|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Quote/  MSA # |  | PO# |  | | Sample Disposition | |  | | --- | | DO NOT OPEN – SAMPLE OVERPACK  Return (See pg. 2)  Discard | |
| Send Final Report To: | | | | Billing Information:  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 | | |
| Shared Samples | | Status |
| Number Sent | Number to Test |
|  | |  | | | |  |  |  |  | GLP  GMP  STAT  RES |
|  | |  | | | |  |  |  |  | GLP  GMP  STAT  RES |
|  | |  | | | |  |  |  |  | GLP  GMP  STAT  RES |
|  | |  | | | |  |  |  |  | GLP  GMP  STAT  RES |
|  | |  | | | |  |  |  |  | GLP  GMP  STAT  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: | | | | | | | | Water Samples | | |
|  | | | | | | | | Sample Pooling Instructions | | |
|  | | |
| Submitted Material Type: | Medical Device | | Pharmaceutical | | Other: | | | | | |
| Storage Conditions: | Room temperature | | Refrigerate (2-8°C) | | Freeze (-10 to -25°C) | | | Other: | | |
| **Applicable Departments:** (please mark all that apply) | | | | | | | | | | |
| **Packaging:** Complete Section A (Sponsor Auth.) | | | | **Chemistry**: Complete Section A (Sponsor Auth) | | | | | | |
| **Microbiology**: Complete Section A (Sponsor Auth.) | | | | **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 |  | Received By | |  | 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. | | |  | |  |  |
| Approved By | |  | Date |
|  | |  |  |
| Test Number(s): |  | | |
|  | | |  | Test numbers verified by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Initial/date  GLP 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 |  | | |

|  |  |
| --- | --- |
| 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: |
| Shipping Speed | Next Day  Next Day - Early  2 Day  Ground |
| Special Instructions | Return Data Loggers Hold for Pick-up  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 Bringhurst Dr Suite 600**  **Bluﬀdale, UT 84065**  [**shiprec@canyonlabs.com**](mailto:shiprec@canyonlabs.com) | **Rochester, NY Location:**  **Attn: (Your Quote Number)**  **Canyon Labs**  **7500 W Henrietta Rd Rush, NY 14543**  [**shiprec@canyonlabs.com**](mailto:shiprec@canyonlabs.com) | **San Diego, CA Location:**  **Attn: (Your Quote Number)**  **Canyon Labs**  **2865 Scott St. #103 Vista, CA 92081**  [**shiprec@canyonlabs.com**](mailto: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? \***  ***\*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:** |  | **Safety Precautions:** |
| Plastic/polymer |  | None/unknown (standard precautions will be used) |
| Elastomer |  | SDS enclosed |
| Coated material, composite, laminate, metal |  | Flammable |
| Pharmaceuticals |  | Biohazard level |
| Other |  | 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 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:** |
| 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:** |
| 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 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). |