Nelson Laboratories, Inc. is an independent testing laboratory that supports many industries, including medical device manufacturers. This industry 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 Sales Department at **sales@nelsonlabs.com**.

NELSON LABORATORIES

Biocompatibility Test Services

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

AVAILABLE TESTING SERVICES: Agar Overlay (USP, ISO), MEM Elution (USP, ISO), & 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, Prothrombin Test, & Ames Mutagenicity test.

Sensitization Testing — ISO 10993-10 ***(in vivo)*** Sensitization or hypersensitivity tests for adverse reactions in animals by exposing the animal to the material. Sensitization reactions are noted by observing redness and swelling as it interacts with the body's immune system.

AVAILABLE TESTING SERVICES: Murine Local Lymph Node Assay (LLNA), Guinea Pig Maximization, & Guinea Pig Repeated Patch (Buehler).

Irritation Testing- ISO 10993-10 (in vivo) Irritation tests the reaction to a single, repeated or continual exposure from device materials that may produce irritation. Different from sensitization in that it is without the involvement of an immunological mechanism.

AVAILABLE TESTING SERVICES: Intracutaneous (USP, ISO), Primary Skin Irritation, Ocular Irritation, & Mucosal Irritation (Oral, Vaginal, Bladder).

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

AVAILABLE TESTING SERVICES: Acute Systemic Toxicity (USP, ISO) & Pyrogen- Materials Mediated (USP, ISO)

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

AVAILABLE TESTING SERVICES: Mouse Lymphoma, Chromosomal Aberration, AMES Mutagenicity, & Mouse Micronucleus.

Implantation Testing — ISO 10993-6 ***(in vivo)*** Implantation determines the local pathological effects on living tissue surrounding the implanted device. A sample is implanted directly into the animal, appropriate for use of the device and is evaluated at the gross level and the microscopic level.

AVAILABLE TESTING SERVICES: Intramuscular Implant (USP, ISO), Subcutaneous Implant, & Intraperitoneal Implant.

Subacute/Subchronic Toxicity — ISO 10993-11 ***(in vivo)*** Subacute and Subchronic Toxicity determines the systemic effect of repeated doses of materials or their extracts. The test substance or extract is administered to the animal for 14 days, and is observed each day for signs of toxicity: weight change, appetite, signs of disease or abnormal behavior. Then, the effects are evaluated and a histopathology is conducted on all animals.

AVAILABLE TESTING SERVICES: 14 day or 28 day Subacute Toxicity, Mouse or Rat, Intravenous or Intraperitoneal.

BIOCOMPATIBILITY TESTING MATRIX
Nelson Laboratories Tests for Consideration
[Based on ISO 10993-1 and FDA G95-1 Guidelines]

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

[1] "Tissue includes tissue fluids and subcutaneous spaces.
[2] For all devices used in extracorporial circuits.
[3] Pyrogenicity/Materials Mediated should be considered.
[4] Supplemental tests for consideration

● ISO Evaluation Tests for Consideration
○ Additional tests which the FDA considers may be applicable