

**LABORATORY SERVICE REQUEST (LSR) - CUSTOMIZED SERVICES (NO TEST ARTICLE)**

**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.)

<b>Sponsor: (Send Report To)</b>	<input type="checkbox"/> <b>Invoice To:</b> (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:

**SERVICE INFO**

STUDY TITLE or SERVICE:

SPECIAL INSTRUCTIONS:

Regulatory Treatment:  Non-regulatory  cGMP  GLP (GLP will incur an additional fee)

**Complete section below if GLP**

Regulatory Compliance Needed:  FDA  European Union  Other: \_\_\_\_\_

Purpose of Testing:  510K  Other: \_\_\_\_\_

GLP Stability Testing and Test Article Characterization (check one box below):

<b>Completed and:</b>	or	<b>To Be Completed by Sponsor and:</b>
<input type="checkbox"/> Will be provided during study		<input type="checkbox"/> Will be provided during study
<input type="checkbox"/> Will not be provided during study		<input type="checkbox"/> 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 (no charge)  Paper (\$6.00 charge for paper copy)

Archive Options:

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 no box is checked the default option will apply:

Paper Records

- Discard after one year (Non GLP Default)
- Return to Client after one year ( GLP Default) - shipping charges apply.
- Return immediately to Client at study completion - shipping charges apply.
- Extended storage by PBL after one year - Invoiced annually per Fee Schedule at [www.PacificBioLabs.com/archivefeeschedule.asp](http://www.PacificBioLabs.com/archivefeeschedule.asp)

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)**