Knowledgeable. Advanced. Reliable.

We can help you ensure the safety of your product.

Biocompatibility

NAMSA®

PEOPLE › SCIENCE › SOLUTIONS

Put our full range of expertise and technology to work for you.

When it comes to biocompatibility testing, you need a flawless protocol—so that's what we deliver. We specialize in advancing your product through the non-clinical development process, getting your product into global markets on time while delivering the highest quality. We conduct safety evaluation studies (*in vitro* and *in vivo*) on a variety of biomaterials, medical devices, and related products to identify the presence of toxins and other potentially harmful effects of the product. Our testing ranges from the initial screening of new materials to product release testing, periodic audit testing, and non-clinical or pre-market safety evaluations to meet current FDA and international standards.

We perform testing to evaluate biocompatibility appropriate to the intended use of the component material or finished product. These tests challenge various biological models with the test material or a suitable extract. Specific safety programs follow U.S. Food and Drug Administration (FDA) guidance and

HISTOPATHOLOGY SERVICES

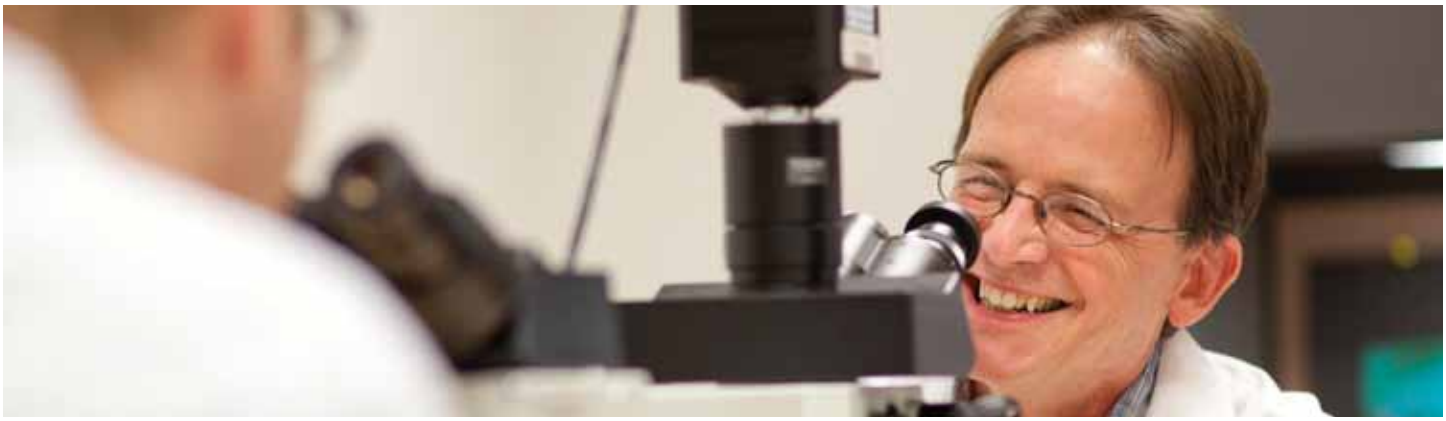
In addition to a wide range of in vitro and in vivo toxicology services, we also offer complete histopathological services. We use advanced histological technology to test and evaluate implanted medical devices. We employ unique equipment that allows hard implants to be processed while maintaining intimate contact with surrounding tissue and that permits high-quality processing of soft implants in hard tissue without decalcification. Valuable tissues can be collected and processed on site under the supervision of a of a board certified pathologist. Services are also provided on fixed tissues from outside sources.

- State-of-the-art histology laboratory
- Specialized tissue-implant processing using the Exakt® Histological System
- Quantitative pathology
- Ultrastructural pathology (SEM, TEM)
- Routine paraffin processing and sectioning
- Soft and hard resin (plastic) processing and sectioning
- Non-decalcified and decalcified processing and sectioning
- Custom sample preparation and sectioning
- Biomarkers and immunohistochemistry capabilities
- Photomicrograph documentation
- Necropsy services
- Timely and efficient reporting
- Consultation

Our specific safety programs follow FDA guidance and ISO 10993 standards. And our people work together—you're likely to work with a team that includes toxicologists, veterinary surgeons and board certified pathologists —giving you a product development process that is driven by the best combination of the very best people and processes available anywhere in the world.

