



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	14M1.23
True Name	Canine Parainfluenza-Bordetella Bronchiseptica Vaccine, Modified Live Virus, Avirulent Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Nobivac Intra-Trac Oral BbPi - Merck Animal Health
Date of Compilation Summary	December 12, 2024

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy									
Pertaining to	<i>Bordetella bronchiseptica</i> (<i>B. bronchiseptica</i>)									
Study Purpose	To demonstrate efficacy against <i>B. bronchiseptica</i>									
Product Administration	One dose administered by the oral route (Day 0)									
Study Animals	7-week-old dogs; 21 vaccinates, 20 controls (placebo-vaccinated)									
Challenge Description	Dogs were challenged with virulent <i>B. bronchiseptica</i> 5 weeks post-vaccination (Day 36).									
Interval observed after challenge	Observations for clinical signs of coughing were conducted twice daily for 28 days post-challenge (Day 37-64).									
Results	An affected dog was defined as having spontaneous coughing or spontaneous coughing with retching on 2 or more consecutive days. <table><tr><th>Treatment Group</th><th># of Animals</th><th># of Animals Affected</th></tr><tr><td>Vaccinates</td><td>21</td><td>9</td></tr><tr><td>Controls</td><td>20</td><td>20</td></tr></table> Raw data shown on attached pages.	Treatment Group	# of Animals	# of Animals Affected	Vaccinates	21	9	Controls	20	20
Treatment Group	# of Animals	# of Animals Affected								
Vaccinates	21	9								
Controls	20	20								
USDA Approval Date	December 9, 2020									

Post Challenge Clinical Observations

Treatment Group	Dog ID	Study Day											
		34	35	36*	37		38		39		40		
		AM	AM	AM	AM	PM	AM	PM	AM	PM	AM	PM	
A (Vaccinates)	USF-0	-	-	-	-	-	-	-	CS	-	CS	-	
	VCE-0	-	-	-	-	-	-	-	-	-	-	-	
	VEE-0	-	-	-	-	-	-	-	-	-	-	-	
	VHE-0	-	-	-	-	-	-	-	-	-	-	-	
	VIE-0	-	-	-	-	-	-	-	CS	-	CS	-	
	VJE-0	-	-	-	-	CR	-	-	-	CR	CR	CS	
	VXF-0	-	-	-	-	-	-	-	-	-	-	-	
	VYF-0	-	-	-	-	-	-	-	-	-	-	-	
	WAE-0	-	-	-	-	-	-	-	CS	-	-	CS	
	WCE-0	-	-	-	-	-	-	-	-	-	-	-	
	WEF-0	-	-	-	-	-	-	-	CS	-	-	-	
	WFF-0	-	-	-	-	-	-	-	-	-	-	-	
	WGF-0	-	-	-	-	CS	-	-	-	-	-	-	
	WKE-0	-	-	-	-	-	-	-	-	-	-	CS	
	WOF-0	-	-	-	-	-	-	-	-	-	-	-	
	WRE-0	-	-	-	-	-	-	-	-	-	-	-	
	WVF-0	-	-	-	-	-	-	-	-	CS	-	-	
	WYE-0	-	-	-	-	-	-	-	-	CS	-	CS	
	XPF-0	-	-	-	-	-	-	-	-	CS	-	-	
	XSF-0	-	-	-	-	-	-	-	-	-	-	-	
	XUE-0	-	-	-	-	-	-	-	-	-	-	-	
B (Placebo-Vaccinated Controls)	UTF-0	-	-	-	-	-	-	-	CR	-	-	CR	
	UWE-0	-	-	-	CS	-	CR	-	-	CR	-	CR	
	VDE-0	-	-	-	-	-	-	-	-	-	-	-	
	VFF-0	-	-	-	-	-	-	-	-	-	-	-	
	VGE-0	-	-	-	-	-	-	-	-	-	-	CR	
	VVF-0	-	-	-	-	-	-	-	-	CR	CS	-	
	VWF-0	-	-	-	-	-	-	-	-	-	-	-	
	VZF-0	-	-	-	-	-	-	-	-	-	-	-	
	WBE-0	-	-	-	-	-	-	-	-	-	-	-	
	WDF-0	-	-	-	-	-	-	-	-	-	CR	CS	
	WHF-0	-	-	-	-	-	-	-	-	-	CS	ND	
	WIF-0	-	-	-	CS	-	-	-	CS	-	-	-	
	WJE-0	-	-	-	-	-	-	-	-	-	-	-	
	WLF-0	-	-	-	-	CR	-	-	-	CS	-	-	
	WPE-0	-	-	-	-	-	-	-	-	-	CS	-	
	WQE-0	-	-	-	-	-	CS	-	-	-	-	CS	
	WWE-0	-	-	-	-	-	-	-	-	ND, CS	ND, CS	CR	
	WXE-0	-	-	-	-	-	-	-	-	-	-	-	
	XQF-0	-	-	-	-	-	-	-	-	CR	-	-	
XTE-0	-	-	-	-	-	-	-	-	CS	-	-		

*Day of challenge

(-) = no clinical observations; ND = nasal discharge; CS = spontaneous cough; CR = spontaneous cough with retching

Post-Challenge Clinical Observations (Continued)

Treatment Group	Dog ID	Study Day									
		41		42		43		44		45	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
A (Vaccinates)	USF-0	-	-	-	-	-	-	-	-	-	-
	VCE-0	-	-	-	-	-	-	-	-	-	-
	VEE-0	-	-	-	-	-	-	-	-	-	-
	VHE-0	-	CS	-	-	-	-	-	-	-	-
	VIE-0	-	-	-	-	-	-	-	-	-	-
	VJE-0	-	-	-	-	-	-	-	-	-	-
	VXF-0	-	-	-	-	-	-	-	-	-	-
	VYF-0	-	-	-	-	-	CR	-	-	-	-
	WAE-0	-	-	-	-	-	-	-	-	-	-
	WCE-0	-	-	-	-	-	-	-	-	-	-
	WEF-0	-	CS	-	-	-	-	-	-	-	-
	WFF-0	-	CS	-	-	-	-	CS	-	CS	-
	WGF-0	CS	-	-	-	-	-	-	-	-	-
	WKE-0	-	-	-	-	-	-	-	-	-	-
	WOF-0	CS	-	-	-	-	-	-	-	CS	CS
	WRE-0	-	-	-	-	-	-	-	-	-	-
	WVF-0	-	-	-	-	-	-	-	CS	-	-
	WYE-0	-	-	-	-	-	-	-	-	-	-
	XPF-0	-	-	-	-	-	-	-	-	CS	-
	XSF-0	-	CS	-	-	-	-	-	-	-	-
	XUE-0	CS	-	-	-	-	-	-	-	-	-
B (Placebo-Vaccinated Controls)	UTF-0	-	CR	-	CR	-	-	-	-	-	-
	UWE-0	CR	CR	CS	CR	CS	CR	CS	CR	-	ND, CS
	VDE-0	CS	-	-	-	-	NA	-	-	-	CS
	VFF-0	-	CR	CS	CR	-	-	-	-	CS	ND
	VGE-0	CS	CR	CS	CR	-	CS	CS	-	CS	-
	VVF-0	-	-	-	CS	CS	-	-	-	-	-
	VWF-0	-	ND	-	ND	-	CR	-	-	-	-
	VZF-0	-	-	ND	-	-	ND	ND	-	ND	ND, CS
	WBE-0	ND	CS	ND, CR	ND, CR	CR	CR	-	ND, CR	ND, CS	CR
	WDF-0	-	-	-	-	ND	CS	-	ND	-	ND
	WHF-0	-	ND, CS	CS	-	-	-	-	CS	-	-
	WIF-0	-	CS	-	CS	CS	-	-	-	-	ND
	WJE-0	-	-	CS	ND	-	-	-	-	-	-
	WLF-0	-	CR	CS	-	-	-	CS	-	CS	CS
	WPE-0	CR	ND, CS	-	CR	CS	CS	ND	CS	-	CR
	WQE-0	-	CR	-	CR	-	CR	-	-	-	CS
	WWE-0	CS	CR	ND, CS	CR	CR	CR	CR	CR	ND, CR	CR
	WXE-0	ND	-	CS	-	-	-	-	-	-	-
	XQF-0	-	CS	-	-	-	CS	CS	-	-	-
	XTE-0	CS	-	-	CR	-	-	-	-	-	-

