

**LABORATORY SERVICE REQUEST (LSR) - MEDICAL DEVICE REPROCESSING VALIDATION**

**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:

<b>Storage Condition:</b> <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	<b>Controlled Substance:</b> <input type="checkbox"/> No <input type="checkbox"/> Yes Schedule: _____	<b>Hazardous:</b> (include MSDS if samples are hazardous, client will incur charges for disposal of hazards.) <input type="checkbox"/> Not Hazardous <input type="checkbox"/> Reactive <input type="checkbox"/> Biohazard <input type="checkbox"/> Toxic <input type="checkbox"/> Other:	<b>Sample Disposition: (Check one box)</b> (Samples will be discarded 30 days after report unless otherwise indicated) <input type="checkbox"/> Return to Sender Carrier: _____ Account: _____ <input type="checkbox"/> Dispose in Municipal waste <input type="checkbox"/> Dispose in hazardous waste
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**TEST ARTICLE INFO (CONT.)**

What is the classification of the test article?  Non-Critical Environmental (Does not come in contact with patient)  
 Non-Critical (Intact skin)  
 Semi-Critical (Mucous Membrane)  
 Critical (Blood barrier)

Final Intended Use: \_\_\_\_\_

Can the test article be immersed in liquid?  Yes  No

Client Provided Surface Area in cm<sup>2</sup> (required for cleaning validations): \_\_\_\_\_

**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.)

**TESTING REQUIRED** (Please check all required tests)

**CLEANING VALIDATION:**

Cleaning Procedure:  PBL will develop a method  
 Client Provided (Specify): \_\_\_\_\_

Method of Cleaning:  Manual  
 Automated (Please Specify Type): \_\_\_\_\_

Cleaning Chemical?  None  Wipes (Specify): \_\_\_\_\_  Detergent (Specify): \_\_\_\_\_

Biomarkers for evaluation:  Protein  Hemoglobin  Carbohydrates

Note: A recovery efficiency validation is required for both the cleaning and disinfection validations.

Project Deadline: \_\_\_\_\_

**DISINFECTION VALIDATION:**

Level of Disinfection:  High  Intermediate  Low

Disinfection Procedure:  PBL will develop a method  
 Client provided (Specify): \_\_\_\_\_

Method of Disinfection:  Chemical  Wipes (Specify): \_\_\_\_\_  
 Disinfectant (Specify): \_\_\_\_\_  
 Thermal (Please Specify Parameters): \_\_\_\_\_  
 Automated (Please Specify Type): \_\_\_\_\_

Disinfectant residual evaluation?  None  Biocompatibility  Other: \_\_\_\_\_

Note: A recovery efficiency validation is required for both the cleaning and disinfection validations.

Project Deadline: \_\_\_\_\_

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)**