Non-Clinical Testing

ORTHOBIOLOGIC TESTING SERVICES

Unparalleled Experience, Comprehensive Breadth of Solutions, Global Reach
All in one CRO.

For over 40 years NAMSA has been the leading contract research organization helping medical device companies bring safe and effective products to market. NAMSA's comprehensive offering of toxicological (*in vitro* and *in vivo*), analytical chemistry and microbiology testing services provide our clients all the global support and service they need, while working with one single source.

Biocompatibility

Safety evaluation studies, *in vitro* and *in vivo*, are conducted on a variety of biomaterials, medical devices, combination products, and products that contain human tissue when combined with other materials to identify the presence of toxins or any potentially harmful effects of the product.

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.

Studies performed include:

- Bone
- Skin
- Collagen
- Cartilage
- Ligaments
- DBM
- Synthetics
- Biomaterials
- Bioresorbables

Demineralized Bone Matrix (DBM) - Lot Release Testing

Alkaline Phosphatase Assay

This *in vitro* assay, utilizing a mouse myoblast cell line, provides evaluation of DBM products' osteoinductive potential through quantifiable detection and measurement of alkaline phosphatase levels.

Osteoinduction Assay

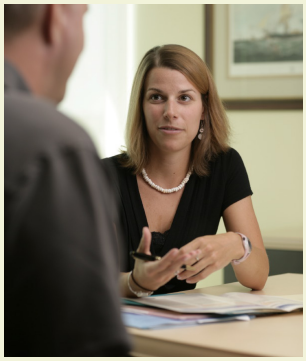
This *in vivo* assay, performed in athymic test models, is used to determine the effectiveness of DBM to induce bone formation by providing a semi-quantifiable measurement of osteoinductive potential. Histopathology, performed by in-house Board Certified Pathologists, quantifies bone formation through a specific scoring method.

Limulus Amebocyte Lysate (LAL)

LAL testing provides quantitative or qualitative detection of endotoxin levels important for predicting pyrogenic responses within various production processes, quality water systems and lot release of products. The LAL test is based upon the reactivity of bacterial endotoxins with a Lysate derived from the circulating cells of the horseshoe crab. NAMSA offers three different LAL methods specific for your product: Kinetic-Chromogenic, Kinetic-Turbidimetric and the gel-clot.

A TAILORED SOLUTION

With insight and a proven approach, we tailor solutions for each client



WITH OUR BREADTH OF SERVICES AND DEPTH OF EXPERIENCE, WE'LL SHOW YOU THE ULTIMATE PATH TO MARKET.

We guide our clients through the simplest submissions and the most complex testing programs, offering strategic guidance at every stage of the entire development process.

- Regulatory & Consulting
- Research & Development
- Non-Clinical Testing
- Clinical Research
- Post-Market Support

NAMSA

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Efficacy Functional Testing

NAMSA's team of in-house veterinary surgeons and scientists offer years of experience in developing and overseeing unique studies designed to demonstrate proof of concept, efficacy and biocompatibility.

Our team offers a broad range of *in vivo* models and analysis tools that will provide data in support of a specific application of a device. NAMSA specializes in a wide variety of different therapies including:

- Orthopedic
- Bone Healing
- Tissue Engineering

Histopathological Capabilities

In addition to the full line of histopathology services, NAMSA has three full-time board certified pathologists in-house. NAMSA provides Advanced Histological Technology for the testing and evaluation of implanted medical devices. Valuable tissues can be collected and processed on site under the supervision of a pathologist. Services are also provided on fixed tissues from outside sources.

Exakt® Histological System for Specialized Tissue-Implant Processing

This unique equipment allows hard implants to be processed while maintaining intimate contact with surrounding tissue and permits the routine high quality processing of soft implants in hard tissue without decalcification. Examples include:

- Bone Cements
- Demineralized Bone
- Bone Plates

Microbiology Services, Sterility Assurance & Packaging Validation

Our well-equipped facilities contain laboratories for bacteriology and sterility testing, clean rooms, aging chambers and media preparation areas. We perform custom and routine studies such as:

- Cleaning Studies
- Antimicrobial Studies
- Disinfection Studies
- Product Sterility
- Sterilization Validation
- Bioburden
- Microbial Identification
- Product/Packaging Aging & Stability

Materials Characterization and Analytical Chemistry

In addition to the tests outlined in the NAMSA Characterization Matrix™, we offer a comprehensive range of chemistry testing services to ensure product quality and consistency during all stages of development. Our technical specialists are prepared to design and implement special studies for medical devices, pharmaceutical container/closure systems and other innovative products.

NAMSA Certifications

NAMSA laboratories are registered with and inspected by the United States Food and Drug Administration (FDA), Department of Agriculture (USDA) and the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). NAMSA's quality system complies with FDA 21 CFR 820, FDA 21 CFR 58, FDA 21 CFR 210/211, FDA CFR 11, ISO 13485:2003 and ISO 17025:2005.

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