(-) = no clinical observations; ND = nasal discharge; CS = spontaneous cough; CR = spontaneous cough with retching

Post-Challenge Clinical Observations (Continued)

Treatment Group	Dog ID	Study Day									
		46		47		48		49		50	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
A (Vaccinates)	USF-0	-	-	-	-	-	-	-	-	-	-
	VCE-0	-	-	-	-	-	-	-	NA	-	-
	VEE-0	-	CR	-	CS	-	-	-	-	-	-
	VHE-0	-	-	CS	-	-	-	CS	-	-	-
	VIE-0	-	-	-	-	-	-	-	-	-	-
	VJE-0	-	-	-	-	CR	-	-	-	-	-
	VXF-0	-	-	-	CS	-	-	-	-	-	-
	VYF-0	-	-	-	CR	-	-	-	-	-	CR
	WAE-0	-	-	-	-	-	-	-	-	-	-
	WCE-0	-	-	-	-	-	-	-	-	CR	-
	WEF-0	-	-	-	CS	-	-	-	NA	-	-
	WFF-0	-	-	-	-	-	-	-	-	-	CS
	WGF-0	-	-	-	-	-	-	-	-	-	-
	WKE-0	-	CS	-	-	-	-	-	-	-	-
	WOF-0	-	-	-	-	-	-	CS	-	-	-
	WRE-0	-	-	CS	-	-	-	-	-	-	-
	WVF-0	-	CS	-	-	-	-	-	-	CR	-
	WYE-0	-	-	-	-	-	-	-	-	-	-
	XPF-0	-	-	NA	CS	-	-	-	-	-	-
	XSF-0	-	-	-	-	-	-	-	-	-	-
	XUE-0	-	-	-	-	-	-	-	-	-	-
B (Placebo-Vaccinated Controls)	UTF-0	-	-	-	CR	CS	CR	-	CR	-	CR
	UWE-0	-	ND, CR	-	CR	CR	CR	-	CR	CS	CR
	VDE-0	-	-	CS	-	-	-	-	-	-	-
	VFF-0	-	-	ND	CR	ND, CS	CR	ND	CR	-	CR
	VGE-0	-	CS	CS	CS	CS	CS	-	-	-	CS
	VVF-0	ND, CS	CR	-	CS	-	CR	-	-	-	CR
	VWF-0	ND	ND	-	CR	CS	-	-	-	-	-
	VZF-0	ND	-	-	CR	-	ND	ND	CS	CS	-
	WBE-0	CS	CS	ND, CS	ND, CR	-	ND, CS	CR	CR	-	CR
	WDF-0	CS	ND, CS	ND, CS	ND, CS	ND	ND	ND	ND	-	CS
	WHF-0	-	CS	-	ND	-	CS	-	-	-	NA
	WIF-0	ND, CS	-	ND	ND	-	CS	ND	NA	-	-
	WJE-0	-	-	-	-	-	CR	CS	ND, CS	-	CR
	WLF-0	-	-	-	-	-	-	-	-	-	CR
	WPE-0	CS	CS	CS	CR	-	CR	CR	CR	CS	CR
	WQE-0	-	CR	CS	-	-	CR	CS	CR	CS	-
	WWE-0	CR	CR	CS	CR	CR	CR	CS	CS	CR	CR
	WXE-0	-	-	CS	-	-	-	-	-	-	-
	XQF-0	-	CS	CR	CR	-	CR	-	CS	CS	CR
	XTE-0	-	-	-	-	-	-	-	-	-	-

(-) = no clinical observations; ND = nasal discharge; CS = spontaneous cough; CR = spontaneous cough with retching

NA = 2 data entries were recorded on study day 49 (PM observation) for dog WEF-0, and no entry was made for dog WIF; data entry for VCE occurred in error; one observation for WEF-0 was normal and the other was spontaneous coughing.

Post-Challenge Clinical Observations (Continued)

Treatment Group	Dog ID	Study Day									
		51		52		53		54		55	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
A (Vaccinates)	USF-0	-	-	-	-	-	-	-	-	-	-
	VCE-0	-	-	-	-	-	-	-	-	-	-
	VEE-0	-	CR	-	-	-	-	-	-	-	-
	VHE-0	CS	-	-	-	-	NA	-	-	-	-
	VIE-0	-	-	-	-	-	-	-	-	-	-
	VJE-0	-	-	CR	-	-	-	CS	-	-	-
	VXF-0	-	-	-	-	-	-	-	-	-	-
	VYF-0	-	-	-	-	-	-	-	-	-	-
	WAE-0	-	-	-	-	-	-	-	-	-	-
	WCE-0	-	-	-	-	-	-	CS	-	-	-
	WEF-0	-	-	-	-	-	-	-	-	-	-
	WFF-0	-	-	-	-	-	NA	-	-	-	-
	WGF-0	-	-	-	-	-	-	-	-	-	-
	WKE-0	-	-	-	-	-	-	-	-	-	-
	WOF-0	-	-	-	-	-	CS	-	-	CS	-
	WRE-0	-	-	-	-	-	-	-	-	-	-
	WVF-0	-	-	-	-	-	-	-	-	CS	-
	WYE-0	-	-	-	-	-	-	-	-	-	-
	XPF-0	CR	-	-	-	-	-	-	-	-	-
	XSF-0	-	-	-	-	-	-	-	-	-	-
	XUE-0	-	-	-	-	-	-	-	-	-	-
B (Placebo-Vaccinated Controls)	UTF-0	-	-	-	CR	CR	CR	-	CR	CR	CS
	UWE-0	CR	CR	-	CR	CR	CR	-	CR	-	ND, CR
	VDE-0	CS	-	-	CS	-	CR	-	CR	CS	-
	VFF-0	CR	CR	CS	CS	ND, CR	-	CR	CR	CS	CR
	VGE-0	CR	CR	-	CR	-	-	CS	CS	-	-
	VVF-0	CS	CR	CR	-	-	CR	CR	CS	CR	CR
	VWF-0	-	-	CR	-	-	CS	-	CR	-	-
	VZF-0	CS	-	CR	-	CR	CR	-	CR	-	CS
	WBE-0	-	ND	CR	-	-	ND, CR	-	-	ND	ND, CR
	WDF-0	-	-	-	-	-	-	-	-	CS	-
	WHF-0	-	-	-	-	-	-	-	-	-	-
	WIF-0	ND	-	ND	ND	-	-	CS	-	-	-
	WJE-0	CR	-	-	CS	-	CS	CR	-	-	CR
	WLF-0	-	CR	-	CR	CR	CR	CR	CR	CS	CR
	WPE-0	CS	CR	CS	CR	CS	CS	CR	CR	-	ND, CR
	WQE-0	-	CR	ND, B, D, CS, E	-	-	-	-	-	-	-
	WWE-0	CR	-	CS	CR	CS	CR	CS	CR	CR	CR
	WXE-0	CS	-	CS	-	-	-	-	-	-	-
	XQF-0	-	-	-	CR	-	CS	-	CS	CS	CS
	XTE-0	-	-	-	-	CS	-	-	-	-	-

(-) = no clinical observations; ND = nasal discharge; CS = spontaneous cough; CR = spontaneous cough with retching; D = depressed; B = dyspnea; E = euthanized

NA = 2 data entry errors were recorded on study day 53 (PM observation) for dog VHE-0, and no entry was made for dog WFF; both observations for VHE-0 were normal

Post-Challenge Clinical Observations (Continued)

