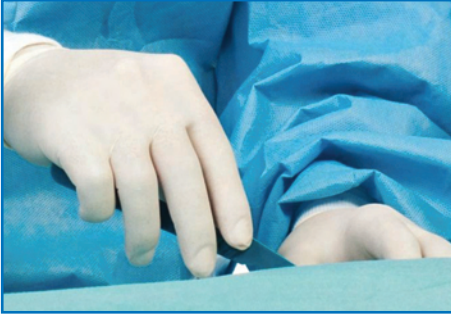


biocompatibility testing



WuXi AppTec's comprehensive menu of biocompatibility services includes all the tests related to the ISO/FDA "Tests for Consideration." [See reverse side.] In addition, we offer the specialized testing services that may be required for Japanese MHLW submissions.

While ISO, FDA and MHLW guidelines provide a general framework, the number and types of specific tests required to assess a product's safety and compliance are dependent on the individual characteristics of the device, its component materials and its intended clinical use. The experts at WuXi AppTec can assist you in designing thorough, well constructed testing programs to satisfy regulatory requirements.

Cytotoxicity (*in-vitro*)

- Agarose Overlay [USP, ISO]
- MEM Elution [USP, ISO]
- Direct Contact
- MTT
- Neutral Red Uptake
- Extract Colony Assay [MHLW]

Sensitization (*in-vivo*)

- Guinea Pig Maximization
- Guinea Pig Repeated Patch (Buehler)
- Murine Local Lymph Node Assay (LLNA)
- Maximization Sensitization Test [MHLW]

Irritation/Intracutaneous Reactivity (*in-vivo*)

- Intracutaneous [USP, ISO, MHLW]
- Primary Skin Irritation [ISO, MHLW]
- Mucosal Irritation: Oral • Vaginal • Bladder
- Acute Dermal Limit

Systemic (Acute) Toxicity (*in-vivo*)

- Acute Systemic Toxicity [USP, ISO, MHLW]
- Pyrogen – Materials Mediated [USP, ISO, MHLW]
- Mouse Safety & Abnormal Toxicity

Subacute / Subchronic Toxicity (*in vivo*)

- Subacute Toxicity
- Intravenous • Intraperitoneal
- Subchronic Toxicity [MHLW]

Genotoxicity (*in-vitro and in-vivo*)

- In-vitro* Bacterial Mutagenicity (Ames)
- In-vitro* Mouse Lymphoma
- In-vitro* Chromosomal Aberration
- In-vivo* Mouse Micronucleus
- Bacterial Reverse Mutation [MHLW]
- In-vitro* Chromosome Aberration [MHLW]

Implantation (*in-vivo*)

- Intramuscular Implant [USP, ISO, MHLW]
- Subcutaneous Implant
- Intraperitoneal Implant

Hemocompatibility (*in-vitro and in-vivo*)

- Hemolysis Test
 - Extract Method [ASTM or NIH]
 - Direct Contact Method [ASTM or NIH]
 - Hemolytic Toxicity [MHLW]
- Complement Activation
- Coagulation Studies
- Platelet and Leukocyte Counts
- Intravascular Thrombogenicity

Chronic Toxicity

- Subcutaneous • Intraperitoneal
- Dermal • Intravenous • Oral

Carcinogenicity

Clinical Pathology

- Clinical Chemistry • Hematology

Histopathology / Immunochemistry

Other Biocompatibility Testing

- USP Rabbit Pyrogen Test
- LAL Bacterial Endotoxin Tests for Pyrogenicity
- USP Safety Test in Mice and Guinea Pigs
- In-Vivo* Assay for Viral Contaminants
- Cytotoxicity Screening of Dissolvable Materials
- USP Class I - VI Plastics Testing

Part 18 Risk Assessment & Materials Characterization

Customized assays, toxicology and custom implant studies also available.

Talk to us and find out how our biocompatibility testing services can work for you.

Contact a WuXi AppTec Account Manager at 651-675-2000 or email: info@wuxiapptec.com



Expert Solutions for Product Development

WuXi AppTec’s comprehensive biocompatibility testing menu features multiple modalities to simulate clinical relevance and achieve the highest quality data, including all the “Tests for Consideration.”

DEVICE CATEGORIES		BIOLOGICAL EFFECT									
		Initial							Other		
Body Contact	Contact Duration A – Limited [≤ 24 hrs] B – Prolonged [>24 hrs to ≤30 days] C – Permanent [>30 days]	Cytotoxicity	Sensitization	Irritation	Systemic Toxicity (Acute)	Subchronic Toxicity (Subacute)	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity
		SURFACE DEVICES	Skin	A	●	●	●				
B	●			●	●						
C	●			●	●						
Mucosal Membranes	A		●	●	●						
	B		●	●	●	◇	◇		◇		
	C		●	●	●	◇	●	●	◇		◇
Breached or Compromised Surfaces	A		●	●	●	◇					◇
	B		●	●	●	◇	◇		◇		
	C		●	●	●	◇	●	●	◇		◇
EXTERNAL COMMUNICATING DEVICES	Blood Path, Indirect	A	●	●	●	●				●	
		B	●	●	●	●	◇			●	
		C	●	●	◇	●	●	●	◇	●	◇
	Tissue /Bone/ Dentin Communicating	A	●	●	●	◇					
		B	●	●	●	●	●	●			
		C	●	●	●	●	●	●		◇	◇
	Circulating Blood	A	●	●	●	●		◇		●	
		B	●	●	●	●	●	●	●		
		C	●	●	●	●	●	●	●	●	◇
IMPLANT DEVICES	Tissue / Bone	A	●	●	●	◇					
		B	●	●	●	●	●	●			
		C	●	●	●	●	●	●	●		◇
	Blood	A	●	●	●	●	●		●		
		B	●	●	●	●	●	●	●		
		C	●	●	●	●	●	●	●	●	◇

● = ISO Evaluation Tests for Consideration ◇ = Additional tests that the FDA considers may be applicable

“TESTS FOR CONSIDERATION”

Per ISO10993 and FDA Guidances

This table outlines the ISO/FDA test modalities frequently used to study the biological safety and biocompatibility of devices and combination products. These tests should be conducted on final product or representative samples according to the category of the device (based on anatomic location and duration of contact).



To learn more about our biocompatibility services, contact a WuXi AppTec Account Manager at 651-675-2000 or email: info@wuxiapptec.com