

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.

<p>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></p>
<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)

<p>Submitted Material Type:</p> <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

<p>Safety Precautions:</p> <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
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<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):

<p>If Samples are submitted for testing requiring USP/ISO biocompatibility-based extractions, complete section B, where applicable below.</p>
<p>If Samples are submitted for USP/ISO biocompatibility-based testing requiring direct application, complete section C, where applicable on Page 3.</p>
<p>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.</p>

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

<p>Extraction Methods for GPMT, Irritation Test, Systemic Injection Test, Material Mediated Pyrogen, Hemolysis Tests</p>
<p>• 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: _____ </p>
<p>• 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: _____ </p>
<p>Extraction Methods for Elution Cytotoxicity Test (USP <87> or ISO 10993-5):</p>
<p>• 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 </p>
<p>Extraction Methods for BET/Rabbit Pyrogen test (Lot Release):</p>
<p>• 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 </p>