Treatment Group	Dog ID	Study Day									
		56		57		58		59		60	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
A (Vaccinates)	USF-0	-	-	-	-	-	-	-	-	-	-
	VCE-0	-	-	-	-	-	-	-	-	-	-
	VEE-0	-	-	-	-	-	-	-	-	-	-
	VHE-0	-	-	-	-	-	CS	-	-	CR	-
	VIE-0	-	-	-	-	-	-	-	-	-	-
	VJE-0	-	-	-	-	-	-	-	-	-	-
	VXF-0	-	-	-	-	-	-	-	CR	-	-
	VYF-0	-	-	-	-	CR	-	-	CR	-	-
	WAE-0	-	-	-	-	-	-	-	-	-	-
	WCE-0	-	-	-	-	-	-	-	-	-	-
	WEF-0	-	-	-	-	-	-	-	-	-	-
	WFF-0	-	-	-	-	-	-	CS	-	-	-
	WGF-0	-	-	-	-	CR	-	-	-	-	-
	WKE-0	-	-	-	-	-	-	-	-	-	-
	WOF-0	-	-	-	-	-	-	-	-	-	-
	WRE-0	-	-	-	-	-	-	-	-	-	-
	WVF-0	-	-	-	-	CR	-	CS	-	-	-
	WYE-0	-	-	CS	-	-	-	CS	-	-	-
	XPF-0	-	-	-	-	-	-	-	-	-	-
	XSF-0	-	-	-	-	-	-	-	-	-	-
	XUE-0	-	-	-	-	-	-	CS	-	-	-
B (Placebo-Vaccinated Controls)	UTF-0	-	CR	CS	CR	-	CR	CS	CR	-	CR
	UWE-0	-	CR	-	-	-	CS	-	CR	-	CS
	VDE-0	-	-	-	CR	-	CR	-	-	-	-
	VFF-0	CR	CR	ND	-	CS	CR	-	ND, CS	ND, CR	CR
	VGE-0	-	-	-	CR	-	CS	CS	-	CS	CR
	VVF-0	CS	CR	CR	CR	CS	CS	CS	CR	CR	CR
	VWF-0	-	-	-	CR	-	CR	-	CR	-	CR
	VZF-0	-	ND, CS	CR	CR	-	CS	-	-	-	CR
	WBE-0	CR	-	ND	D, CR, E						
	WDF-0	-	-	-	-	CS	CR	-	-	-	-
	WHF-0	-	-	-	CR	-	CR	CR	-	-	-
	WIF-0	CS	-	ND	-	-	ND, CR	-	-	-	-
	WJE-0	-	CS	-	CR	ND	CR	CR	CR	-	CR
	WLF-0	CS	CR	CS	CR	CR	CR	-	CR	CS	CS
	WPE-0	-	CR	-	CS	-	CR	-	CR	CS	-
	WQE-0										
	WWE-0	CS	CS	CR	CR	CS	CR	CS	CR	CR	CR
	WXE-0	-	-	-	-	-	-	-	-	-	CS
	XQF-0	-	CS	-	CR	ND	CR	CR	CR	CS	CR
	XTE-0	-	-	-	-	-	-	-	-	-	-

(-) = no clinical observations; N = nasal discharge; CS = spontaneous cough; CR = spontaneous cough with retching; D = depression; E = euthanized

Post-Challenge Clinical Observations (Continued)

Treatment Group	Dog ID	Study Day							
		61		62		63		64	
		AM	PM	AM	PM	AM	PM	AM	PM
A (Vaccinates)	USF-0	-	CR	-	-	-	-	-	-
	VCE-0	-	-	-	-	-	-	-	-
	VEE-0	-	CS	-	-	-	-	-	-
	VHE-0	-	-	-	-	-	-	-	-
	VIE-0	-	-	-	-	-	-	-	-
	VJE-0	-	-	-	CS	-	-	-	-
	VXF-0	-	-	-	-	-	-	-	-
	VYF-0	-	-	-	-	-	-	-	CR
	WAE-0	-	-	-	-	-	-	-	-
	WCE-0	-	-	-	-	-	-	-	-
	WEF-0	-	-	-	-	-	-	-	-
	WFF-0	-	-	-	-	-	-	-	-
	WGF-0	-	-	-	-	-	-	-	-
	WKE-0	-	-	-	-	-	-	-	-
	WOF-0	-	-	-	-	-	-	-	-
	WRE-0	-	-	-	-	-	-	-	-
	WVF-0	-	-	-	-	-	-	-	-
	WYE-0	-	-	-	-	-	-	-	-
	XPF-0	-	-	-	-	-	CS	-	-
	XSF-0	-	-	CS	-	-	-	-	-
	XUE-0	-	-	-	-	-	-	-	-
B (Placebo-Vaccinated Controls)	UTF-0	CS	CR	-	CR	-	CR	-	-
	UWE-0	-	CR	-	CR	CR	-	CS	-
	VDE-0	-	-	CS	CS	-	-	-	-
	VFF-0	CS	CR	CR	CS	-	CR	CS	CR
	VGE-0	CS	CR	CS	CR	-	-	CR	CR
	VVF-0	CR	CS	CR	CR	-	CR	-	CR
	VWF-0	-	CR	CR	CR	-	CR	CR	CR
	VZF-0	-	-	CS	-	-	CR	-	-
	WBE-0								
	WDF-0	-	-	-	-	CS	-	-	-
	WHF-0	-	-	-	-	CS	-	-	-
	WIF-0	-	-	-	-	-	-	-	-
	WJE-0	ND, CS	CS	-	CS	-	CS	CR	CS
	WLF-0	CS	ND, CR	ND, CR	CR	CR	CR	CS	CR
	WPE-0	-	-	-	CR	CS	ND, CS	CR	-
	WQE-0								
	WWE-0	CR	CS	CR	CS	CR	CR	-	CR
	WXE-0	-	CR	-	CS	-	-	-	-
	XQF-0	CR	CS	ND, CR	CR	ND, CS	CR	CS	ND, CS
	XTE-0	-	CR	ND, CR	-	CR	CR	-	CR

(-) = no clinical observations; ND = nasal discharge; CS = spontaneous cough, CR = spontaneous cough with retching

Study Type	Efficacy									
Pertaining to	<i>Bordetella bronchiseptica</i>									
Study Purpose	Duration of immunity against <i>Bordetella bronchiseptica</i> in dogs									
Product Administration	One dose administered by the oral route									
Study Animals	7- to 8-week-old dogs; 23 vaccinates and 23 controls									
Challenge Description	All dogs were challenged with <i>B. bronchiseptica</i> 13 months after vaccination (study day 405).									
Interval observed after challenge	Dogs were observed daily for at least 30 minutes each day, twice a day, for 28 days for clinical signs.									
Results	Primary outcome variable was coughing. An affected dog was defined as having spontaneous coughing or spontaneous coughing with retching on 2 or more consecutive days. <table><tr><th>Treatment Group</th><th># of Dogs</th><th># of Dogs Affected</th></tr><tr><td>Vaccinates</td><td>22*</td><td>2</td></tr><tr><td>Controls</td><td>23</td><td>17</td></tr></table> *Dog removed from study prior to challenge. Raw data shown on attached page.	Treatment Group	# of Dogs	# of Dogs Affected	Vaccinates	22*	2	Controls	23	17
Treatment Group	# of Dogs	# of Dogs Affected								
Vaccinates	22*	2								
Controls	23	17								
USDA Approval Date	January 26, 2024									

