GUIDE TO SAMPLE REQUIREMENTS FOR BIOCOMPATIBILITY TESTING

This chart is designed as a convenient quick guide for some of our most commonly ordered tests (and does not list all available tests).

Sample requirements represent the total number of extracts / replicates needed. For example, Partial Thromboplastin Time requires three replicates at 4 cm^2 each. The sample sizes reflect the minimum amount of sample, depending on the test being performed. For liquid samples, please inquire.

TESTS PERFORMED USING EXTRACTION RATIOS				
	< 0.5 mm thickness Ratio: 6 cm^2 / 1 mL	> 0.5 mm thickness Ratio: 3 cm^2/ 1 mL	Irregularly Shaped Ratio: 0.2 g / 1 mL	Membranes /Textiles Ratio: 0.1 g / 1 mL
CYTOTOXICITY				
MEM Elution Using L-929 Mouse Fibroblast Cells - ISO/USP	1 x 30 cm^2	1 x 15 cm^2	1 x 1 g	1 x 0.5 g
MEM Endpoint Dilution Using L-929 Mouse Fibroblast Cells	1 x 48 cm^2	1 x 24 cm^2	1 x 1 g	1 x 0.8 g
MTT Cytotoxicity Using L-929 Mouse Fibroblast Cells	1 x 30 cm^2	1 x 15 cm^2	1 x 1 g	1 x 0.5 g
Neutral Red Uptake (NRU)	1 x 42 cm^2	1 x 21 cm^2	1 x 1.4 g	1 x 0.7 g
SENSITIZATION				
Maximization Sensitization (Guinea Pig) — ISO	6 x 60 cm^2	6 x 30 cm^2	6 x 2 g	6 x 1 g
IRRITATION				
Intracutaneous Irritation — ISO / USP	2 x 36 cm^2	2 x 18 cm^2	2 x 1.2 g	2 x 0.6 g
Vaginal Mucosal Irritation — ISO	10 x 60 cm^2	10 x 30 cm^2	10 x 2 g	10 x 1 g
ACUTE SYSTEMIC TOXICITY				
Acute Systemic Toxicity— ISO / USP	2 x 48 cm^2	2 x 24 cm^2	2 x 1.6 g	2 x 0.8 g
PYROGENICITY				
Materials Mediated Rabbit Pyrogen — ISO	900 cm^2	450 cm^2	30 g	6 x 1 g
SUBACUTE / SUBCHRONIC TOXICITY				
Subchronic Intravenous Toxicity (Mice) — 14 Dose	14 x 48 cm^2	14 x 24 cm^2	14 x 1.6 g	2 x 0.8 g
Subacute Intraperitoneal Toxicity (Mice) — 14 Dose	14 x 30 cm^2	14 x 15 cm^2	14 x 1 g	14 x 0.5 g
Subchronic Intravenous Toxicity (Rats) — 14 Dose	14 x 270 cm^2	14 x 135 cm^2	14 x 9 g	14 x 4.5 g
Subacute Intraperitoneal Toxicity (Rats) — 14 Dose	14 x 90 cm^2	14 x 45 cm^2	14 x 3 g	14 x 1.5 g
Subacute Intravenous Toxicity (Rats) — 28 Dose	28 x 270 cm^2	28 x 135 cm^2	28 x 9 g	28 x 4.5 g
GENOTOXICITY				
Bacterial Mutagenicity (Ames)	2 x 24 cm^2	2 x 12 cm^2	2 x 0.8 g	2 x 0.4 g
in-Vitro Chromosome Aberration*	2 x 42 cm^2	2 x 21 cm^2	2 x 1.4 g	2 x 0.7 g
in-Vitro Mouse Lymphoma with Extended Treatment*	2 x 60 cm^2	2 x 30 cm^2	2 x 2 g	2 x 1 g
in-Vivo Mouse Micronucleus	2 x 120 cm^2	2 x 60 cm^2	2 x 4 g	2 x 2 g

*Additional sample is required for each ratio for extraction temperatures below 50 degrees Celsius (i.e., if culture media is used); please inquire.

IMPLANTATION TESTS (NOTE: Turnaround times are in addition to implant duration.)		
Intramuscular / Subcutaneous Implantation (3 Rabbits) — ISO	Sufficient material to produce 18 implants, approx. 10 mm x 3 mm each	**For GLP Testing:** Part 58 of the Code of Federal Regulations (CFR), which describes the requirements for Good Laboratory Practice (GLP) for Non Clinical Laboratory Studies, states in section 58. 105, part (d), that "For studies of more than 4 weeks duration, reserve samples from each batch of test and control articles shall be retained for the period of time provided by 58. 195." Please provide one additional sample per batch of test and control article for WuXi Medical Device Testing to retain. If you are unable to supply the additional sample, it will be noted in the final report.
Intramuscular / Subcutaneous Implantation (5 Rabbits) — ISO	Sufficient material to produce 28 implants, approx. 10 mm x 3 mm each	
Intramuscular Implantation — USP	Sufficient material to produce 13 implants, approx. 10 mm x 3 mm each	

