

Sample Requirements for Biocompatibility Testing (per extract)

Test Method	* <i>Minimum</i> Sample Requirement for:	**Turnaround Time
Cytotoxicity	material thickness of ≥ 0.5 mm = 60 cm ² material thickness of < 0.5 mm = 120 cm ² 4 grams if surface area cannot be determined	1 – 2 weeks
GPMT (Kligman) Sensitization	material thickness of ≥ 0.5 mm = 180 cm ² material thickness of < 0.5 mm = 360 cm ² 12 grams if surface area cannot be determined	5 – 7 weeks
Closed Patch (Buehler)	material thickness of ≥ 0.5 mm = 360 cm ² material thickness of < 0.5 mm = 720 cm ² 24 grams if surface area cannot be determined	7 – 9 weeks
Primary Skin Irritation	material thickness of ≥ 0.5 mm = 60 cm ² material thickness of < 0.5 mm = 120 cm ² 4 grams if surface area cannot be determined	2 – 3 weeks
Intracutaneous Reactivity	material thickness of ≥ 0.5 mm = 60 cm ² material thickness of < 0.5 mm = 120 cm ² 4 grams if surface area cannot be determined	2 – 3 weeks
Systemic Toxicity; acute	material thickness of ≥ 0.5 mm = 60 cm ² material thickness of < 0.5 mm = 120 cm ² 4 grams if surface area cannot be determined	2 – 3 weeks
Systemic Toxicity; subacute	material thickness of ≥ 0.5 mm = 840 cm ² material thickness of < 0.5 mm = 1,680 cm ² 56 grams if surface area cannot be determined	6 – 7 weeks
Genotoxicity; Ames Test	60 cm ² or 4 grams	6 – 7 weeks
Implantation	18 pcs. (1 – 3 mm) x 10 mm	Various time frames
Hemocompatibility; Hemolysis	310 cm ² or 11 grams	2 – 3 weeks
Material Characterization		
Infrared analysis	10 grams	3 – 5 days
Physicochemical Test	600 cm ² or 20 grams	1 – 2 weeks
Material mediated pyrogen	600 cm ² or 20 grams or 3 – 10 final product units	4 – 5 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.