Table 1. Clinical Observations Post-Challenge

Treatment Group	Dog ID	Study Day											
		-1 PC	0 PC*	1 PC		2 PC		3 PC		4 PC		5 PC	
		AM	AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Vaccinates	IIB-2	-	-	-	-	-	-	-	-	-	-	-	-
	IUB-2	-	-	CR	-	-	-	-	-	-	-	-	-
	IVA-2	-	-	-	-	-	-	-	-	-	-	-	-
	IZA-2	-	-	-	-	-	-	-	-	-	-	-	-
	JIB-2	-	-	-	-	-	-	-	-	-	-	-	-
	JWB-2	-	-	-	-	-	-	-	-	-	-	-	-
	JXB-2	-	-	-	-	-	-	-	-	-	-	-	-
	KJB-2	-	-	-	-	-	-	-	-	-	-	CS	-
	KOA-2	-	-	-	-	-	-	-	-	-	-	-	-
	KQB-2	-	-	-	-	-	-	-	-	-	-	-	-
	KYA-2	-	-	-	-	-	-	-	-	-	-	-	-
	LEA-2	-	-	-	-	-	-	-	CS	-	-	-	-
	LFA-2	-	-	-	-	-	-	-	-	-	-	-	-
	OKA-2	-	-	-	-	-	-	-	-	-	-	-	-
	PAB-2	-	-	-	-	-	-	-	-	-	-	-	-
	PCB-2	-	-	-	-	-	-	-	-	-	-	-	CS
	PTB-2	-	-	-	-	-	-	-	-	-	-	-	-
	PVA-2	-	-	-	-	-	-	-	-	-	CS	-	-
	PWA-2	-	-	-	-	-	-	-	-	-	-	-	-
	QGA-2	-	-	-	-	-	-	-	-	-	-	-	-
	QUA-2	-	-	-	-	-	-	-	-	-	-	-	-
	QZB-2	-	-	-	-	-	-	-	-	-	-	-	-
Controls	IGB-2	-	-	-	-	-	-	-	-	-	-	-	-
	IHB-2	-	-	-	-	-	-	-	-	-	-	-	-
	IWA-2	-	-	-	-	-	-	CS	-	-	-	-	-
	IYA-2	-	-	-	-	CS	-	-	-	-	-	-	-
	JLA-2	-	-	-	-	-	-	CS	-	CS	-	-	-
	JOA-2	-	-	-	-	-	-	-	-	CS	-	-	-
	KAA-2	-	-	-	-	-	-	CS	-	-	CS	-	-
	KKB-2	-	-	-	-	-	-	-	-	-	-	-	-
	KPB-2	-	-	-	-	-	-	CS	-	-	-	-	-
	KTB-2	-	-	-	-	-	-	-	-	-	-	-	-
	LAB-2	-	-	-	-	-	-	-	-	-	-	-	-
	OHB-2	-	-	-	-	-	-	CS	-	-	-	-	-
	OSA-2	-	-	-	-	-	-	-	-	-	-	-	-
	PBB-2	-	-	-	-	-	-	-	-	-	-	-	-
	PFA-2	-	-	-	-	-	-	-	CS	-	CR	-	-
	PRB-2	-	-	-	-	-	-	-	-	-	-	-	-
	PSB-2	-	-	-	-	-	-	-	-	-	-	-	-
	QEB-2	-	-	-	-	-	CS	-	-	-	CS	-	-
	QJB-2	-	-	CS	-	-	-	-	-	-	-	-	-
	QTB-2	-	-	-	-	-	-	-	-	-	-	-	-
	QVA-2	-	-	-	-	-	-	-	-	-	-	-	-
	RAA-2	-	-	-	-	-	-	-	-	-	-	-	-
	RBA-2	-	-	-	-	-	-	-	-	-	-	-	-

* Day of challenge

(-) = Normal; CS = spontaneous coughing; CR = spontaneous coughing with retching

Table 1. Clinical Observations Post-Challenge - continued

Treatment Group	Dog ID	Study Day											
		6 PC		7 PC		8 PC		9 PC		10 PC		11 PC	
		AM	AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Vaccinates	IIB-2	CR	-	-	-	-	-	-	-	-	-	-	-
	IUB-2	-	-	-	-	-	-	-	-	-	-	-	-
	IVA-2	-	-	-	-	-	-	-	-	-	-	-	-
	IZA-2	-	-	-	-	-	-	-	-	-	-	-	-
	JIB-2	-	-	-	-	-	-	-	-	-	-	-	-
	JWB-2	-	-	-	-	-	-	-	-	-	-	-	-
	JXB-2	-	-	-	-	-	-	-	-	-	-	-	-
	KJB-2	-	-	-	-	-	-	-	-	-	-	-	-
	KOA-2	-	-	-	-	-	-	-	-	-	-	-	-
	KQB-2	-	-	-	-	-	-	-	-	-	-	-	-
	KYA-2	-	-	-	-	-	-	-	-	-	-	-	-
	LEA-2	-	-	-	-	-	-	-	-	-	-	-	-
	LFA-2	-	-	-	-	-	-	-	-	-	-	-	-
	OKA-2	-	-	-	-	-	-	-	-	-	-	-	-
	PAB-2	-	-	-	-	-	-	-	-	-	-	-	-
	PCB-2	CS	-	-	-	-	-	-	-	-	-	-	-
	PTB-2	-	-	-	-	-	-	-	-	-	-	-	-
	PVA-2	-	-	-	-	-	-	CR	-	-	-	-	-
	PWA-2	-	-	-	-	-	-	-	-	-	-	-	-
	QGA-2	-	-	-	-	-	-	-	-	-	-	-	-
	QUA-2	-	-	-	-	-	-	-	-	-	-	-	-
	QZB-2	-	-	-	-	-	-	-	-	-	-	-	-
Controls	IGB-2	-	-	-	-	-	-	-	-	-	-	-	-
	IHB-2	-	-	-	-	-	-	-	-	-	-	-	-
	IWA-2	CS	-	-	-	-	-	CS	CS	-	CS	-	-
	IYA-2	-	-	-	-	-	-	-	-	-	-	-	-
	JLA-2	CS	-	CS	-	-	-	-	-	-	-	-	-
	JOA-2	-	-	-	-	CR	CS	-	CS	-	CS	-	-
	KAA-2	-	-	CS	-	CS	-	-	-	CR	-	-	-
	KKB-2	-	-	-	-	-	-	-	-	-	-	-	-
	KPB-2	-	-	-	-	CS	-	CS	-	-	-	CR	-
	KTB-2	-	-	-	-	-	-	-	-	-	-	-	-
	LAB-2	-	-	-	-	CS	-	-	-	-	CS	-	-
	OHB-2	-	-	-	-	CS	-	CS	-	-	-	-	-
	OSA-2	-	-	CS	-	-	-	-	-	CS	CS	CS	-
	PBB-2	-	-	-	-	-	-	-	-	-	-	-	-
	PFA-2	-	-	-	-	-	-	-	-	-	-	-	-
	PRB-2	-	-	-	-	-	-	-	-	-	-	-	-
	PSB-2	-	-	-	-	-	-	-	-	-	-	-	-
	QEB-2	-	-	-	-	-	-	-	CS	-	CS	-	-
	QJB-2	-	-	-	-	-	-	-	-	-	-	-	-
	QTB-2	-	-	-	-	-	-	-	-	-	-	-	-
	QVA-2	-	-	-	-	-	-	-	-	-	-	-	-
	RAA-2	CS	-	-	-	-	-	CS	-	-	CS	-	-
	RBA-2	-	-	-	-	-	-	-	-	-	-	-	-

(-) = Normal; CS = spontaneous coughing; CR = spontaneous coughing with retching

Table 1. Clinical Observations Post-Challenge - continued

Treatment Group	Dog ID	Study Day											
		12 PC		13 PC		14 PC		15 PC		16 PC		17 PC	
		AM	AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Vaccinates	IIB-2	-	-	-	-	-	-	-	-	-	-	-	-
	IUB-2	-	-	-	-	-	-	-	-	-	-	-	-
	IVA-2	-	-	-	-	-	-	-	-	-	-	-	-
	IZA-2	-	-	-	-	-	-	-	-	-	-	-	-
	JIB-2	-	CS	-	-	-	-	-	-	-	-	-	-
	JWB-2	-	-	-	-	-	-	-	-	-	-	-	-
	JXB-2	-	-	-	-	-	-	-	-	-	-	-	-
	KJB-2	-	-	-	-	-	-	-	-	-	-	-	-
	KOA-2	CS	-	-	-	-	-	-	-	-	-	-	-
	KQB-2	-	-	-	-	-	-	-	-	-	-	-	-
	KYA-2	-	-	-	-	-	-	-	-	-	-	-	-
	LEA-2	-	-	-	-	-	-	-	-	-	-	-	-
	LFA-2	-	-	-	-	-	-	-	-	-	-	-	-
	OKA-2	-	-	-	-	CS	-	-	-	-	-	-	-
	PAB-2	-	-	-	-	-	-	-	-	-	-	-	-
	PCB-2	-	-	-	-	-	-	-	-	-	-	-	-
	PTB-2	-	-	-	-	-	-	-	-	-	-	-	-
	PVA-2	-	-	-	-	-	-	-	-	-	-	-	-
	PWA-2	CS	-	-	-	-	-	-	-	-	-	-	-
	QGA-2	-	-	-	-	-	-	-	-	-	-	-	-
	QUA-2	-	-	-	-	-	-	-	-	-	-	-	-
	QZB-2	-	-	-	CR	-	-	-	-	-	-	-	-
Controls	IGB-2	-	-	-	-	-	-	-	-	-	-	-	-
	IHB-2	-	-	-	-	-	-	CS	-	-	-	-	-
	IWA-2	CS	-	-	-	-	-	-	-	-	-	-	-
	IYA-2	-	-	-	-	-	-	-	-	-	-	-	CS
	JLA-2	CS	-	-	-	-	-	-	-	-	-	-	-
	JOA-2	CS	-	-	-	-	-	-	-	-	-	CS	-
	KAA-2	-	-	-	-	-	-	-	-	-	-	-	-
	KKB-2	-	-	CS	-	-	CS	CS	-	-	-	-	-
	KPB-2	CS	-	-	-	-	-	-	-	CS	-	CS	CS
	KTB-2	-	-	CS	-	-	-	-	-	-	-	-	-
	LAB-2	CS	-	-	-	-	CS	-	-	CS	-	-	-
	OHB-2	CS	-	-	-	-	-	-	-	-	-	-	-
	OSA-2	-	-	-	-	-	-	CS	-	CS	CR	-	CR
	PBB-2	-	-	-	-	-	-	CS	-	-	-	-	-
	PFA-2	-	-	CS	-	-	CS	CS	-	-	-	-	-
	PRB-2	-	CR	CS	-	-	-	CS	-	-	-	-	-
	PSB-2	-	-	CS	-	CS	-	CS	-	-	-	CR	-
	QEB-2	CS	-	-	-	-	-	-	CR	CS	-	-	-
	QJB-2	-	-	-	-	-	-	CS	-	-	CS	-	-
	QTB-2	-	-	CS	-	-	-	-	-	-	-	-	-
	QVA-2	-	-	-	-	-	-	-	-	-	-	-	-
	RAA-2	-	-	-	-	-	-	-	-	-	CS	CS	CS
	RBA-2	-	-	-	-	-	-	-	-	CS	CS	-	CS