GUIDE TO SAMPLE REQUIREMENTS FOR BIOCOMPATIBILITY TESTING

HEMOCOMPATIBILILTY / BLOOD COMPATIBILITY TESTS			
	< 0.5 mm thickness Ratio: 6 cm^2 / 1 mL	> 0.5 mm thickness Ratio : 3 cm^2 / 1 mL	Irregularly Shaped Ratio: 0.2 g / 1 mL
Complement Activation C3a and SC5b-9	6 cm^2	3 cm^2	0.2 g
Hemolysis: ASTM — Direct Contact	3 x 42 cm^2	3 x 21 cm^2	3 x 1.4 g
Hemolysis: ASTM — Extract	3 x 60 cm^2	3 x 30 cm^2	3 x 2 g
In-Vitro Hemocompatibility	3 x 12 cm^2		
Partial Thromboplastin Time	3 x 6 cm^2		
Platelet and Leukocyte Count	3 x 12 cm^2		
Thromboresistance (*in-vivo*)	1 test sample and 1 comparison sample per animal (minimum of 2 each)		
** Concurrent testing of sponsor-supplied comparison product is recommended. (Required for thromboresistance studies.) Sample size of the comparison product should be the same as that of the test article*			

TESTS PERFORMED USING EXTRACTION RATIOS				
	< 0.5 mm thickness Ratio: 6 cm^2 / 1 mL	> 0.5 mm thickness Ratio: 3 cm^2 / 1 mL	Irregularly Shaped Ratio: 0.2 g / 1 mL	Membranes / Textiles Ratio: 0.1 g / 1 mL
JAPANESE MINISTRY OF HEALTH, LABOR AND WELFARE (MHLW)				
MHLW Cytotoxicity Test Colony Microassay by Elution	150 cm^2	150 cm^2	2 g	2 g
MHLW Hemolysis	3 x 120 cm^2	3 x 60 cm^2	3 x 4 g	3 x 2 g
MHLW Intracutaneous Irritation	2 x 36 cm^2	2 x 18 cm^2	2 x 1.2 g	2 x 0.6 g
MHLW Materials Mediated Rabbit Pyrogen	900 cm^2	120 cm^2	2 g	2 g
MHLW Acute Systemic Toxicity	2 x 48 cm^2	2 x 24 cm^2	2 x 1.6 g	2 x 0.8 g
MHLW Subacute Intravenous Toxicity (28 Day / 28 Dose)	28 x 600 cm^2	28 x 300 cm^2	28 x 20 g	28 x 10 g
MHLW Intramuscular / Subcutaneous Implantation	Sufficient material to produce 18 implants, approx. 10 mm x 3 mm each			

TESTS PERFORMED USING EXHAUSTIVE EXTRACTION METHODS				
	PRETEST	METHOD 1	METHOD 2	
			Ratio: 0.2 g / 1 mL	Ratio: 6 cm^2 / 1 mL
MHLW Bacterial Reverse Mutation (Ames Assay)	1 x 30 cm^2	1 x 15 cm^2	1 x 1 g	1 x 0.5 g
MHLW *In-Vitro* Mouse Lymphoma			1 x 1 g	1 x 0.8 g
MHLW *In-Vitro* Chromosome Aberration			1 x 1.2 g	1 x 0.6 g
MHLW *In-Vivo* Mouse Micronucleus			2 x 1.4 g	2 x 0.7 g
MHLW Maximization Sensitization			2 x 1.4 g	

TESTS PERFORMED USING THE PATCH METHOD (SKIN CONTACTING)	
Agarose Overlay Using L-929 Cells – ISO / USP	Sufficient material to produce 3 patches, 1 cm x 1 cm each — Maximum of 2 materials per test Sufficient material to produce 7 patches, 2.5 cm x 2.5 cm each — Maximum of 4 materials per test
Primary Skin Irritation - ISO	Sufficient material to produce 116 patches, 2.5 cm x 2.5 cm each — Maximum of 4 materials per test
Repeated Patch Dermal Sensitization Test - Buehler	Sufficient material to produce 116 patches, approx. 2.5 cm x 2.5 cm each 50 mL of liquid **For GLP Testing:** Part 58 of the Code of Federal Regulations (CFR), which describes the requirements for Good Laboratory Practice (GLP) for Non Clinical Laboratory Studies, states in section 58. 105, part (d), that "For studies of more than 4 weeks duration, reserve samples from each batch of test and control articles shall be retained for the period of time provided by 58. 195." Please provide one additional sample per batch of test and control article for WuXi Medical Device Testing to retain. If you are unable to supply the additional sample, it will be noted in the final report.