TOXICOLOGY SUPPLEMENTAL SAMPLE SUBMISSION FORM

Reference SRP-13 (ROC)

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

Submitted Material Type:
☐ Plastic/polymer
☐ Elastomer
☐ Coated material, composite, laminate
☐ Metal
☐ Pharmaceuticals
☐ Other

Safety Precautions:
☐ None/unknown (standard precautions will be used)
☐ SDS enclosed
☐ Flammable
☐ Biohazard level
☐ Other

☐ Test entire sample, sample may be subdivided/cut into appropriate sizes for testing.
☐ Test entire sample, DO NOT sub-divide (cut) test sample for testing
☐ Do NOT test entire sample (Identify specific components or materials to be ☐ excluded or ☐ 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 2.
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 B: 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:**
☐ 121°C – 1 hour ☐ 70°C – 24 hour ☐ 50°C – 72 hour ☐ 37°C – 72 hour (requires justification) ☐ Other:
• **Extraction Media Options (unless otherwise requested by Sponsor):**
☐ Saline & Vegetable Oil (GPMT, Irritation, and Systemic Toxicity tests, unless indicated in "Other" below)
☐ Saline (Material Mediated Pyrogen test)
☐ Saline, Vegetable Oil, 1:20 Alcohol: Saline, & Polyethylene Glycol (USP <88> Class VI plastics testing)
☐ Phosphate Buffered Saline (PBS) (ASTM Hemolysis Test)
☐ Other:
Extraction Methods for Elution Cytotoxicity Test (USP <87> or ISO 10993-5):
• **Extraction Condition/Media Options:**

TOXICOLOGY SUPPLEMENTAL SAMPLE SUBMISSION FORM

Reference SRP-13 (ROC)

☐ 37°C – 24 hour in Serum Supplemented MEM (for devices with contact < 24 hours)
☐ 37°C – 72 hour in Serum Supplemented MEM (for devices with contact ≥ 24 hours)
☐ 121°C – 1 hour ☐ 70°C – 24 hour ☐ 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 C: 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).

SAMPLE SUBMISSION FORM

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

***All fields are required to be completed**

Quote/MSA # ____________________ PO# ____________________ Sample Disposition ☐ Discard ☐ Return (See pg. 2)

Send Final Report To:		Billing Information: ☐ Same	
Company:	____________________	Company:	____________________
Contact:	____________________	Contact:	____________________
Address:	____________________	Address:	____________________
	____________________		____________________
Email:	____________________	Email:	____________________
Phone:	____________________	Phone:	____________________

Sample Information:				Test Articles			
				☐ DO NOT OPEN – SAMPLES OVERPACKED			
Test Code and Name / Guideline	Test Article Name	Part #	Lot #	☐ Shared Samples		Pooling Instructions	Status
				# Sent	# to Test		
						☐ Individual ☐ Pooled: _____ Samples into _____ Results	☐R&D/ Other ☐GMP ☐GLP Extra fee incurred ☐STAT Extra fee incurred
						☐ Individual ☐ Pooled: _____ Samples into _____ Results	☐R&D/ Other ☐GMP ☐GLP Extra fee incurred ☐STAT Extra fee incurred
						☐ Individual ☐ Pooled: _____ Samples into _____ Results	☐R&D/ Other ☐GMP ☐GLP Extra fee incurred ☐STAT Extra fee incurred
						☐ Individual ☐ Pooled: _____ Samples into _____ Results	☐R&D/ Other ☐GMP ☐GLP Extra fee incurred ☐STAT Extra fee incurred
						☐ Individual ☐ Pooled: _____ Samples into _____ Results	☐R&D/ Other ☐GMP ☐GLP Extra fee incurred ☐STAT Extra fee incurred
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: ☐ N/A

Submitted Material Type:	☐ Medical Device	☐ Pharmaceutical	☐ Controlled Substance	☐ Water Sample	☐ Other
Samples Submitted Sterilized:	☐ Yes ☐ No				
Storage Conditions:	☐ Room Temperature	☐ Refrigerate (2-8°C)	☐ Freeze (-10 to -25°C)	☐ Other	

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.

Canyon Labs Internal Use Only

Received By _____ Date _____

Approved By _____ Date _____

Test Number(s): _____

Test numbers verified by: _____ Initial/date

GLP Study No(s): _____

(if applicable) _____

Verify address for Return/Forwarding samples: ☐ Same as above ☐ N/A

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

☐ Untested Samples ☐ Tested Samples ☐ Dataloggers ☐Other:_____	
Shipping Conditions	☐ Ambient/ Room Temp ☐ Ice Packs ☐ Dry Ice ☐Original Containers
Shipping Information (include account number)	☐ FedEx Account #: _____ ☐ UPS Account #: _____ ☐ Other:_____Account #: _____
Shipping Speed	☐ Next Day ☐Next Day - Early ☐ 2 Day ☐ Ground
Special Instructions	☐ Return Data Loggers ☐Hold for Pick-up ☐Other:_____

Sample Shipment Instructions

1. Label every sample for quick identification. Please label your boxes with the quote number of your study.
2. **Include a copy of your Sample Submission Form with your shipment.** Testing cannot begin nor samples processed until we have a complete 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 test location that is listed on your quote or MSA:

Salt Lake City, UT Location:

Attn: (Your Quote Number)
Canyon Labs
16217 S Bringhurst Dr Suite 600
Bluffdale, UT 84065

Rochester, NY Location:

Attn: (Your Quote Number)
Canyon Labs
7500 W Henrietta Rd
Rush, NY 14543

San Diego, CA Location:

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

