

**LABORATORY SERVICE REQUEST FORM (LSR) - CYTOTOXICITY**

**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:

**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:

<p>Storage Condition:</p> <p><input type="checkbox"/> 20 to 25°C</p> <p><input type="checkbox"/> 2 to 8°C</p> <p><input type="checkbox"/> -16 to -24°C</p> <p><input type="checkbox"/> -60 to -80°C</p>	<p>Controlled Substance:</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes</p> <p>Schedule: _____</p>	<p>Hazardous: (include MSDS if samples are hazardous, client will incur charges for disposal of hazards.)</p> <p><input type="checkbox"/> Not Hazardous</p> <p><input type="checkbox"/> Reactive</p> <p><input type="checkbox"/> Biohazard</p> <p><input type="checkbox"/> Toxic</p> <p><input type="checkbox"/> Other:</p>	<p>Sample Disposition: (Check one box) (Samples will be discarded 30 days after report unless otherwise indicated)</p> <p><input type="checkbox"/> Return to Sender</p> <p>Carrier: _____</p> <p>Account: _____</p> <p><input type="checkbox"/> Dispose in Municipal waste</p> <p><input type="checkbox"/> Dispose in hazardous waste</p>
---	--	---	---

**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) \_\_\_\_\_

Surface Area in cm<sup>2</sup> 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.)

**CYTOTOXICITY TESTS**

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

Please specify test method:  Agar Diffusion  Direct Contact  MEM Elution (*extract test*)

MTT - Quatitative Evaluation (*extract test*)

*All cytotoxicity samples for the MEM Elution test will be extracted and/or incubated at 37°C for 24 hours in MEM, unless otherwise specified by Sponsor.*

If modifications are required please specify:

OTHER TESTS/SPECIAL INSTRUCTIONS:

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)**