PACIFIC BIOLABS
The Service Leader in Life Science Testing

551 Linus Pauling Drive
Hercules, CA 94547
510.964.9000
PacificBioLabs.com

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:**
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

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:	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 issuance unless otherwise indicated.)
☐ Room Temperature	☐ No	☐ Not Hazardous	☐ Discard
☐ 2 to 8°C		☐ Reactive	☐ Hazardous Waste ☐ Municipal Waste
☐ -10 to -25°C	☐ Yes	☐ Biohazard	☐ Return Unused
☐ -60 to -90°C	Schedule: _____	☐ Toxic	☐ Return All
		☐ Other: _____	Carrier: _____
			Account: _____

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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 of one device (cm^2): _____ Thickness (mm): _____

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.

Note: *Non-patient contacting portions of the medical device should, if possible, be excluded either physically from test sample extracts or by exclusion of the surface area in the calculation of the extraction ratio. When this is not possible, the extraction ratio shall be justified, Ensure that all contacting portions are covered by the selected extraction vehicle volume.*

The extraction ratios are selected based on the thickness of the sample to be tested. Please use the following criteria to select the proper extraction ratio (ISO 10993-12):

☐ 3 cm^2 / 1 mL for samples ≥ 0.5mm thick

☐ 6 cm^2 / 1 mL for samples < 0.5mm thick

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.)

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ANALYSIS REQUIRED - Please check all required tests

CYTOTOXICITY TESTS *ISO 10993-5*:

☐ Agar Diffusion

☐ Direct Contact

☐ MEM Elution (extract test)

Please select extraction condition: ☐ 37°C for 24 hrs ☐ 37°C for 72 hrs (extended extraction)

☐ MTT - Quantitative Evaluation (extract test)

Please select extraction condition: ☐ 37°C for 24 hrs ☐ 37°C for 72 hrs (extended extraction)

Please select if images of the 24-hour and 48-hour scoring are to be included in final report (additional fee will apply).
(Final Reports will not include images unless otherwise indicated.)

☐ Yes, include cell images ☐ No, cell images are not required

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 10993-23:*

☐ Intracutaneous (intradermal) 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

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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*

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)