(-) = Normal; CS = spontaneous coughing; CR = spontaneous coughing with retching

Table 1. Clinical Observations Post-Challenge - continued

Treatment Group	Dog ID	Study Day											
		18 PC		19 PC		20 PC		21 PC		22 PC		23 PC	
		AM	AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Vaccinates	IIB-2	-	-	-	-	-	-	-	-	-	-	-	-
	IUB-2	-	-	-	-	-	-	-	-	-	-	-	-
	IVA-2	-	-	-	-	-	-	-	-	-	-	-	-
	IZA-2	-	-	-	-	-	-	-	-	-	-	-	-
	JIB-2	-	-	-	-	-	-	CS	-	-	-	-	-
	JWB-2	-	-	-	-	-	-	-	-	-	CS	-	-
	JXB-2	-	-	-	-	-	-	-	-	-	-	-	-
	KJB-2	-	-	-	-	-	-	-	-	-	-	-	-
	KOA-2	-	-	-	-	-	-	-	-	-	-	-	-
	KQB-2	-	-	-	-	-	-	-	-	-	-	-	-
	KYA-2	-	-	-	-	-	-	-	-	-	-	-	-
	LEA-2	-	-	-	-	-	-	-	-	-	-	-	CS
	LFA-2	-	-	-	-	-	-	-	CS	-	-	-	-
	OKA-2	CS	-	-	-	-	-	-	CS	-	-	-	-
	PAB-2	-	-	-	-	-	-	-	-	-	-	-	-
	PCB-2	-	-	-	-	CS	-	-	-	-	-	-	-
	PTB-2	-	-	-	CS	-	-	-	-	-	-	-	-
	PVA-2	-	-	-	-	-	-	-	-	-	-	-	-
	PWA-2	-	-	-	-	-	-	-	-	-	-	-	-
	QGA-2	-	-	-	-	-	-	-	CR	-	-	-	-
	QUA-2	-	-	-	-	-	-	-	-	-	-	-	-
	QZB-2	-	-	-	-	-	-	-	-	-	-	-	-
Controls	IGB-2	-	-	-	-	-	-	-	-	-	-	-	-
	IHB-2	-	-	-	-	-	-	-	-	-	-	-	-
	IWA-2	-	-	-	-	-	-	-	-	CS	-	-	CS
	IYA-2	-	CS	-	CS	-	-	-	-	CS	-	-	-
	JLA-2	-	CS	-	-	-	-	-	-	-	-	-	-
	JOA-2	-	-	-	-	-	-	CS	-	CS	-	-	-
	KAA-2	-	CS	-	-	-	-	-	-	-	-	-	-
	KKB-2	-	-	-	-	-	-	CS	-	-	-	-	-
	KPB-2	-	-	-	-	-	-	CS	-	-	-	CS	-
	KTB-2	-	-	-	-	-	-	-	-	-	-	-	CS
	LAB-2	-	-	-	-	-	-	-	-	CS	-	-	-
	OHB-2	-	-	-	-	-	-	-	-	-	-	CS	-
	OSA-2	-	CS	-	-	-	-	-	-	-	-	-	-
	PBB-2	-	-	-	-	-	-	-	-	-	-	-	-
	PFA-2	-	-	-	-	-	-	CS	-	-	-	-	-
	PRB-2	-	-	-	-	-	-	-	-	-	-	CR	-
	PSB-2	-	-	-	-	-	-	CS	-	-	-	-	-
	QEB-2	-	-	-	-	-	-	CS	CR	-	-	-	-
	QJB-2	-	-	-	-	-	-	-	-	-	-	-	-
	QTB-2	-	-	-	-	-	-	-	-	-	-	-	-
	QVA-2	-	-	-	-	-	-	CS	-	-	-	-	-
	RAA-2	-	CS	-	-	-	-	-	-	-	-	-	-
	RBA-2	-	-	-	-	-	-	CS	-	CS	-	-	-

(-) = Normal; CS = spontaneous coughing; CR = spontaneous coughing with retching

Table 1. Clinical Observations Post-Challenge - continued

Treatment Group	Dog ID	Study Day									
		24 PC		25 PC		26 PC		27 PC		28 PC	
		AM	AM	AM	PM	AM	PM	AM	PM	AM	PM
Vaccinates	IIB-2	-	-	-	-	-	-	-	-	-	-
	IUB-2	-	CS	-	-	-	-	-	-	-	-
	IVA-2	-	-	-	-	-	-	-	-	-	-
	IZA-2	-	-	-	-	-	-	-	-	-	-
	JIB-2	-	-	-	-	-	-	-	-	CR	-
	JWB-2	-	-	-	-	-	-	-	-	-	-
	JXB-2	-	-	-	-	-	-	-	-	-	-
	KJB-2	-	-	-	-	-	-	-	-	-	-
	KOA-2	-	-	-	-	-	-	-	-	-	-
	KQB-2	-	-	-	-	-	-	-	-	-	-
	KYA-2	-	-	-	-	-	-	-	-	-	-
	LEA-2	CS	-	-	-	-	-	-	-	-	-
	LFA-2	-	-	CR	-	-	-	-	-	CS	-
	OKA-2	-	-	-	-	-	-	-	-	CR	-
	PAB-2	-	-	-	-	-	-	-	-	-	-
	PCB-2	-	-	-	-	-	-	-	-	-	-
	PTB-2	-	-	-	-	-	-	-	-	-	-
	PVA-2	-	-	-	-	-	-	-	-	-	-
	PWA-2	-	-	-	-	-	-	-	-	-	-
	QGA-2	-	-	-	-	-	-	-	-	-	-
	QUA-2	-	-	-	-	-	-	-	-	-	-
	QZB-2	-	-	-	-	-	-	-	-	-	-
Controls	IGB-2	-	-	-	-	-	-	-	-	-	-
	IHB-2	-	-	-	-	-	-	-	-	-	-
	IWA-2	-	-	-	-	-	-	-	-	CS	-
	IYA-2	-	-	-	-	-	-	-	-	-	-
	JLA-2	-	-	-	-	-	-	-	-	-	-
	JOA-2	-	CS	-	-	CS	-	-	-	-	-
	KAA-2	-	-	-	-	-	-	-	CS	-	-
	KKB-2	-	-	-	-	-	-	CS	-	-	CS
	KPB-2	-	-	-	-	-	-	-	-	-	-
	KTB-2	-	-	-	-	-	-	-	-	-	-
	LAB-2	-	-	CR	-	CS	-	-	-	CS	-
	OHB-2	CR	-	-	-	-	-	-	-	-	-
	OSA-2	-	CS	CR	-	-	-	-	CS	-	-
	PBB-2	-	-	-	-	-	-	-	-	-	-
	PFA-2	-	-	-	-	-	-	CS	CS	-	-
	PRB-2	-	-	-	-	-	-	-	-	-	-
	PSB-2	-	-	-	-	CR	-	CS	-	-	-
	QEB-2	-	-	-	-	-	-	CR	-	CS	-
	QJB-2	-	-	-	-	-	-	-	-	-	-
	QTB-2	-	-	-	-	-	-	-	-	-	-
	QVA-2	-	-	-	-	-	-	-	-	-	-
	RAA-2	-	-	-	-	-	-	-	CS	-	-
	RBA-2	-	-	-	-	-	-	CS	-	-	-

