

## Sample Requirements for Biocompatibility Testing (per extract)

Test Method	* <b>Minimum</b> Sample Requirement for:	**Turnaround Time
Cytotoxicity	material thickness of $\geq 0.5$ mm = 60 cm <sup>2</sup> material thickness of $< 0.5$ mm = 120 cm <sup>2</sup> 4 grams if surface area cannot be determined	2 - 3 weeks
GPMT (Kligman) Sensitization	material thickness of $\geq 0.5$ mm = 180 cm <sup>2</sup> material thickness of $< 0.5$ mm = 360 cm <sup>2</sup> 12 grams if surface area cannot be determined	7 - 9 weeks
Closed Patch (Buehler)	material thickness of $\geq 0.5$ mm = 360 cm <sup>2</sup> material thickness of $< 0.5$ mm = 720 cm <sup>2</sup> 24 grams if surface area cannot be determined	7 - 9 weeks
Primary Skin Irritation	material thickness of $\geq 0.5$ mm = 60 cm <sup>2</sup> material thickness of $< 0.5$ mm = 120 cm <sup>2</sup> 4 grams if surface area cannot be determined	2 - 3 weeks
Intracutaneous Reactivity	material thickness of $\geq 0.5$ mm = 60 cm <sup>2</sup> material thickness of $< 0.5$ mm = 120 cm <sup>2</sup> 4 grams if surface area cannot be determined	2 - 3 weeks
Systemic Toxicity; acute	material thickness of $\geq 0.5$ mm = 60 cm <sup>2</sup> material thickness of $< 0.5$ mm = 120 cm <sup>2</sup> 4 grams if surface area cannot be determined	2 - 3 weeks
Implantation	18 pcs. (1 - 3 mm) x 10 mm	Various time frames
Hemocompatibility; Hemolysis	270 cm <sup>2</sup> $\geq 0.5$ mm thick 540 cm <sup>2</sup> $< 0.5$ mm thick and at least 3 units <i>per method requested</i>	2 - 3 weeks
Material Characterization		
Infrared analysis	10 grams	3 - 5 days
Physicochemical Test	600 cm <sup>2</sup> or 20 grams	1 - 2 weeks

\*Please contact our customer service department if sample requirements are not attainable. If possible, additional material is desired to avoid delay in processing due to possible sample shortage.

\*\*Turn around time is based on actual set-up and test time. Please call prior to sample submittal to confirm turn around times.