PACIFIC BIOLABS
The Service Leader in Life Science Testing
PBL

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

LABORATORY SERVICE REQUEST (LSR) - BIOASSAY TESTING

CLIENT INFORMATION

(**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:**
Contact Name:	AP Contact Name:
Company Name:	Company Name:
Address:	Address:
City/State/Zip:	City/State/Zip:
Country:	Country:
Phone:	Invoice to Email:
Email:	AP Email:
PBL Quote Number:	AP Phone:
PO Number:	☐ Credit Card to be used for payment

TEST ARTICLE INFORMATION

Test Article ID (Please use the test article name or unique identifier (eg. product name, Glucagon/Insulin/Tetracosactide API/for Injection, etc.)

Physical Description (e.g. color, lyophilized powder, clear liquid, opaque suspension, etc.)

As Appropriate:

Type (if product is insulin): ☐ Human Insulin ☐ Insulin Aspart ☐ Insulin Lispro ☐ Insulin Glargine ☐ Other:

Lot Number:	Sample Code:	Other Identifier:
Quantity:	Expiration Date:	Sterility Status: ☐ Sterile ☐ Non-Sterile

Storage Condition:	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)
☐ Room Temperature	☐ Not Hazardous	☐ Return to Sender
☐ 2 to 8°C	☐ Biohazard	Carrier: _____
☐ -10 to -25°C	☐ Toxic	Account: _____
☐ -60 to -90°C	☐ Other: _____	☐ Dispose in pharmaceutical waste
☐ Protect from Light		☐ Dispose in hazardous waste

TEST ARTICLE CHARACTERIZATION

Potency is <u>required</u> for test article preparation and must be provided in order to avoid delays in testing.
Rescheduled testing will be based on availability.

Potency of API (Units/mg): (Used for Calculations)	Water Content: (if Potency is on dried basis)	Percent Active Peptide:
Potency of Formulation (for injection): (Used for Calculations)	☐ Units/mL ☐ Units/Vial	Concentration (mg/mL): (if potency is Units/mL)
Will a Certificate of Analysis be provided (preferred):	☐ No ☐ Yes	

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SERVICE INFO

Regulatory Treatment: ☐ Non-regulatory ☐ cGMP ☐ GLP

Complete 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 ☐ Paper and PDF ☐ Paper (Note: A fee will apply for paper copy of report.)

TEST PROCEDURE

USP Bioassays

☐ Insulin Biopotency - (Quantitative Assay) ☐ Insulin Bioidentity Test ☐ Glucagon Bioidentity Test

EP Guidelines

☐ Tetracosactide Bioidentity Test

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)