PBL Pacific BioLabs
The Service Leader in Bioscience Testing

551 Linus Pauling Drive
Hercules, CA 94547
510.964.9000 ph.
510.964.0551 fax
PacificBioLabs.com

LABORATORY SERVICE REQUEST (LSR) - COMPENDIAL TESTS UNDER TOXICOLOGY

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:** (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:	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)
☐ 20 to 25°C	☐ No	☐ Not Hazardous	☐ Return to Sender
☐ 2 to 8°C		☐ Reactive	Carrier: _____
☐ -16 to -24°C	☐ Yes	☐ Biohazard	Account: _____
☐ -60 to -80°C	Schedule: _____	☐ Toxic	☐ Dispose in Municipal waste
		☐ Other:	☐ 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 cm^2 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.)

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TESTS BY PROCEDURE

CYTOTOXICITY TESTS

Please specify guidelines: ☐ USP <87> ☐ ISO 10993-5

Please 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: ☐ Direct ☐ Indirect ☐ Direct and Indirect

PYROGEN TESTS *(Please include sample preparation and dosing instructions with submission of test article)*

☐ USP Rabbit Pyrogen Test

☐ EP 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 ☐ Acute Oral Toxicity ☐ Acute Eye Irritation

☐ Acute Dermal Irritation ☐ Acute Inhalation Toxicity ☐ Buehler Method - Skin Sensitization

EPA GUIDELINES (OPPTS)

☐ Acute Dermal Toxicity ☐ Acute Oral Toxicity ☐ Acute Eye Irritation

☐ Acute Dermal Irritation ☐ Acute Inhalation Toxicity ☐ Buehler Method - Skin Sensitization

FHSA GUIDELINES

☐ Acute Oral Toxicity ☐ Primary Skin Irritation ☐ Primary Eye Irritation

USP PLASTICS TESTING GUIDELINES

☐ Class I <88>

☐ Class II <88>

☐ Class III <88>

☐ Class IV with 7 Day Implant <88>

☐ Class V <88>

☐ Class VI with 7 Day Implant <88>

☐ PhysicoChemical <661>

Additional 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 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)