

**LABORATORY SERVICE REQUEST- BIOCOMPATIBILITY (ISO)**

<b>Client Info</b>	Report To <i>(Please include contact name and company info.)</i>		Invoice To <i>(If different than Report To info.)</i>	
	Phone	Fax		Client P.O. Number
	Email			PBL Quote Number

<b>Test Article Info</b>	Test Article ID <i>(Please use the exact wording you want to appear in the final report.)</i>			
	Quantity	Lot No.		Sample Code
	Part Number		Expiration Date	
	Storage Conditions <input type="checkbox"/> 20 to 25°C <input type="checkbox"/> 2 to 8°C <input type="checkbox"/> -16 to -24°C <input type="checkbox"/> -60 to -80°C			
	Controlled Substance <input type="checkbox"/> No <input type="checkbox"/> Yes Schedule			
	Hazardous <input type="checkbox"/> No <input type="checkbox"/> Yes Type of Hazard <i>(Please include MSDS if samples are hazardous. Client will incur charges for disposal of hazards.)</i>			
	Return Test Articles <input type="checkbox"/> No <input type="checkbox"/> Yes Carrier Account # <i>(Client will incur charges for shipping and handling)</i>			
	List part(s) of the Test Article that should be tested			
	Final intended use/application of Test Article?			
	GLP Stability Testing and Test Article Characterization			
	<b>Completed and:</b>		<b>To Be Completed by Sponsor and:</b>	
	<input type="checkbox"/> Will be provided during study		<input type="checkbox"/> Will be provided during study	
	<input type="checkbox"/> Will <b>not</b> be provided during study		<input type="checkbox"/> Will <b>not</b> be provided during study	
	Note: Failure to provide test article characterization/stability information may constitute a regulatory violation.			
	Sterility Status <input type="checkbox"/> Non-Sterile <input type="checkbox"/> Sterile <i>(Please indicate method)</i>			
Can Test Article be cut? <input type="checkbox"/> Yes <input type="checkbox"/> No				
Extraction Conditions <i>(for tests other than the Cytotoxicity tests)</i> <input type="checkbox"/> 121°C for 1 hour <input type="checkbox"/> 70°C for 24 hours <input type="checkbox"/> 50°C for 72 hours <input type="checkbox"/> 37°C for 72 hours <input type="checkbox"/> Other <i>(provide justification)</i>				
Surface Area in cm <sup>2</sup> if Known		Thickness		
Surface Area Calculations Completed By: <input type="checkbox"/> Client <input type="checkbox"/> Consultant <input type="checkbox"/> via CAD (technical) Drawing <input type="checkbox"/> To Be Completed By PBL <input type="checkbox"/> Other				

<b>Service</b>	Regulatory Treatment <input type="checkbox"/> cGMP <input type="checkbox"/> GLP <input type="checkbox"/> Non-regulatory <i>(GLP will incur an additional fee.)</i>			
	Regulatory Compliance Needed (GLP only): <input type="checkbox"/> FDA <input type="checkbox"/> European Union <input type="checkbox"/> Other			
	Purpose of Testing: <input type="checkbox"/> 510K <input type="checkbox"/> IND <input type="checkbox"/> Other			
	Rush <i>(Will incur a 50% surcharge.)</i> <input type="checkbox"/> No <input type="checkbox"/> Yes			
	Do You Want Report Date Confirmation? <input type="checkbox"/> No <input type="checkbox"/> Yes			
Report Format <input type="checkbox"/> Paper <input type="checkbox"/> PDF <input type="checkbox"/> Paper and PDF <i>(First format NC, \$6.00 for each additional.)</i>				

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<b>Service</b>	<b>Archive Options (for Paper Records and Specimens – tissues, blocks and slides)</b>			
	All paper records will be scanned and stored at PBL indefinitely by a system that is validated to comply with GMP and GLP regulations. Paper records and GLP Specimens will be stored by PBL at no charge for the first year after study completion. If no options are selected, default options will take effect. Extended storage will be invoiced annually per Fee Schedule at <a href="http://www.PacificBioLabs.com/archivefeeschedule.asp">www.PacificBioLabs.com/archivefeeschedule.asp</a> .			
	<b>Non GLP RPT</b>	<b>GLP RPT</b>	<b>GLP Specimen</b>	<b>Archive Options</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Discard (after one year) – <b>Non-GLP Default</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Return to Client (after one year) – <b>GLP Default</b> (Shipping charges apply)
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Return Immediately to Client (at study completion) – (Shipping charges apply)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Extended Storage by PBL (after one year) - Invoiced annually for continued PBL retention.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Client Default – Previously selected options by Client	

ISO 10993-12, *The standard surface area can be used to determine the volume of extraction vehicle needed. This area includes the combined area of both sides of the sample and excludes indeterminate surface irregularities. When surface area cannot be determined due to the configuration of the sample, a mass/volume of extracting fluid shall be used.*

Unusually complex surface area calculations that are to be performed by PBL may incur additional charges.

