



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 (See pg. 2) <input type="checkbox"/> Discard
Send Final Report To:		Billing Information:	<input type="checkbox"/> Same
Company:		Company:	
Contact:		Contact:	
Address:		Address:	
Email:		Email:	
Phone:		Phone:	

Sample Information:						
Test Name or Code / Guideline	Test Article Name	Part #	Lot #	Test Articles		
				<input type="checkbox"/> Shared Samples		Status
				Number Sent	Number to Test	
						<input type="checkbox"/> GLP <input type="checkbox"/> GMP <input type="checkbox"/> STAT <input type="checkbox"/> RES
						<input type="checkbox"/> GLP <input type="checkbox"/> GMP <input type="checkbox"/> STAT <input type="checkbox"/> RES
						<input type="checkbox"/> GLP <input type="checkbox"/> GMP <input type="checkbox"/> STAT <input type="checkbox"/> RES
						<input type="checkbox"/> GLP <input type="checkbox"/> GMP <input type="checkbox"/> STAT <input type="checkbox"/> RES
						<input type="checkbox"/> GLP <input type="checkbox"/> GMP <input type="checkbox"/> STAT <input type="checkbox"/> RES

Replacement Value: ☐ N/A

Disclaimer: If samples are submitted to Canyon Labs without specific handling or testing instructions, Canyon Labs will follow its default testing and handling processes applicable to the sample type received.

Comments or Special Handling Instructions:	<input type="checkbox"/> Water Samples <input type="checkbox"/> 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)
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: 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.

ROC Internal Use Only

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.

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			

<input type="checkbox"/> Untested Samples	<input type="checkbox"/> Tested Samples	<input type="checkbox"/> Dataloggers	<input type="checkbox"/> Other: _____
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:

Attn: (Your Quote Number)
Canyon Labs Utah
16217 S Bringham Dr Suite 600
Bluffdale, UT 84065
shiprec@canyonlabs.com

Rochester, NY Location:

Attn: (Your Quote Number)
Canyon Labs
7500 W Henrietta Rd
Rush, NY 14543
shiprec@canyonlabs.com

San Diego, CA Location:

Attn: (Your Quote Number)
Canyon Labs
2865 Scott St. #103
Vista, CA 92081
shiprec@canyonlabs.com

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 <input type="checkbox"/> Other: _____	
<input type="checkbox"/> No, Canyon Labs to process per following method prior to testing: <input type="checkbox"/> Ethylene Oxide <input type="checkbox"/> Steam <input type="checkbox"/> 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**
☐ As per Test System Suitability (Method Validation): Reference Validation Study #:

☐ 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

☐ **Cytotoxicity (Direct Contact Test)**
☐ **Sensitization (Closed Patch Test)**
☐ **Skin Irritation Test**
☐ **ASTM Hemolysis**
☐ **Implantation Evaluation:**** ☐ **Histopathology (required per ISO 10993-6)** ☐ **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).