscular Implant (USP, ISO), Subcutaneous Implant, and Intraperitoneal Implant.



6280 So. Redwood Road  
Salt Lake City, UT  
84123-6600-80  
800.826.2088

# BIOCOMPATIBILITY TEST SERVICES

**Subacute/Subchronic Toxicity** – ISO 10993-11 (*in vivo*) – Subacute and subchronic toxicity testing determines the systemic effect of repeated doses of materials or their extracts. The test sample is administered to the animal for 14 days. The animal is examined daily for signs of toxicity, which include a change in weight or appetite, signs of disease or abnormal behavior. The effects are then evaluated and histopathology is conducted on all animals.

*Available Testing Services:* 14 day or 28 day Subacute Toxicity, Mouse or Rat, and Intravenous or Intraperitoneal.

## BIOCOMPATIBILITY TESTING MATRIX

Nelson Laboratories Tests for Consideration  
 (Based on ISO 10993-1:2003(E) and FDA G95-1 Guidelines)

Device Categories		Biological Effect										
		Initial								Other <sup>4</sup>		
Body Contact	Contact Duration	Cytotoxicity	Sensitization	Irritation	Systemic Toxicity	Subacute (Subchronic Toxicity)	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	
	A- Limited [≤ 24 hrs]											
	B- Prolonged [>24 hrs to ≤30 days]											
	C- Permanent [>30 days]											
Surface Devices	Skin	A	■	■	■							
		B	■	■	■							
		C	■	■	■							
	Mucosal Membranes	A	■	■	■							
		B	■	■	■	◇	◇		◇			
		C	■	■	■	◇	◇	■	◇		◇	
	Breached or Compromised Surfaces	A	■	■	■	◇						
		B	■	■	■	◇	◇		◇			
		C	■	■	■	◇	■	■	◇		◇	
External Communicating Devices	Blood Path, Indirect <sup>3</sup>	A	■	■	■	■				■		
		B	■	■	■	■	◇			■		
		C	■	■	◇	■	■	■	◇	■	■	■
	Tissue <sup>1</sup> /Bone/Dentin Communicating	A	■	■	■	◇						
		B	■	■	■	■	■	■	■			
		C	■	■	■	■	■	■	■		■	■
	Circulating Blood <sup>3</sup>	A	■	■	■	■		◇ <sup>2</sup>		■		
		B	■	■	■	■	■	■	■	■		
		C	■	■	■	■	■	■	■	■	■	■
Implant Devices	Tissue/Bone	A	■	■	■	◇						
		B	■	■	■	■	■	■	■			
		C	■	■	■	■	■	■	■		■	■
	Blood <sup>3</sup>	A	■	■	■	■	■		■	■		
		B	■	■	■	■	■	■	■	■		
		C	■	■	■	■	■	■	■	■	■	■



<sup>1</sup> "Tissue includes tissue fluids and subcutaneous spaces.

<sup>2</sup> For all devices used in extracorporeal circuits.

<sup>3</sup> Pyrogenicity/Materials Mediated should be considered.

<sup>4</sup> Supplemental tests for consideration

■ - ISO Evaluation Tests for Consideration

◇ - Additional tests which the FDA considers may be applicable