

Biocompatibility Testing



HOW TO

Keep your product on course to meet regulatory requirements worldwide



The Leader in Combination Product Services



Biocompatibility Testing

Expert guidance and testing to keep your device / combination product on track

For nearly 20 years, the experienced, knowledgeable scientists at WuXi AppTec have provided medical device and combination product manufacturers with expert guidance in designing biocompatibility testing programs that lead to regulatory submission success.

And our comprehensive menu of services includes all the tests related to the ISO/FDA test modalities frequently used to study the biological safety and biocompatibility of devices and combination products – as outlined in the table below – as well as tests that may be required for Japanese (JMHLW) submissions.



DEVICE CATEGORIES		Contact Duration	BIOLOGICAL EFFECT										
			Initial							Other ⁴			
Body Contact		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 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	●	●	●	●	●	●	●	●	◇	◇	

TESTS FOR CONSIDERATION

This table is based on ISO 10993-1:2009 and FDA G95-1 Guidelines

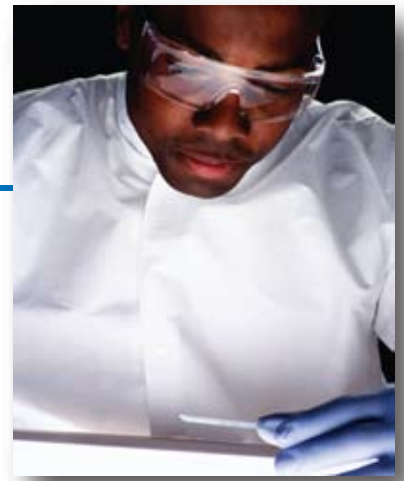
- – ISO Evaluation Tests for Consideration
- ◇ – Additional tests that the FDA considers may be applicable

¹ "Tissue" includes tissue fluids and subcutaneous spaces.

² For all devices used in extracorporeal circuits.

³ Pyrogenicity / Materials Mediated should be considered.

⁴ Supplemental tests for consideration.



CHOOSING THE RIGHT COURSE

The wrong program or study design can, at a minimum, require retesting or even possibly delay or derail a promising product in the regulatory cycle.

Establishing the safety of a medical device is the fundamental purpose of biocompatibility testing. The ability of a testing program to accurately assess safety issues can be dramatically impacted by the design of the study plan. Programs must be designed to adequately identify hazards, distinguish between presence and bioavailability of potential hazards, and estimate overall risk.

Medical Devices

The intended clinical use of a medical device is the key factor in constructing a correct study plan and assay design.

In setting up testing programs for devices, guidance documents such as 10993-1 are invaluable. But choosing the correct testing program for a particular device requires interpretation of those guidances based on an understanding of the intended clinical use of the device, with assays designed to mimic the actual clinical application. When determining the best program for your product, you can count on the expert assistance of WuXi AppTec, with our experience based on thousands of biocompatibility studies.

Combination Products

By their nature, combination products add an additional layer of complexity when choosing the correct regulatory path and creating study designs.

Combination products present a more complicated challenge in the development of testing plans and assay designs to meet regulatory submission requirements. Not only might studies involve complexities such as altered dosing routes and dose range studies, but sample preparation often must be adapted to best characterize the product. As the leader in combination product services, WuXi AppTec has the expertise to help your design team develop successful testing plans for your specific product.



Custom In-Life Services for Device & Materials Testing

Medical devices and combination products frequently require testing beyond the standard ISO/FDA 10993 testing methods. These additional tests may be performed to better understand material performance, device performance and design, and implant methodologies and training. WuXi AppTec's capabilities support a comprehensive range of GLP and R&D device/material testing. Because of the diversity of medical device/combination product design and usage, we recognize that each device and situation must be evaluated with the client and a systematic approach developed that successfully meets all of the project requirements.

Biocompatibility Testing

PRODUCT EXPERTISE

With over 20 years of experience, WuXi AppTec is a recognized leader in biocompatibility testing for a variety of devices/combination products, including:

- Device/Drug Combinations
- Device/Tissue Combinations
- Device Implants
- Single-Use Devices
- Hemostasis / Wound Healing
- Orthopedic Devices
- Cardiology Devices
 - Catheters and Coronary Stents
 - Atherectomy Devices
 - Pacing and Defibrillation Products
 - Chronic Sensors
 - Fabrics and Vascular Grafts
- Other Devices and Materials
 - Monoclonal Antibodies
 - Laparoscopic/Endoscopic Devices
 - Allografts, Autografts and Xenografts
 - Neurostimulation Devices

PROGRAM FEATURES

- ISO 17025 accreditation
- Experienced staff
- Service on ISO Technical Advisory Group
- In-house surgeons and veterinarians
- On-site histopathology
- On-site clinical pathology, including clinical chemistry, hematology, urine analysis and coagulation
- Protocols on file
- Specific programs to meet worldwide regulatory expectations
- Thousands of biocompatibility assays performed; hundreds of them on combination products



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Contact us to learn more about biocompatibility testing for your product:

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