(-) = Normal; CS = spontaneous coughing; CR = spontaneous coughing with retching

Study Type	Efficacy																		
Pertaining to	Canine Parainfluenza (CPI)																		
Study Purpose	To demonstrate efficacy against canine parainfluenza																		
Product Administration	One dose administered by the oral route (Day 0)																		
Study Animals	7-week-old dogs; 20 vaccinates, 19 controls (placebo-vaccinated)																		
Challenge Description	Dogs were challenged with canine parainfluenza virus 21 days post vaccination (Day 21).																		
Interval observed after challenge	Clinical signs were observed daily for 14 days post challenge (through Day 35). Viral shedding was conducted daily for 10 days post challenge.																		
Results	The study met the requirements of 9 CFR 113.316.																		
	Five Number Summary for Duration of Shedding (Days)*																		
	<table><tr><td>Group</td><td>Min</td><td>Q1</td><td>Med</td><td>Q3</td><td>Max</td></tr><tr><td>Vaccinate</td><td>0</td><td>0</td><td>2</td><td>4</td><td>9</td></tr><tr><td>Control</td><td>0</td><td>5</td><td>6</td><td>7</td><td>9</td></tr></table>	Group	Min	Q1	Med	Q3	Max	Vaccinate	0	0	2	4	9	Control	0	5	6	7	9
	Group	Min	Q1	Med	Q3	Max													
	Vaccinate	0	0	2	4	9													
	Control	0	5	6	7	9													
<i>*Two animals were shedding on the last observation day; a value of max duration of shedding by any animal +1 was assigned.</i>																			
Raw data shown on attached pages.																			
USDA Approval Date	June 8, 2020																		

Serum Antibody Titers to CPI

Treatment Group	Dog ID	Day -1	Day 21	Day 35
A Vaccinates	6590225	< 2	861	431
	6590250	< 2	181	> 4096
	6590276	< 2	< 2	108
	6590292	< 2	< 2	3
	6590306	< 2	2	152
	6590349	< 2	108	91
	6590373	< 2	215	256
	6590390	< 2	128	362
	6590403	< 2	27	724
	6590471	< 2	64	1218
	6590501	< 2	431	> 4096
	6590535	< 2	< 2	431
	6590578	< 2	152	256
	6590608	< 2	6	1448
	6590616	< 2	54	304
	6590624	< 2	23	76
	6590632	< 2	64	2896
	6590641	< 2	64	1448
	6590675	< 2	181	3444
	6590713	< 2	< 2	512
B Placebo-vaccinated Controls	6590233	< 2	< 2	431
	6590268	< 2	< 2	512
	6590284	< 2	< 2	181
	6590314	< 2	< 2	128
	6590322	< 2	< 2	215
	6590331	< 2	< 2	181
	6590365	< 2	< 2	512
	6590381	< 2	< 2	609
	6590462	< 2	< 2	431
	6590489	< 2	< 2	431
	6590519	< 2	< 2	1448
	6590527	< 2	< 2	431
	6590543	< 2	< 2	431
	6590586	< 2	< 2	76
	6590594	< 2	< 2	215
	6590659	< 2	< 2	304
	6590667	< 2	< 2	181
	6590683	< 2	< 2	215
	6590730	< 2	< 2	215

GMT (Geometric Mean Titer) calculation.

Day -1 = 1 Day prior to vaccination

Day 21 = Day of challenge

Day 35 = End of Study

Post-Challenge Clinical Observations

Treatment Group	Dog ID	Day 20	Day 21 ^{&}	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28
A Vaccinates	6590225	-	-	-	-	-	-	-	-	-
	6590250	-	-	-	-	-	-	-	-	-
	6590276	-	-	-	-	-	-	-	-	-
	6590292	-	-	-	-	-	-	-	-	-
	6590306	-	-	-	-	-	-	-	-	-
	6590349	-	-	-	-	-	-	-	-	-
	6590373	-	-	-	-	-	-	-	-	-
	6590390	S	-	-	-	-	-	-	-	-
	6590403	-	-	-	-	-	-	-	-	-
	6590471	-	-	-	-	-	-	-	-	-
	6590501	-	-	-	-	-	-	-	-	-
	6590535	-	-	-	-	-	-	-	-	-
	6590578	-	-	-	-	-	-	-	-	-
	6590608	-	-	-	-	-	-	-	-	-
	6590616	-	-	-	-	-	-	-	-	-
	6590624	-	-	-	-	-	-	-	-	-
	6590632	-	-	-	-	-	-	-	-	-
	6590641	-	-	-	-	-	-	-	-	-
	6590675	-	-	-	-	-	-	-	-	-
	6590713	-	-	-	-	-	-	-	-	-
B Placebo- vaccinated Controls	6590233	-	-	-	-	-	-	-	S	-
	6590268	-	-	-	-	-	-	-	-	-
	6590284	-	-	-	-	-	-	-	-	-
	6590314	-	-	-	-	-	-	-	-	-
	6590322	-	-	-	-	-	-	-	-	-
	6590331	-	-	-	-	-	-	-	-	-
	6590365	-	-	-	-	-	-	-	-	-
	6590381	-	-	-	-	-	-	-	-	-
	6590462	-	-	-	-	-	-	-	-	-
	6590489	-	-	-	-	-	-	-	-	-
	6590519	-	-	-	S	-	-	-	-	-
	6590527	-	-	-	-	-	-	-	-	-
	6590543	-	-	-	-	-	-	-	-	-
	6590586	-	-	-	-	-	-	-	-	-
	6590594	-	-	-	-	-	-	-	-	-
	6590659	-	-	-	-	-	-	-	-	-
	6590667	-	-	-	-	-	-	-	-	-
	6590683	-	-	-	-	-	-	-	-	-
	6590730	-	-	-	-	-	-	-	-	-

[&] Indicates day of challenge
 (-) = Normal; S = Sneezing

Post-Challenge Clinical Observations (Continued)

Treatment Group	Dog ID	Day 29	Day 30	Day 31	Day 32	Day 33	Day 34	Day 35
A Vaccinates	6590225	-	-	-	-	-	-	-
	6590250	-	-	-	-	-	-	-
	6590276	-	-	-	-	-	-	-
	6590292	-	-	-	-	-	-	-
	6590306	-	-	-	-	-	-	-
	6590349	-	-	-	-	-	-	-
	6590373	-	-	-	-	-	-	-
	6590390	-	-	-	-	-	-	-
	6590403	-	-	-	-	-	-	-
	6590471	-	-	-	-	-	-	-
	6590501	-	-	-	-	-	-	-
	6590535	-	-	-	-	-	-	-
	6590578	-	-	-	-	-	-	-
	6590608	-	-	-	-	-	-	-
	6590616	-	-	-	-	-	-	-
	6590624	-	-	-	-	-	-	-
	6590632	-	-	-	-	-	-	-
	6590641	-	-	-	-	-	-	-
	6590675	-	-	-	-	-	-	-
	6590713	-	-	-	-	-	-	-
B Placebo- vaccinated Controls	6590233	-	-	-	-	-	-	-
	6590268	-	-	-	-	-	-	-
	6590284	-	-	-	-	-	-	-
	6590314	-	-	-	-	-	-	-
	6590322	-	-	-	-	-	-	-
	6590331	-	-	-	-	-	-	-
	6590365	-	-	-	-	-	-	-
	6590381	-	-	-	-	-	-	-
	6590462	-	-	-	-	-	-	-
	6590489	-	-	-	-	-	-	-
	6590519	-	-	-	-	-	-	-
	6590527	-	-	-	-	-	-	-
	6590543	-	-	-	-	-	-	-
	6590586	-	-	-	-	-	-	-
	6590594	-	-	-	-	-	-	-
	6590659	-	-	-	-	-	-	-
	6590667	-	-	-	-	-	-	-
	6590683	-	-	-	-	-	-	-
	6590730	CS	-	-	-	-	-	-

(-) = Normal; CS = Spontaneous Cough

Day 35 = End of Study

Rectal Temperatures (°F)

