NORTH AMERICAN BIOMEDICAL INSTITUTE

- Good Laboratory Practice **(GLP)** certified
- **US FDA 21CFR 58** compliant
- **ISO 17025** accredited
- Laboratories located in **USA, United Kingdom** and **Poland**

Our studies are recognized by **Competent Authorities** (e.g. FDA, MHLW, MFDS, ANVISA) and **Notified Bodies**

We provide **comprehensive**, in-house **biocompatibility** and **chemistry testing** of medical devices according to the ISO 10993 standards.

International Organization for Standardization ISO 17025

CERTIFIED GLP GOOD LABORATORY PRACTICE

+1 407-278-6815
www.nabi.bio
contact@nabi.bio

NORTH AMERICAN BIOMEDICAL INSTITUTE

List of routinely conducted tests:

Biological Evaluation Plan (**BEP**)	ISO 10993-1
Physical and/or chemical information (**extractables & leachables**)	ISO 10993-18
Toxicological risk assessment	ISO 10993-17
Cytotoxicity	ISO 10993-5
Sensitization	ISO 10993-10
Irritation or Intracutaneous reactivity	ISO 10993-23
Material mediated pyrogenicity	ISO 10993-11
Acute systemic toxicity	ISO 10993-11
Subacute toxicity	ISO 10993-11
Subchronic toxicity	ISO 10993-11
Chronic toxicity	ISO 10993-11
Implantation effects	ISO 10993-6
Hemocompatibility	ISO 10993-4
Genotoxicity	ISO 10993-3
Carcinogenicity	ISO 10993-11
Reproductive/developmental toxicity	ISO 10993-3
Degradation	ISO 10993-13, -14, -15, -16
Nanomaterials	ISO 10993-22
Biological Evaluation Report (**BER**)	ISO 10993-1

BIOLOGICAL SAFETY TESTING - BIOCOMPATIBILITY

CHEMISTRY TESTING

MICROBIOLOGY & STERILITY

PACKAGE & REPROCESSING VALIDATIONS

Contact us to receive a **competitive offer** and **professional advice**:

+1 407-278-6815 www.nabi.bio contact@nabi.bio

LinkedIn