

LABORATORY SERVICE REQUEST (LSR) – BIOCOMPATIBILITY (ISO)

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|--------------------|--|------|---|--|
| Client Info | Report To (Please include contact name and company info.) | | Invoice To (If different than Report To info.) | |
| | Contact Name: | | Contact Name: | |
| | Company Name: | | Company Name: | |
| | Address: | | Address: | |
| | City/State/Zip: | | City/State/Zip: | |
| | Country: | | Country: | |
| | Phone: | Fax: | Client P.O. Number: | |
| | Email: | | PBL Quote Number: | |

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|--|--|---|---|--|-----------|---|
| Test Article Info | Test Article ID (Please use the exact wording you want to appear in the final report.) | | | | | |
| | 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 Article | <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 Test Article Characterization and Stability (CofA): <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> Completed and: <input type="checkbox"/> Will be provided during study <input type="checkbox"/> Will not be provided during study </td> <td style="width: 10%; text-align: center; vertical-align: top;">or</td> <td style="width: 40%; vertical-align: top;"> To Be Completed by Sponsor and: <input type="checkbox"/> Will be provided during study <input type="checkbox"/> Will not be provided during study </td> </tr> </table> <p>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.</p> | | | Completed and: <input type="checkbox"/> Will be provided during study <input type="checkbox"/> Will not be provided during study | or | To Be Completed by Sponsor and: <input type="checkbox"/> Will be provided during study <input type="checkbox"/> Will not be provided during study |
| | Completed and: <input type="checkbox"/> Will be provided during study <input type="checkbox"/> Will not be provided during study | or | To Be Completed by Sponsor and: <input type="checkbox"/> Will be provided during study <input type="checkbox"/> Will not be provided during study | | | |
| Sterility Status <input type="checkbox"/> Non-Sterile <input type="checkbox"/> Sterile (Please indicate method) _____ Note: Test Articles shall be submitted sterile by Sponsor | | | | | | |

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| Service | 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 _____ <small>(provide justification)</small> |
| | Surface Area in cm ² 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 _____ ISO 10993-12, <i>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.</i> <i>Unusually complex surface area calculations that are to be performed by PBL may incur additional charges.</i> <i>Extraction of large samples may incur additional media charges.</i> |

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| Service | Regulatory Treatment <input type="checkbox"/> Non-regulatory <input type="checkbox"/> cGMP <input type="checkbox"/> GLP <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 |
| | Report Format <input type="checkbox"/> PDF <input type="checkbox"/> Paper <input type="checkbox"/> Paper and PDF <i>(First format No Charge, \$6.00 for each additional.)</i> |

| Service | Archive Options (for Paper Records and Specimens – tissues, blocks and slides) All paper records will be scanned and stored at PBL indefinitely by a system that is validated to comply with GMP and GLP regulations. If archive option is not selected, the default option will be implemented. | | | | | | | | | | | | | | | |
|--------------------------|--|---|---|--|--------------------------|--------------------------|---|--------------------------|--------------------------|---|--------------------------|--------------------------|---|--------------------------|--------------------------|---|
| | <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:15%;">Paper Records (Check One)</th> <th style="width:15%;">Specimen (Check One if Applicable)</th> <th></th> </tr> </thead> <tbody> <tr> <td style="text-align:center;"><input type="checkbox"/></td> <td style="text-align:center;"><input type="checkbox"/></td> <td>Discard (after one year) – Non-GLP Default</td> </tr> <tr> <td style="text-align:center;"><input type="checkbox"/></td> <td style="text-align:center;"><input type="checkbox"/></td> <td>Return to Client (after one year) – GLP Default (Shipping charges apply)</td> </tr> <tr> <td style="text-align:center;"><input type="checkbox"/></td> <td style="text-align:center;"><input type="checkbox"/></td> <td>Return Immediately to Client (at study completion) – (Shipping charges apply)</td> </tr> <tr> <td style="text-align:center;"><input type="checkbox"/></td> <td style="text-align:center;"><input type="checkbox"/></td> <td>Extended Storage by PBL (after one year) - Invoiced annually per Fee Schedule at www.PacificBioLabs.com/archivefeeschedule.asp</td> </tr> </tbody> </table> | Paper Records (Check One) | Specimen (Check One if Applicable) | | <input type="checkbox"/> | <input type="checkbox"/> | Discard (after one year) – Non-GLP Default | <input type="checkbox"/> | <input type="checkbox"/> | Return to Client (after one year) – GLP Default (Shipping charges apply) | <input type="checkbox"/> | <input type="checkbox"/> | Return Immediately to Client (at study completion) – (Shipping charges apply) | <input type="checkbox"/> | <input type="checkbox"/> | Extended Storage by PBL (after one year) - Invoiced annually per Fee Schedule at www.PacificBioLabs.com/archivefeeschedule.asp |
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Please check all required tests.

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| ANALYSIS REQUIRED <i>(Please check all required tests.)</i> | CYTOTOXICITY <i>ISO 10993-5:</i> | |
| | <table style="width:100%;"> <tr> <td style="width:50%; vertical-align:top;"> 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> <input type="checkbox"/> Agar Diffusion <input type="checkbox"/> MEM Elution (extract test) <input type="checkbox"/> Direct Contact <input type="checkbox"/> MTT - Quantitative Evaluation (extract test) <input type="checkbox"/> Colony Formation (extract test) </td> <td style="width:50%; vertical-align:top;"> 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 <input type="checkbox"/> Direct Contact <input type="checkbox"/> MTT - Quantitative Evaluation <input type="checkbox"/> Colony Formation 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 _____ </td> </tr> </table> | 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> <input type="checkbox"/> Agar Diffusion <input type="checkbox"/> MEM Elution (extract test) <input type="checkbox"/> Direct Contact <input type="checkbox"/> MTT - Quantitative Evaluation (extract test) <input type="checkbox"/> Colony Formation (extract test) |
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SENSITIZATION *ISO 10993-10:*

- Maximization Test for Delayed Hypersensitivity
Please select extraction medium: Saline Vegetable Oil Other _____
- Closed Patch Test
- ASTM Murine Local Lymph Node Assay (LLNA) – *mainly for single entity chemicals*

IRRITATION *ISO 10993-10:*

- Intracutaneous (Intradermal) Reactivity Test
- Skin Irritation Test
- Ocular Irritation Test
- Please select extraction medium:** Saline Vegetable Oil Other _____
- Mucous Membrane → Oral Mucosal (Hamster Cheek Pouch) Vaginal Rectal Penile

SYSTEMIC *ISO 10993-11:*

- Acute Systemic Toxicity Test
- Please select extraction medium:** Saline Vegetable Oil Other _____
- Material Mediated Pyrogenicity (*Saline Extract Only*)

SUBACUTE *ISO 10993-11:*

- Repeated Dose Toxicity Study → Duration: _____ Days
- Please select route:** Intravenous Intraperitoneal Oral Dermal Other _____

SUBCHRONIC/CHRONIC *ISO 10993-11:*

- Repeated Dose Toxicity Study → Duration: _____ Days
- Please select route:** Intravenous Intraperitoneal Oral Dermal 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*)
 Direct and Indirect Direct 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 _____

Additional Service: Sterilization Processing (121°C for 30 Minutes) (*Will incur an additional fee.*)

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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 is required for testing to begin, unsigned LSR forms will be not be processed)