Treatment Group	Dog ID	Day 0*	Day 19	Day 20	Day 21 ^a	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28
A Vaccinates	6590225	100.9	101.8	102.2	101.4	99.8	101.1	101.8	101.6	101.3	101.4	101.3
	6590250	100.7	100.1	101.4	101.0	100.2	100.8	101.0	100.5	101.4	100.8	101.2
	6590276	101.0	100.0	101.7	101.1	101.4	100.8	102.0	101.5	101.7	101.6	101.3
	6590292	100.5	101.2	101.2	101.7	101.6	101.3	102.4	102.1	101.4	101.1	100.0
	6590306	101.5	101.2	102.2	102.0	100.2	101.7	102.1	102.7	100.7	100.3	100.9
	6590349	101.4	99.2	101.5	100.8	100.3	100.7	100.6	101.0	101.5	100.9	102.0
	6590373	101.3	100.2	101.3	100.7	101.4	99.5	100.9	101.9	101.1	101.1	101.5
	6590390	100.3	101.3	101.6	100.4	101.3	101.2	100.2	100.6	101.0	99.0	101.5
	6590403	101.5	102.3	102.3	100.6	100.8	101.6	101.0	101.8	100.6	101.3	101.6
	6590471	100.9	100.7	100.6	101.0	101.4	101.2	101.3	101.5	101.4	101.1	100.8
	6590501	100.7	100.6	102.3	100.5	102.0	100.8	101.5	101.6	101.5	101.0	100.6
	6590535	100.8	100.0	100.8	100.8	100.7	100.5	101.0	101.9	101.0	101.5	101.8
	6590578	101.3	101.7	101.9	100.8	101.6	101.0	101.0	101.8	101.9	101.8	100.6
	6590608	100.7	101.1	102.5	100.4	101.1	101.9	100.3	102.0	101.4	101.1	101.8
	6590616	100.7	101.1	102.0	100.5	101.5	101.2	101.8	101.7	100.9	100.8	102.2
	6590624	100.4	102.5	102.4	100.4	100.4	101.5	101.4	102.4	101.8	101.3	102.0
	6590632	100.9	101.0	101.8	101.6	100.4	101.0	102.0	100.7	102.1	101.6	101.5
	6590641	101.0	101.8	101.2	101.5	101.1	101.2	101.5	102.9	101.8	102.0	100.8
	6590675	100.9	101.0	101.4	101.4	101.5	100.7	100.5	101.2	101.5	100.8	101.4
	6590713	100.7	100.5	101.7	100.5	100.8	100.4	100.0	101.1	101.1	100.6	101.3
B Placebo-vaccinated Controls	6590233	101.4	102.4	102.3	101.2	101.7	100.7	100.8	101.6	101.0	100.4	100.8
	6590268	100.6	100.4	101.4	101.5	101.3	101.7	101.2	100.0	101.5	101.8	101.8
	6590284	101.2	101.6	102.6	101.5	102.0	101.2	101.9	102.4	102.0	101.4	102.4
	6590314	101.0	100.5	102.1	101.1	101.4	101.0	102.8	102.4	102.7	101.0	101.5
	6590322	101.6	100.5	101.2	102.6	100.4	100.1	101.9	100.6	101.3	101.5	100.8
	6590331	100.6	101.3	101.4	100.9	99.8	102.2	101.1	101.1	101.4	100.9	101.4
	6590365	99.9	100.1	101.4	101.0	101.2	101.3	100.8	102.1	101.1	100.4	101.8
	6590381	101.0	100.5	102.0	101.1	101.0	100.9	100.8	101.5	101.1	101.1	101.8
	6590462	100.7	101.1	100.8	100.7	102.0	101.5	101.6	100.9	102.3	101.5	100.8
	6590489	100.4	99.3	102.0	100.4	101.3	101.7	102.0	102.0	102.7	102.2	101.8
	6590519	102.0	101.3	101.0	101.1	100.0	101.3	101.3	102.5	101.8	101.0	101.7
	6590527	100.3	101.5	101.4	100.8	101.2	101.0	100.8	101.5	101.2	101.3	101.6
	6590543	100.4	100.4	100.1	100.9	101.6	101.3	100.9	101.1	102.5	101.9	101.4
	6590586	101.9	100.2	102.5	101.2	102.0	101.5	100.7	102.1	101.5	101.8	101.5
	6590594	100.7	101.7	101.3	101.8	101.7	102.0	101.4	102.1	101.5	102.3	100.7
	6590659	100.8	100.5	101.0	101.0	101.1	100.6	101.3	100.9	101.0	101.4	101.9
	6590667	101.4	100.5	101.3	101.0	101.4	101.0	101.7	100.8	101.6	101.4	101.5
	6590683	100.5	101.0	101.0	101.3	100.6	101.5	101.3	101.2	101.6	100.8	101.9
	6590730	100.2	101.2	101.5	101.2	101.7	100.8	101.3	102.1	101.1	101.5	101.6

*Indicates day of vaccination

^aIndicates day of challenge

Rectal Temperatures (°F) (Continued)

Treatment Group	Dog ID	Day 29	Day 30	Day 31	Day 32	Day 33	Day 34	Day 35
A Vaccinates	6590225	101.5	100.3	101.7	101.2	101.2	101.3	100.6
	6590250	100.6	100.2	101.5	101.8	101.3	101.1	102.0
	6590276	101.0	100.7	101.4	101.2	100.9	102.0	102.3
	6590292	101.3	101.3	100.1	101.9	100.8	101.3	102.1
	6590306	101.4	101.7	101.1	101.3	101.9	102.3	101.2
	6590349	102.0	101.9	101.3	101.2	100.5	101.6	101.7
	6590373	102.0	101.9	100.7	101.6	100.9	101.4	101.8
	6590390	101.1	101.2	100.8	101.4	100.1	101.5	100.6
	6590403	101.0	102.0	99.9	101.5	101.2	102.3	101.6
	6590471	100.8	101.3	100.8	101.2	101.5	101.6	102.1
	6590501	101.4	100.3	100.9	100.9	101.3	101.1	101.4
	6590535	101.2	101.8	100.6	101.2	101.6	101.6	101.2
	6590578	102.1	101.3	100.0	101.3	101.2	102.1	101.8
	6590608	101.9	101.1	101.1	101.7	101.5	102.3	101.5
	6590616	100.8	101.1	101.4	101.6	102.1	101.3	99.7
	6590624	101.4	102.0	101.8	101.6	101.6	101.8	101.7
	6590632	100.6	101.1	101.9	101.7	101.7	100.9	101.4
	6590641	100.6	100.7	100.7	101.4	101.5	101.4	101.3
	6590675	100.4	100.3	100.0	100.6	100.6	100.3	101.1
	6590713	101.5	102.0	101.2	101.0	101.6	101.4	101.3
B Placebo- vaccinated Controls	6590233	101.7	101.6	100.8	101.3	101.5	101.1	102.1
	6590268	100.7	101.7	101.8	100.5	101.6	101.4	101.8
	6590284	101.1	101.5	101.6	102.3	101.1	101.6	101.8
	6590314	101.5	101.5	102.8	100.7	102.0	101.9	101.5
	6590322	101.2	101.9	101.9	101.2	101.2	102.6	102.4
	6590331	101.0	102.0	101.3	101.5	100.5	101.8	101.3
	6590365	101.5	101.8	101.1	101.3	100.8	101.4	101.1
	6590381	101.7	102.1	101.5	101.8	100.6	101.7	101.2
	6590462	101.5	101.5	101.5	100.2	101.3	101.6	102.6
	6590489	100.9	101.1	101.4	101.0	102.0	100.5	102.1
	6590519	100.6	101.3	102.0	101.7	102.1	101.9	101.3
	6590527	101.4	100.7	101.1	100.3	101.2	101.4	101.5
	6590543	100.6	102.6	100.7	101.7	102.1	101.0	101.2
	6590586	102.1	102.3	102.3	102.2	100.5	102.7	101.4
	6590594	102.0	102.7	102.3	101.8	102.3	102.4	101.2
	6590659	101.2	100.2	100.5	100.9	101.3	100.9	101.8
	6590667	101.5	100.6	101.4	100.3	100.7	101.7	101.7
	6590683	101.0	100.3	100.8	100.9	101.9	100.8	101.9
	6590730	101.6	101.5	101.5	100.9	100.6	101.9	101.0

Day 35 = End of Study

Nasal Swab CPI Titrations (log₁₀FAID₅₀/mL)

