



CATEGORY	TESTING OPTIONS	TEST CODE	SAMPLE AMOUNT*
Cytotoxicity	MEM Elution (USP) 48 hr. MEM Elution (USP) 72 hr. Agar Overlay (USP)	CTX115 CTX120 CTX101	Up to 120 sq cm or 4 grams
Sensitization	Maximization (MAX) or Magnusson-Kligman method (ISO) with 2 extracts Local Lymph Node Assay (LLNA)with 2 extracts Buehler Method	SCX110 SCX120 SCX130	480 sq cm or 32 grams (min. of 6 samples) 480 sq cm or 32 grams (min. of 6 samples) 240 sq cm or 8 grams
Irritation	Intracutaneous Reactivity (USP) with 2 extracts Intracutaneous Reactivity (ISO) with 2 extracts Primary Eye Irritation (ISO) Primary Skin Irritation (ISO) Bladder Irritation Vaginal Irritation Penile Irritation	SCX210 SCX220 SCX230 SCX240 SCX250 SCX260 XPS112	240 sq cm or 8 grams 240 sq cm or 8 grams 50 sq cm or 10 g/10 mL 50 sq cm or 10 g/10 mL 120 sq cm or 8 grams 120 sq cm or 8 grams 120 sq cm or 8 grams
Systemic Toxicity	USP/ISO Systemic Injection with 2 extracts Material Mediated Pyrogen	SCX310 SCX320	240 sq cm or 8 grams 570 sq cm or 30 grams
Sub-Acute/ (Sub-chronic) Toxicity	Sub-Acute Toxicity w/Histopathology (14 day) Sub-Acute Toxicity w/Histopathology (28 day)	SCX410 SCX420	Quote Quote
Genotoxicity	Ames Test w/ 2 extracts Mouse Micronucleus (ISO)Chromosomal Aberration w/ 2 extracts (ISO) Mouse Lymphoma w/ 2 extracts	GTX110 SCX510 GTX220 SCX530	240 sq cm or 8 grams 240 sq cm or 8 grams 400 sq cm or 20 grams 240 sq cm or 8 grams
Implantation w/Histopathology	7 Day Observation (ISO) 7 Day Observation (USP) 14 Day Observation (ISO) 30 Day Observation (ISO) 60 Day Observation (ISO) 90 Day Observation (ISO)	SCX610 SCX615 SCX620 SCX630 SCX640 SCX650	14, 1 x 10mm strips



Hemo-compatibility * = A predicate device is recommended for these studies	Dog Thrombogenicity (ISO) (Predicate required)	SCX670	2 test devices, 2 predicate devices. 8-15 cm in length
	Hemolysis (extract)	HCX140	150 sq cm or 5 grams
	Hemolysis (direct)	HCX145	150 sq cm or 5 grams
	Prothrombin Time (PT)*	HCX210	150 sq cm or 5 grams
	Partial Thromboplastin Time* (PTT Non-Activated)	HCX220	
	Immunology/Complement (C3a, SCb-9) (First sample) (Predicate Required)	HCX250	One device

*Sample amounts are device specific and will vary.