Extraction of large samples may incur additional media charges.

**Please check all required tests.**

<b>ANALYSIS REQUIRED (Please check all required tests.)</b>	<b>CYTOTOXICITY</b> <i>ISO 10993-5:</i>			
	STANDARD METHOD <i>(Only elution tests will be extracted and/or incubated at 37°C for 24 hours in MEM, unless otherwise specified by sponsor.)</i>		MODIFIED METHOD <i>(All cytotoxicity samples will be extracted in 0.9% Sodium Chloride Injection (SCI) USP, unless otherwise specified by sponsor.)</i>	
	<input type="checkbox"/> Agar Diffusion <input type="checkbox"/> MEM Elution (extract test) <input type="checkbox"/> Direct Contact		<input type="checkbox"/> Agar Diffusion <input type="checkbox"/> MEM Elution (extract test) <input type="checkbox"/> Direct Contact	
	Select one extraction condition per modified test			
			<input type="checkbox"/> 121°C for 1 hour <input type="checkbox"/> 70°C for 24 hours <input type="checkbox"/> 50°C for 72 hours <input type="checkbox"/> 37°C for 72 hours <input type="checkbox"/> Other	
<b>SENSITIZATION</b> <i>ISO 10993-10:</i>				
<input type="checkbox"/> Murine Local Lymph Node Assay (LLNA) <b>Please select extraction medium:</b> <input type="checkbox"/> Saline <input type="checkbox"/> Acetone in Olive Oil <input type="checkbox"/> DMSO <input type="checkbox"/> Other				
<input type="checkbox"/> Maximization Test for Delayed Hypersensitivity <b>Please select extraction medium:</b> <input type="checkbox"/> Saline <input type="checkbox"/> Vegetable Oil <input type="checkbox"/> Other				
<input type="checkbox"/> Closed Patch Test				
<b>IRRITATION</b> <i>ISO 10993-10:</i>				
<input type="checkbox"/> Intracutaneous (Intradermal) Reactivity Test <input type="checkbox"/> Skin Irritation Test <input type="checkbox"/> Ocular Irritation Test				
Mucous Membrane → <input type="checkbox"/> Vaginal <input type="checkbox"/> Rectal <input type="checkbox"/> Penile <input type="checkbox"/> Oral Mucosal (Hamster Cheek Pouch)				
<b>Please select extraction medium:</b> <input type="checkbox"/> Saline <input type="checkbox"/> Vegetable Oil <input type="checkbox"/> Other				
<b>SYSTEMIC</b> <i>ISO 10993-11:</i>				
<input type="checkbox"/> Acute Systemic Toxicity Test <b>Please select extraction medium:</b> <input type="checkbox"/> Saline <input type="checkbox"/> Vegetable Oil <input type="checkbox"/> Other				
<input type="checkbox"/> Material Mediated Pyrogenicity ( <i>Saline Extract Only</i> )				

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**SUBACUTE** *ISO 10993-11:*

Repeated Dose Toxicity Study → Duration:  14 Days  28 Days

**Please select route:**  Oral  Dermal  Intravenous  Intraperitoneal  Other

**SUBCHRONIC/CHRONIC** *ISO 10993-11:*

Repeated Dose Toxicity Study → Duration: \_\_\_\_\_ Days

**Please select route:**  Oral  Dermal  Intravenous  Intraperitoneal  Other

**GENOTOXICITY** *ISO 10993-3:*

Ames Test  Mouse Lymphoma  Chromosomal Abberation  Mouse Micronucleus

**Please select extracts:**  Saline  DMSO  PEG 400  Other

**IMPLANTATION\*** *ISO 10993-6:*

Subacute → Duration:  7 Days  14 Days  30 Days

Subchronic → Duration:  60 Days  90 Days

Chronic → Duration:  180 Days  365 Days

*\*Histopathology is included in all ISO implantation studies*

**HEMOCOMPATIBILITY** *ISO 10993-4:*

Hemolysis → **Please select method:**  ASTM Method (*select route*)  NIH Method  
 Direct  
 Indirect  
 Direct and Indirect

Prothrombin Time (PT)  Partial Thromboplastin Time (PTT)

Complement Activation

Platelet Aggregation  Platelet Count  Platelet Activation

*In Vivo* Thrombogenicity (*device must be tubular in nature*)

Other

OTHER TESTS/SPECIAL INSTRUCTIONS

TESTING AUTHORIZED BY (Please sign) \_\_\_\_\_

DATE: \_\_\_\_\_