



SAMPLE SUBMISSION FORM

Reference SRP-13 (ROC), QA-3 (SLC)

Quote/ MSA #	PO#	Sample Disposition	<input type="checkbox"/> DO NOT OPEN – SAMPLE OVERPACK <input type="checkbox"/> Return / Hold for Pickup (see pg. 2) <input type="checkbox"/> Discard
-----------------	-----	-----------------------	---

Send Final Report To:

Company: _____

Contact: _____

Address: _____

Email: _____

Phone: _____

Billing Information:

Company: _____

Contact: _____

Address: _____

Email: _____

Phone: _____

Sample Information:

Test Name or Code / Guideline (AAMI, ISO, USP, etc.)	Test Article Name	Part #	Lot #	Samples <input type="checkbox"/> Shared Samples		Sample Status
				No. of Samples Sent	No. of Samples to be Tested	
						<input type="checkbox"/> GLP <input type="checkbox"/> STAT <input type="checkbox"/> RES
						<input type="checkbox"/> GLP <input type="checkbox"/> STAT <input type="checkbox"/> RES
						<input type="checkbox"/> GLP <input type="checkbox"/> STAT <input type="checkbox"/> RES
						<input type="checkbox"/> GLP <input type="checkbox"/> STAT <input type="checkbox"/> RES
						<input type="checkbox"/> GLP <input type="checkbox"/> STAT <input type="checkbox"/> RES

Replacement Value:

Comments or Special Handling Instructions:

☐ Sample Pooling Instructions

Submitted Material Type:	<input type="checkbox"/> Medical Device	<input type="checkbox"/> Pharmaceutical	<input type="checkbox"/> Other:
Storage Conditions:	<input type="checkbox"/> Room temperature	<input type="checkbox"/> Refrigerate (2-8°C)	<input type="checkbox"/> Freeze (-10 to -25°C) <input type="checkbox"/> Other:

Applicable Departments: (please mark all that apply)

<input type="checkbox"/> Packaging: Complete Section A (Sponsor Auth.)	<input type="checkbox"/> Chemistry: Complete Section A (Sponsor Auth)
<input type="checkbox"/> Microbiology / BI / Reusables: Complete Section A (Sponsor Auth.)	<input type="checkbox"/> Toxicology: For Toxicology/Biocompatibility Specific Test Requirements, complete Section A (Sponsor Authorization) and Addendum A (including Section B, Section C, and Section D)

Section A: Sponsor Authorization for testing, sign/date below:

Reports will be released by email unless otherwise requested.

Sponsor Authorization _____

Date _____

Unless other arrangements have been made, payment terms are net 30, prices are FOB Canyon Labs and are valid for 6 months after acceptance of the quote.

ROC Internal Use Only

Received By _____

Date _____

Approved By _____

Date _____

Test Number(s): _____

Test numbers verified by: _____
Initial/dateGLP Study No(s): _____
(if applicable) _____**To Be Completed if Sample Return/Forwarding Requested****Verify address for Return/Forwarding samples:**☐ Same as above

Address			
City		State/Province:	
Zip/Post Code		Country:	
Phone			

Shipping Conditions	<input type="checkbox"/> Ambient/ Room Temp	<input type="checkbox"/> Ice Packs	<input type="checkbox"/> Dry Ice	<input type="checkbox"/> Original Containers
Shipping Information (include account number)	<input type="checkbox"/> FedEx Account:	<input type="checkbox"/> UPS Account:	<input type="checkbox"/> Other:	
Shipping Speed	<input type="checkbox"/> Next Day	<input type="checkbox"/> Next Day - Early	<input type="checkbox"/> 2 Day	<input type="checkbox"/> Ground
Special Instructions	<input type="checkbox"/> Return Data Loggers <input type="checkbox"/> Hold for Pick-up <input type="checkbox"/> Other: _____			

Sample Shipment Guidelines

1. Label every sample for quick identification. Please label your boxes with the quote number of your study.
2. **Please include a copy of your Sample Submission Form with your shipment.** Testing cannot begin nor samples processed until we have a completed Sample Submission Form.
3. Utilize protective packaging to ensure your samples get here safe. If working with the packaging test lab, it is suggested that samples be **shipped** in overpacks. Please label the overpacks accordingly so we know to remove prior to testing. If your samples are GLP, need to be refrigerated, and/or requires special handling ensure it is labeled on the shipment.
4. Samples must be shipped prepaid.
5. Ship samples to the following address:

Salt Lake City, UT Location:**Rochester, NY Location:****San Diego, CA Location:****Attn: (Your Quote Number)****Attn: (Your Quote Number)****Attn: (Your Quote Number)****Canyon Labs****Canyon Labs****Canyon Labs****16217 S Bringhurst Dr Suite 600****7500 W Henrietta Rd Rush,****2865 Scott St. #103****Bluffdale, UT 84065****NY 14543****Vista, CA 92081**

Addendum A

Section B: Toxicology and/or Biocompatibility Specific Test Requirements (to be completed where applicable):

Note: if testing requires a formal protocol (as requested by sponsor), the approved protocol will supersede information selected on this form.

