

LABORATORY SERVICE REQUEST (LSR) - BIOCOMPATIBILITY (ISO)

CLIENT INFO

(Instructions: Use ONE form for each group of similar samples requiring the same storage, handling, analyses, and compliance. Fill in the form as completely as possible. Submit the form along with sample(s). Initiation of sample analysis will be delayed if form is not complete.)

Sponsor: (Send Report To)		Invoice To: <input type="checkbox"/> (Check Box if same as Sponsor)	
Contact Name:	AP Contact Name:		
Company Name:	Company Name:		
Address:	Address:		
City/State/Zip:	City/State/Zip:		
Country:	Country:		
Phone:	Fax:		
Email:			
PBL Quote Number:	Client P.O. Number:		

TEST ARTICLE INFO

Test Article ID (Please use the exact wording you want to appear in the final report.)

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 article.)

Physical Description:
 Device Solid Liquid Powder Gel Other:

Storage Condition: <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: (include MSDS if samples are hazardous, client will incur charges for disposal of hazards.) <input type="checkbox"/> Not Hazardous <input type="checkbox"/> Reactive <input type="checkbox"/> Biohazard <input type="checkbox"/> Toxic <input type="checkbox"/> Other:	Sample Disposition: (Check one box) (Samples will be discarded 30 days after report unless otherwise indicated) <input type="checkbox"/> Return to Sender Carrier: _____ Account: _____ <input type="checkbox"/> Dispose in Municipal waste <input type="checkbox"/> Dispose in hazardous waste
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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? Yes No

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 GLP

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.)

ANALYSIS REQUIRED - Please check all required tests

CYTOTOXICITY TESTS ISO 10993-5:

(Standard Method - Only elution test will be extracted and/or incubated at 37°C for 24 hours in MEM, unless otherwise specified by sponsor.)

- Agar Diffusion
- Direct Contact
- MEM Elution (extract test)
- MTT - Quantitative Evaluation (extract test)

If modifications are required please specify:

SENSITIZATION TESTS ISO 10993-10:

- Closed Patch Test for Delayed-Type Hypersensitivity
- Maximization Test for Delayed-Type Hypersensitivity

Please select extraction medium: Cottonseed Oil Saline No Extract (Direct Application) Other:

IRRITATION TESTS ISO 10993-10:

- Intracutaneous (intra-dermal) Reactivity Test
- Dermal Irritation Test
- Ocular Irritation Test
- Vaginal Irritation Test
- Rectal Irritation Test
- Penile Irritation Test
- Oral Irritation Test (Hamster Cheek Pouch)

Please select extraction medium: Cottonseed Oil Saline No Extract (Direct Application) Other:

SYSTEMIC TESTS ISO 10993-11:

- Acute Systemic Toxicity Test

Please select extraction medium: Cottonseed Oil Saline No Extract (Direct Application) Other:

- Material Mediated Pyrogenicity (*Saline Extract Only*)

SUBACUTE TOXICITY TESTS ISO 10993-11:

- Repeated Dose Toxicity Study → Custom designed, as per protocol.

SUBCHRONIC/CHRONIC TOXICITY TESTS ISO 10993-11:

- Repeated Dose Toxicity Study → Custom designed, as per protocol.

IMPLANTATION TESTS* ISO 10993-6:

Please select route: Intramuscular Subcutaneous Other:

Please select duration: 7 Days 14 Days 30 Days 60 Days 90 Days 180 Days 365 Days

*Histopathology is included in all implantation studies.

HEMOCOMPATIBILITY ISO 10993-4:

- Hemolysis: ASTM Method

Please select route: Direct and Indirect Direct Indirect

ANALYSIS REQUIRED - Please check all required tests (continued)

SUBCONTRACTED TESTS

GENOTOXICITY ISO 10993-3:

- Ames Test Mouse Lymphoma Chromosomal Aberration Mouse Micronucleus

Please select extracts: Saline DMSO PEG 400 Other: _____

HEMOCOMPATIBILITY ISO 10993-4:

- Prothrombin Time (PT) Partial Thromboplastin Time (PTT)

- Platelet Aggregation Platelet Count

- Compliment Activation

- In Vivo* Thrombogenicity

- Other: _____

Additional Service: Autoclaving (121°C for ~30 minutes) *will incur an additional fee*

Rinsing with sterile water for injection prior to testing - no additional fee

OTHER TESTS/SPECIAL INSTRUCTIONS:

The signature of the Sponsor (or Sponsor's representative) below is assurance that 1) the study is appropriate to the Sponsor's project goals and that no alternative *in vitro* or decreased *in vivo* 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 assurances may be obtained from the

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)