Elanco Animal Health
Fiscal Year: 2018-2019
Registration No: 32-R-0053

						CATEGORY "E"
Species	Protocol Category	Title	Explanation of Procedure / Event Producing Pain and/or Distress in the Animal(s)	Scientific Justification and/or Regulations Requiring Procedure	3Rs considerations / alternatives	Total of Animal
Hamsters	E	Quality Control Umbrella for (b) (4) Challenge Culture Passage in Hamsters for Potency Testing of Serials and In-Process Antigens.	This passage process is necessary to maintain virulence of (b) (4) organisms for challenge preparation for use in the below potency test.	Supports a Codified Test. USDA (APHIS CVB): (b) (4)	These tests with (b) state that moribund animals exhibiting clinical signs consistent with the disease and were unable to rise or move will be humanely euthanized and considered as deaths. However, despite the additional daily observations, these reported had rapid progression of disease and were found dead, therefore are categorized as "E".	81
Hamsters	E	(b) (4) Blood and Tissue Passage in Hamsters	This passage process is necessary to maintain virulence of (b) (4) organisms for challenge preparation for use in the below potency test.	Supports a Codified Test. USDA (APHIS CVB): (b) (4)		1186
Hamsters	E	Quality Control Umbrella for (b) (4) Potency Testing in Hamsters of Serials and In-Process Antigens.	This test is to assure potency for the release of vaccine serials.	These are tests are prescribed in Title 9 of the Code of Federal Regulations. Codified Test. USDA (APHIS CVB) (b) (4) (b) (4) These are tests are prescribed in Title 9 of the Code of Federal Regulations. Codified Test. USDA (APHIS CVB) (b) (4) (b) (4) CVB approval for this test to remove titrations for (b) (4) serovars, thus reducing numbers		38
Hamsters	E	(b) (4) (b) (4) Hamster Potency Test	This test is to assure potency for the release of vaccine serials.	These are tests are prescribed in Title 9 of the Code of Federal Regulations. Codified Test. USDA (APHIS CVB) (b) (4) (b) (4)		3204

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Hamsters	E	Evaluation of Virulence Status of (b) (4) of Genus (b) (4) (b) (4) in Hamsters	To evaluate the virulence status of newly acquired (b) (4) isolates of the genus (b) (4) (b) (4) in order to assess virulence and reduce risk of repeating the study, hamsters receive a high challenge dosage, therefore progress quickly in clinical disease.	Study to select a virulent isolate of each serovar. Virulent isolates will be used to develop a global challenge model in dogs.	Hamsters exhibiting overt and severe clinical signs of (b) (4) and are depressed may be humanely euthanized before reaching the moribund state and will be considered as death. Despite additional welfare checks, these reported had rapid progression of disease and were found dead, therefore are categorized as "E".	106
Hamsters	E	In vivo potency Testing of (b) (4) (b) (4) in Hamsters for Vaccine Antigen Selection	To evaluate the efficacy of (b) (4) (b) (4) antigen selection. The design is to demonstrate 100% mortality in the non-vaccinated control groups.	Study to select an efficacious isolate of each serovar. The selected serovar may be used as the vaccine antigen for future canine studies. Federal Regulations require 10 -12 hamsters for test and control groups. These are tests are prescribed in Title 9 of the Code of Federal Regulations. Codified Test. USDA (APHIS CVB) (b) (4) (b) (4) was conducted in accordance to the other codified serovars.		122
Hamsters	E	(b) (4) (b) (4) (b) (4) Serovars Challenge Dose Titration in Hamster	Confirm the virulence status of newly acquired (b) (4) serovar isolates and determine optimal challenge dose in hamsters. Animals are expected to either be under or over -challanged in this model, resulting in Category C or E respectively.	The study used to confirm a select isolate for further development of challenge model in dogs and potency test in hamsters.		94
					Hamster TOTAL	**4831**

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Rabbit	E	Quality Control Umbrella for Serology Testing in Rabbits of Serial Release and In-Process Antigens for (b) (4)	Rabbits receive a large volume of vaccination IM in one or both rear limbs, and have been deemed painful due to reluctance to move, or lameness.	USDA (APHIS) 9CFR (b) (4) (b) (4)	Refinements to test under investigation	50
Rabbit	E	Dosage Serology Testing in Rabbits of Serial Antigens for (b) (4) (b) (4)	Vaccine administered was by 2.5mL, 1mL, 0.5mL, which is lower than the 5 ml field dose typically run with (b) seriels.	Ongoing efforts are to convert th(b) n-vivo rabbit potency assay into an in-vitro direct ELISA potency assay as a result from a letter received from CVB or (b) (4) (b) (4) The primary purpose of this study protocol is to assess the serum antibody response of rabbits to different dosages of (b) (4) (b) vaccines using a modified version of Special Outline (b) (4) These assay improvements have the potential to decrease, or even eliminate, the pain and/or distress in rabbits as a result of the test.	Despite the lower volumes administered IM, rabbits still exhibited signs of mild lameness suggesting discomfort. However, was subjectively less than the larger volume typically administered.	30
Rabbit	E	(b) (4) Serology Testing in Rabbits of Serial Release and In-Process Antigens.	Rabbits receive a large volume of vaccination IM in one or both rear limbs, and have been deemed painful due to reluctance to move, or lameness.	These animals are required by Special (b) (4) Production Outlines and USDA (APHIS (b) (4)	Refinements to test under investigation	131
					Rabbit Total	**211**

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Dog	D	Qualification of Elanco's Canine (b) (4) Reference for (b) (4) (b) (4)	Dog XXX-9 in this study was restrained for blood collection and intratracheal swabbing. After sampling, exhibited increased in respiratory effort and slow capillary refill time (shocky). Monitored and improved without intervention, however deemed in distress after sampling, therefore category E.	This study to qualify a new Master Reference vaccine for use in the in-vitro potency test for serial release of (b) (4) (b) (4)	NA	1
Dog	E	Evaluation of Virulence and Challenge Dose Titration of (b) (4) (b) (4) erovars in dogs	The objective of this study is to confirm the virulence status and determine the optimal challenge dosage of newly acquired (b) (4) Tha (b) (4) requires the efficacy of a vaccine be tested in the host animal. (b) in which dogs exhibit clinical signs of (b) such as jaundice, diarrhea, inappetance, vomiting) to assess virulence		Death is not an intended outcome, however (b) (4) an be lethal in dogs and the higher challenge concentrations may be lethal. These dogs reached established humane endpoints and were euthanized.	14
					Dog Total	**15**