We evaluate a wide variety of devices and materials. Here's a sampling of

- Absorbent Incontinence Products
- Adhesives
- Blood Collection & Storage Devices
- Bone Void Fillers
- Central Nervous System Implants
- Combination Products
- Contact Lenses
- Dental Implants
- Devices Containing Antimicrobials
- Device Raw Materials
- Hemodialysis Disposables
- Implantable Drug Delivery Devices
- Infusion/transfusion Devices
- Intraocular Lenses
- Laparoscopes & Endoscopes
- Ocular Implants
- Orthodontic Devices
- Orthopedic Implants
- Ostomy Devices
- Reusable Devices
- Surgical Gloves
- Sutures
- Syringes
- Urinary Stents
- Urologic Catheters
- Vascular Catheters
- Vascular Grafts
- Vascular Stents
- Ventricular Assist Devices
- Wound Drainage Devices
- Wound Dressings



BIOCOMPATIBILITY TEST MATRIX

Specific safety evaluation programs follow International Organization for Standardization (ISO) 10993 standards and Food and Drug Administration (FDA) guidance (May 1, 1995). The table is based on ISO 10993-1 Evaluation and Testing, 2009 edition. While the table has been developed as a guideline for biocompatibility testing, it is essential that each device be evaluated based on its own unique characteristics.

DEVICE CATEGORIES			BIOLOGICAL EFFECT											
BODY CONTACT		**CONTACT DURATION** **A** = LIMITED (≤24 HOURS) **B** = PROLONGED (24 HOURS – 30 DAYS) **C** = PERMANENT (>30 DAYS)	Cytotoxicity	Sensitization	Irritation/Intracutaneous	Acute Systemic Toxicity	Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	Reproductive/Developmental	Biodegradation
SURFACE DEVICES	SKIN	A	x	x	x									
		B	x	x	x									
		C	x	x	x									
	MUCOSAL MEMBRANE	A	x	x	x									
		B	x	x	x	o	o		o					
		C	x	x	x	o	x	x	o		o			
	BREACHED OR COMPROMISED SURFACES	A	x	x	x	o								
		B	x	x	x	o	o		o					
		C	x	x	x	o	x	x	o		o			
SURFACE DEVICES	BLOOD PATH, INDIRECT	A	x	x	x	x				x				
		B	x	x	x	x	o			x				
		C	x	x	o	x	x	x	o	x	o	o		
	TISSUE / BONE / DENTIN COMMUNICATING[1]	A	x	x	x	o								
		B	x	x	x	x	x	x	x					
		C	x	x	x	x	x	x	x		o	o		
	CIRCULATING BLOOD	A	x	x	x	x		o[2]		x				
		B	x	x	x	x	x	x	x	x				
		C	x	x	x	x	x	x	x	x	o	o		
IMPLANT DEVICES	TISSUE / BONE	A	x	x	x	o								
		B	x	x	x	x	x	x	x					
		C	x	x	x	x	x	x	x		o	o		
	BLOOD	A	x	x	x	x	x		x	x				
		B	x	x	x	x	x	x	x	x				
		C	x	x	x	x	x	x	x	x	o	o		

X = Tests per ISO 10993-1

O = Additional tests that may be applicable in the U.S.

Note[1] - Tissue includes tissue fluid and subcutaneous spaces

Note[2] - For all devices used in extracorporeal circuits

To access a copy of this online, visit: www.namsa.com and search "biocompatibility-matrix"

We've been the world's leading medical device research organization for over 40 years.

You want sound advice and action from a partner who can quickly move your product into a global market. So we've made a science out of service, identifying challenges and solving them with the right advice at exactly the right time. We can guide and support you through the most complex submissions and the most rigorous testing programs. We do the work that moves things forward quickly without ever compromising quality. And our passion for scientific integrity gives you the security that you're on the optimal path to market, anywhere in the world.

We've worked with thousands of companies to date—bringing safe, effective, and compliant medical products to market. We are passionate about our people, our scientific integrity, and the breadth of solutions we offer our clients globally. And we're ready. Ready to take you to market.

OUR SERVICES

Regulatory and Quality Systems Consulting
Research and Development Support
Non-Clinical Testing
Clinical Research
Post-Market Support

World Headquarters
6750 Wales Road
Northwood, Ohio 43619 USA

Telephone:
866.666.9455 (toll free)
+1.419.666.9455 (outside of USA)
+1.419.662.4386 (fax)

For more information and a listing of locations worldwide, visit www.namsa.com.

NAMSA®

PEOPLE › SCIENCE › SOLUTIONS