

## QUICK GUIDE TO SAMPLE REQUIREMENTS AND TURNAROUND TIMES

This chart is intended as a quick guide for your reference.  
For additional information on these tests, please see this section's test listings.

**NOTE: All samples for biocompatibility testing should be sent directly to AppTec's St. Paul facility.  
As applicable, samples should be submitted after exposure to the Sponsor's sterilization process.  
For tests involving extracts, sample requirements are *per extract*.**

	RECOMMENDED SAMPLE REQUIREMENTS	TURNAROUND TIME
<b>Cytotoxicity Testing</b>		
Agarose Overlay	Solid: 4 samples of 1 cm <sup>2</sup> (sterile) Liquid: 3 ml (sterile)	4 days
MEM Elution	By Thickness: <0.5mm thick = 120cm <sup>2</sup> >0.5mm thick = 60cm <sup>2</sup> By Weight: 4 grams <i>(Tests are set up Monday and Thursday. Samples must arrive one day prior.)</i>	ISO – 7 days USP – 6 days Screen – 5 days Endpoint – 7 days
Direct Contact	4 samples of 1 cm <sup>2</sup> (sterile)	4 days
Extract Colony Assay Cytotoxicity Test	1 gram or 50 cm <sup>2</sup>	3 weeks

### Genotoxicology / Mutagenicity Testing

Bacterial Reverse Mutation		25 days
<i>In Vitro</i> Chromosomal Aberration	By Thickness: <0.5mm thick = 60cm <sup>2</sup> >0.5mm thick = 30cm <sup>2</sup> By Weight: 2 grams Liquid: Contact lab.	8 weeks 10 weeks (JMHW)
<i>In Vitro</i> Mouse Lymphoma Assay		7 weeks
<i>In Vitro</i> Sister Chromatid Exchange		7 weeks
<i>In Vitro</i> Unscheduled DNA Synthesis		12 weeks
<i>In Vivo</i> Mouse Micronucleus Screen		By Thickness: <0.5mm thick = 120cm <sup>2</sup> >0.5mm thick = 60cm <sup>2</sup> By Weight: 4 grams Liquid: Contact lab.
<i>In Vivo</i> Mouse Micronucleus Test		10 weeks
EPA Genotoxicology Tests	Solid: 1 gram Liquid: Concentration dependent.	2 weeks

### Hemocompatibility Testing

Complement Activation	6 cm <sup>2</sup> per assay	2 weeks
Partial Thromboplastin Time	12 cm <sup>2</sup>	2 weeks
Platelet and Leukocyte Counts	36 cm <sup>2</sup>	2 weeks
NIH Hemolysis Tests	15 grams or 3 products for whole product testing <i>(Samples must arrive by Monday for testing on Tuesday.)</i>	2 - 5 days
Thrombosis (In Vivo)	2 test products and 2 control products	20-25 days

### Implantation Testing

USP / ISO Intramuscular Implantation	Minimum of 15 implant samples: 1mm x 10mm (each)	See test description.
USP / ISO Subcutaneous Implantation	Representative portions of the device (minimum 12)	See test description.
Long-Term Implant Test in Rabbits with Additional Chronic Data Collection	See test description.	See test description.
Intramuscular or Subcutaneous Implant Screen Test (Custom)	Custom	Custom

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## RECOMMENDED SAMPLE REQUIREMENTS

## TURNAROUND TIME

### Irritation Testing

USP / ISO Intracutaneous Irritation Test	By Thickness: <0.5mm thick = 120cm <sup>2</sup> >0.5mm thick = 60cm <sup>2</sup> By Weight: 4 grams	26 days
ISO Vaginal Mucosal Irritation Test	By Thickness: <0.5mm thick = 600cm <sup>2</sup> >0.5mm thick = 300cm <sup>2</sup> By Weight: 20 grams Liquid: 10 ml	63 days
Ocular Irritation Test [Topical]	By Thickness: <0.5mm thick = 120cm <sup>2</sup> >0.5mm thick = 60cm <sup>2</sup> By Weight: 4 grams	26 days
Intraocular Irritation Test	By Thickness: <0.5mm thick = 120cm <sup>2</sup> >0.5mm thick = 60cm <sup>2</sup> By Weight: 4 grams	26 days
ISO Primary Skin Irritation Test	At least 12 one-square-inch portions of the test material Liquid: 10 ml	23 days

### Physicochemical Testing

See "Chemistry" section of this catalog – Page C-7.

### Pyrogenicity Testing

USP Rabbit Pyrogen Test	10 devices or device assemblies to represent lot under test	24 days
ISO Rabbit Pyrogen – Materials Mediated	By Thickness: <0.5mm thick = 900cm <sup>2</sup> >0.5mm thick = 450cm <sup>2</sup> By Weight: 30 grams	24 days
Rabbit Pyrogen Re-Test	By Thickness: <0.5mm thick = 900cm <sup>2</sup> >0.5mm thick = 450cm <sup>2</sup> By Weight: 30 grams	23 days

### Sensitization Testing

Guinea Pig Maximization Tests for Sensitization (including ISO)	By Thickness: <0.5mm thick = 360cm <sup>2</sup> >0.5mm thick = 180cm <sup>2</sup> By Weight: 12 grams	47 days (60 days for ISO)
Repeated Patch Dermal Sensitization Test	Solid Sheets: 150 x 1 in <sup>2</sup> Liquid: 60 ml	63 days

### Subchronic (Subacute) Toxicity Testing

14-day Subchronic Toxicity Test in Mice	By Thickness: <0.5mm thick = 600cm <sup>2</sup> >0.5mm thick = 300cm <sup>2</sup> By Weight: 20 grams	57 days <i>See test listing for note.</i>
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### Systemic (Acute) Toxicity Testing

USP Acute Systemic Toxicity Test	By Thickness: <0.5mm thick = 120cm <sup>2</sup> >0.5mm thick = 60cm <sup>2</sup> By Weight: 4 grams	26 days
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### Finished Product Release Testing

USP Safety Test in Mice	One (1) device to represent the lot under test	25 days
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