Have samples been submitted sterile? * <i>*Note: Samples that are sold and used sterile should be submitted sterile or be processed by the intended sterilization method prior to testing.</i>
<input type="checkbox"/> Yes, customer sterilized per following method: <input type="checkbox"/> Ethylene Oxide <input type="checkbox"/> Steam <input type="checkbox"/> Gamma Irradiation Other: _____
<input type="checkbox"/> No, Canyon Labs to process per following method prior to testing: <input type="checkbox"/> Ethylene Oxide <input type="checkbox"/> Steam Other: _____
<input type="checkbox"/> No, samples not intended to be sold or used sterile.
<input type="checkbox"/> N/A (Testing to be performed on sample as submitted)

Submitted Material Type: <input type="checkbox"/> Plastic/polymer <input type="checkbox"/> Elastomer <input type="checkbox"/> Coated material, composite, laminate, metal <input type="checkbox"/> Pharmaceuticals <input type="checkbox"/> Other	Safety Precautions: <input type="checkbox"/> None/unknown (standard precautions will be used) <input type="checkbox"/> SDS enclosed <input type="checkbox"/> Flammable <input type="checkbox"/> Biohazard level <input type="checkbox"/> Other
---	--

<input type="checkbox"/> Test entire sample, sample may be subdivided/cut into appropriate sizes for testing.
<input type="checkbox"/> Test entire sample, DO NOT sub-divide (cut) test sample for testing
<input type="checkbox"/> Do NOT test entire sample (Identify specific components or materials to be <input type="checkbox"/> excluded or <input type="checkbox"/> included below): _____ _____ _____

If Samples are submitted for testing requiring USP/ISO biocompatibility-based extractions, complete section B, where applicable below.
If Samples are submitted for USP/ISO biocompatibility-based testing requiring direct application, complete section C, where applicable on Page 3.
Canyon Labs Biocompatibility Questionnaire (for ISO 10993 GLP studies) and/or Canyon Labs Chemical Characterization Test (10993-18) Questionnaire may be required for protocol preparation.

Section C: Extraction Method Selections: ☐ N/A OR ☐ as selected below

Extraction Methods for GPMT, Irritation Test, Systemic Injection Test, Material Mediated Pyrogen, Hemolysis Tests
• Extraction Condition Options: <input type="checkbox"/> 121°C – 1 hour <input type="checkbox"/> 70°C – 24 hour <input type="checkbox"/> 50°C – 72 hour <input type="checkbox"/> 37°C – 72 hour (requires justification) <input type="checkbox"/> Other: _____
• Extraction Media Options (unless otherwise requested by Sponsor): <input type="checkbox"/> Saline & Vegetable Oil (GPMT, Irritation, and Systemic Toxicity tests, unless indicated in "Other" below) <input type="checkbox"/> Saline (Material Mediated Pyrogen test) <input type="checkbox"/> Saline, Vegetable Oil, 1:20 Alcohol:Saline, & Polyethylene Glycol (USP <88> Class VI plastics testing) <input type="checkbox"/> Phosphate Buffered Saline (PBS) (ASTM Hemolysis Test) <input type="checkbox"/> Other: _____
Extraction Methods for Elution Cytotoxicity Test (USP <87> or ISO 10993-5):
• Extraction Condition/Media Options: <input type="checkbox"/> 37°C – 24 hour in Serum Supplemented MEM (for devices with contact < 24 hours) <input type="checkbox"/> 37°C – 72 hour in Serum Supplemented MEM (for devices with contact ≥ 24 hours) <input type="checkbox"/> 121°C – 1 hour <input type="checkbox"/> 70°C – 24 hour <input type="checkbox"/> 50°C – 72 hour in Saline with justification

Extraction Methods for BET/Rabbit Pyrogen test (Lot Release):
• Extraction Condition/Media Options
<input type="checkbox"/> As per Test System Suitability (Method Validation): Reference Validation Study #:
<input type="checkbox"/> As per Canyon Labs internal work instruction, PYT-8

Toxicology and/or Biocompatibility Specific Test Requirements (Continued from page 2; to be completed where applicable):

Section D: Direct Contact Method Selections: ☐ N/A OR ☐ as selected below

<input type="checkbox"/> Cytotoxicity (Direct Contact Test)
<input type="checkbox"/> Sensitization (Closed Patch Test)
<input type="checkbox"/> Skin Irritation Test
<input type="checkbox"/> ASTM Hemolysis
<input type="checkbox"/> Implantation Evaluation:** <input type="checkbox"/> Histopathology (required per ISO 10993-6) <input type="checkbox"/> Macroscopic (USP <88>)
**Samples for histology and post mortem clinical evaluation will be submitted to an approved vendor. Samples submitted for implantation testing must be submitted sterile or be sterilized before testing (make appropriate selection above).