

Biocompatibility Testing

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).

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

