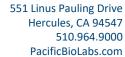


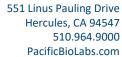
LABORATORY SERVICE REQUEST (LSR) - COMPENDIAL TESTS, IN VIVO SERVICES

CLIENT INFO							
		mples requiring the same storage, handling, a th sample(s). Initiation of sample analysis will					
Sponsor: (Send Report To)		Invoice To:					
Contact Name:		AP Contact Name:					
Company Name:		Company Name:					
Address:		Address:					
City/State/Zip:		City/State/Zip:					
Country:		Country:					
Phone:		Invoice To Email:					
Email:		AP Email:					
PBL Quote Number:		AP Phone:					
PO Number:		☐ Credit Card to be used for payment					
TECT ADTICLE INFO							
TEST ARTICLE INFO							
Lot Number:							
Part Number:							
Other Identifier: (ex. Sample Code)							
Expiration Date:							
Quantity of Test Articles	Submitted: (Please indicate the	number of units, volume, and/or weight of test artic	:le.)				
Physical Description:							
☐ Device ☐	Solid Liquid	Powder Gel	Other:				
Storage Condition:	Controlled Substance:	Hazardous: (include MSDS if samples are hazardous, client will incur charges for disposal of hazards.)	Sample Disposition: (Check one box) (Samples will be discarded 30 days after report unless otherwise indicated)				
☐ Room Temperature ☐ No		☐ Not Hazardous	Return to Sender				
☐ 2 to 8°C		☐ Reactive	Carrier:				
☐ -10 to -25°C ☐ Yes		☐ Biohazard	Account:				
☐ -60 to -90°C	Schedule:	☐ Toxic	Dispose in Municipal waste				
		Other:	☐ Dispose in hazardous waste				





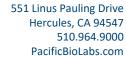
TEST ARTICLE INFO (CONT.)						
List part(s) of the Test Article that should be tested:						
List part(s) of the Test Article that should be excluded:						
Final intended use/application of Test Article?:						
Can Test Article be cut?						
Sterility Status: Non-Sterile Sterile (Please indicate method)						
Extraction Conditions: (for tests other than the Cytotoxicity tests)						
☐ 121°C for 1 hr ☐ 70°C for 24 hrs ☐ 50°C for 72 hrs ☐ 37°C for 72 hrs ☐ Other:						
Surface Area in cm² if Known: Thickness:						
Surface Area Calculations Completed By:						
☐ Client ☐ To be completed by PBL						
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.						
SERVICE INFO						
Regulatory Treatment: Non-regulatory CGMP CLP						
Complete the following section if GLP:						
GLP Stability Testing and Test Article Characterization (Certificate of Analysis):						
☐ Will be provided during study ☐ Will not be provided during study						
Note: GLP testing requires, by Federal regulation, accurate identification of the test and control articles (e.g., a lot number, batch number or sample code) that allows unambiguous traceability of the tested material. GLP testing also requires that the testing laboratory document characterization of the test and control articles for stability, strength, purity, and composition, or other characteristics which will appropriately define the test or control article. This information is typically provided by the Sponsor and is required for each batch of test or control article tested; this documentation is often in the form of a Certificate of Analysis (C of A). For testing of biomedical devices that contain no drugs, Pacific BioLabs requires documentation of the identity, composition, and stability of the material tested. Failure to provide this information will be noted as noncompliance with GLP regulations in the Final Report.						
Rush Services: No Yes (will incur a 50% surcharge)						
Report Format: PDF PDF and Paper Paper (Note: A fee will apply for paper copy of report.)						





TESTS BY PROCEDURE								
CYTOTOXICITY TESTS								
Please specify guidelines: U	se specify guidelines: USP <87> ISO 10993-5							
Please specify test method: A	ease specify test method: Agar Diffusion Direct Contact MEM Elution (extract test)							
All cytotoxicity samples will be extracted and/or incubated at 37°C for 24 hours in MEM, unless otherwise specified by sponsor.								
HEMOCOMPATIBILITY TESTS								
Hemolysis (ASTM Method)								
Please select route: Di	ect	☐ Indirect	☐ Direct and I	ndirect				
PYROGEN TESTS (Please include sample preparation and dosing instructions with submission of test article)								
USP Rabbit Pyrogen Test								
ISO Material Mediated Rabbit Pyrogen Test								
BIOLOGICAL SAFETY TESTS (Please include sample preparation instructions with submission of test article)								
☐ CFR Safety Test ☐ USP Acute Toxicity for Iron Dextran Injection Test ☐ EP Safety Test								
TESTS BY GUIDELINES								
OECD GUIDELINES								
☐ Acute Dermal Toxicity		ute Oral Toxicity		Acute Eye Irritation				
☐ Acute Dermal Irritation	□ Ac	ute Inhalation Toxicity		Buehler Method - Skin Sensitization				
EPA GUIDELINES (OPPTS)								
☐ Acute Dermal Toxicity	☐ Acut	e Oral Toxicity		Acute Eye Irritation				
Acute Dermal Irritation	☐ Acut	e Inhalation Toxicity		Buehler Method - Skin Sensitization				
FHSA GUIDELINES								
☐ Acute Oral Toxicity	Prim	ary Skin Irritation		Primary Eye Irritation				
USP PLASTICS TESTING GUIDELINES								
Class I <88>								
Class II <88>								
Class III <88>								
Class IV <88>								
Class V <88>								
Class VI <88>								
PhysicoChemical <661>								
dditional Service: Autoclaving (121°C for 30 Minutes) (Will incur an additional fee.)								
EP GUIDELINES								
Abnormal Toxicity for Immunosera and Vaccines								

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OTHER TESTS/SPECIAL INSTRUCTIONS:							
The signature of the Sponsor (or Sponsor's representative) below is assurance that 1) the study is ap							
goals and that no alternative <i>in vitro</i> or decreased <i>in vivo</i> animal use procedures are available to meet the stated purpose of the study, 2)							
the species chosen is appropriate to the stated purpose of the study and that use of alternative species has been considered, 3) the study is not an unnecessary duplication of previous work, and 4) the number of animals used is appropriate to establish biological or statistical							
significance as required by the study. The Sponsor also specifies that documentation for the above							
Sponsor.	•						
TESTING AUTHORIZED BY (Please Sign):	DATE:						
(Signature and date, or electronic signature is required for testing to begin; unsigned LSR forms will not be processed)							
(Signature and date) of electronic signature is required for testing to begin, unsigned Estitotins will not be processed)							