Treatment Group	Dog ID	Day -1	Day 21 ^{&}	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28	Day 29	Day 30	Day 31
A Vaccinates	6590225	-	-	-	-	-	-	-	-	-	-	-	≤0.75
	6590250	-	-	-	-	-	1.00	1.50	2.00	1.00	-	-	-
	6590276	-	-	-	-	-	≤0.75	≤0.75	1.50	1.25	-	-	-
	6590292	-	-	-	-	≤0.75	2.00	2.75	2.50	-	-	-	-
	6590306	-	-	-	-	-	-	-	-	-	-	-	-
	6590349	-	-	-	-	-	-	-	-	-	-	-	-
	6590373	-	-	-	-	-	-	-	-	-	-	-	-
	6590390	-	-	-	-	-	-	-	-	-	-	-	-
	6590403	-	-	-	-	-	-	-	-	-	-	-	-
	6590471	-	-	-	1.00	-	-	≤0.75	-	-	-	-	-
	6590501	-	-	-	-	-	-	1.00	≤0.75	-	-	-	-
	6590535	-	-	-	-	1.50	2.00	1.75	2.75	2.75	3.00	≤0.75	-
	6590578	-	-	-	-	-	-	-	-	-	-	-	-
	6590608	-	-	-	-	-	-	-	1.25	≤0.75	-	-	-
	6590616	-	-	-	-	-	-	-	-	-	-	-	-
	6590624	-	-	-	-	-	-	-	-	-	-	-	-
	6590632	-	-	-	2.25	1.50	1.00	-	-	-	-	-	-
	6590641	-	-	-	-	-	-	-	-	-	-	-	-
	6590675	-	-	-	2.00	≤0.75	-	≤0.75	-	-	-	-	-
	6590713	-	-	-	-	≤0.75	2.50	2.00	2.25	1.00	-	-	-
B Placebo-vaccinated Controls	6590233	-	-	-	2.50	4.00	4.00	2.00	3.00	1.25	2.50	1.25	-
	6590268	-	-	-	2.25	2.25	3.25	3.50	3.25	3.25	3.25	2.25	-
	6590284	-	-	-	-	2.75	3.75	3.25	2.50	1.50	1.00	-	-
	6590314	-	-	-	≤0.75	2.25	3.00	3.75	3.75	4.00	3.50	-	-
	6590322	-	-	-	-	1.50	3.00	1.50	3.00	2.75	2.50	-	-
	6590331	-	-	-	-	≤0.75	≤0.75	1.00	≤0.75	-	-	-	-
	6590365	-	-	-	-	-	-	≤0.75	1.50	2.75	3.50	-	-
	6590381	-	-	-	-	≤0.75	1.75	1.75	3.00	3.00	2.50	-	-
	6590462	-	-	-	-	≤0.75	1.75	2.50	2.50	3.25	1.25	≤0.75	-
	6590489	-	-	-	1.00	-	1.25	2.25	2.00	1.25	-	-	-
	6590519	-	-	-	-	2.25	2.00	1.50	2.25	3.50	3.50	1.75	-
	6590527	-	-	-	-	≤0.75	2.00	3.25	3.25	3.00	2.75	-	-
	6590543	-	-	-	-	2.50	3.25	3.25	2.50	3.00	3.00	≤0.75	-
	6590586	-	-	-	-	1.75	1.00	1.50	3.50	3.25	1.75	-	-
	6590594	-	-	-	-	-	-	≤0.75	1.00	1.75	2.75	-	-
	6590659	-	-	-	-	≤0.75	-	1.75	3.25	4.00	2.00	-	≤0.75
	6590667	-	-	-	-	≤0.75	-	-	-	-	-	-	-
	6590683	-	-	-	-	1.00	2.75	3.25	4.25	3.75	2.00	-	-
	6590730	-	-	-	-	-	-	-	-	-	-	-	-

[&] = Day of challenge; (-) = No virus detected

Day -1 = 1 Day prior to vaccination

CPI Viral Shedding Post-Challenge

Treatment Group	Dog ID	Duration of Viral Shedding (Days)
A Vaccinates	6590225	1
	6590250	4
	6590276	4
	6590292	4
	6590306	0
	6590349	0
	6590373	0
	6590390	0
	6590403	0
	6590471	4
	6590501	2
	6590535	7
	6590578	0
	6590608	2
	6590616	0
	6590624	0
	6590632	3
	6590641	0
	6590675	4
	6590713	5
B Placebo- Vaccinated Controls	6590233	8
	6590268	8
	6590284	6
	6590314	7
	6590322	6
	6590331	4
	6590365	4
	6590381	6
	6590462	7
	6590489	6
	6590519	7
	6590527	6
	6590543	7
	6590586	6
	6590594	4
	6590659	8
	6590667	1
	6590683	6
	6590730	0

Study Type	Efficacy																		
Pertaining to	Canine Parainfluenza (CPI)																		
Study Purpose	To demonstrate efficacy against canine parainfluenza 12 months after vaccination																		
Product Administration	One dose administered by the oral route (Day 0)																		
Study Animals	6-8-week-old dogs; 23 vaccinates, 23 placebo-vaccinated controls																		
Challenge Description	Dogs were challenged with canine parainfluenza virus 53 weeks post-vaccination (Day 372).																		
Interval observed after challenge	Clinical signs were observed daily and body temperature recorded for 14 days post-challenge (through Day 386). Nasal swabs were collected daily for 10 days post-challenge to evaluate viral shedding,																		
Results	The study met the requirements of 9 CFR 113.316.																		
	Five Number Summary for Duration of Shedding (Days)																		
	<table><tr><th>Treatment Group</th><th>Minimum</th><th>Q1</th><th>Median</th><th>Q3</th><th>Maximum</th></tr><tr><td>Vaccinates</td><td>0</td><td>0</td><td>1</td><td>3.5</td><td>7</td></tr><tr><td>Controls</td><td>0</td><td>3</td><td>6</td><td>7.5</td><td>9</td></tr></table>	Treatment Group	Minimum	Q1	Median	Q3	Maximum	Vaccinates	0	0	1	3.5	7	Controls	0	3	6	7.5	9
	Treatment Group	Minimum	Q1	Median	Q3	Maximum													
	Vaccinates	0	0	1	3.5	7													
Controls	0	3	6	7.5	9														
Raw data shown on attached pages.																			
USDA Approval Date	February 7, 2023																		

Serum Antibody Titers to CPI

Treatment Group	Dog ID	Day 0	Day 35	Day 372*
A Vaccinates	1	< 2	304	181
	2	< 2	152	91
	3	< 2	861	64
	4	< 2	215	181
	5	< 2	23	4
	6	< 2	1218	181
	7	< 2	215	181
	8	< 2	2435	45
	9	< 2	64	19
	10	< 2	512	91
	11	< 2	512	16
	12	< 2	362	152
	13	< 2	91	2
	14	< 2	181	23
	15	< 2	304	91
	16	< 2	128	11
	17	< 2	304	76
	18	< 2	91	16
	19	< 2	2	< 2
	20	< 2	64	4
	21	< 2	108	5
	22	< 2	609	23
	23	< 2	< 2	< 2
B Placebo-vaccinated Controls	24	< 2	< 2	< 2
	25	< 2	< 2	< 2
	26	< 2	< 2	< 2
	27	< 2	< 2	< 2
	28	< 2	< 2	< 2
	29	< 2	< 2	< 2
	30	< 2	< 2	< 2
	31	< 2	< 2	< 2
	32	< 2	< 2	< 2
	33	< 2	< 2	< 2
	34	< 2	< 2	< 2
	35	< 2	< 2	< 2
	36	< 2	< 2	< 2
	37	< 2	< 2	< 2
	38	< 2	< 2	< 2
	39	< 2	< 2	< 2
	40	< 2	< 2	< 2
	41	< 2	< 2	< 2
	42	< 2	< 2	< 2
	43	< 2	< 2	< 2
	44	< 2	< 2	< 2
	45	< 2	< 2	< 2
	46	< 2	< 2	< 2

*day of challenge

Post-Challenge Clinical Observations

Treatment Group	Dog ID	Day -1 PC	Day 0 PC	Day 1 PC	Day 2 PC	Day 3 PC	Day 4 PC	Day 5 PC	Day 6 PC	Day 7 PC
A Vaccinates	1	-	-	-	-	-	-	-	-	-
	2	-	-	-	-	-	-	-	-	-
	3	-	-	-	-	-	-	-	-	-
	4	-	-	-	-	-	-	-	-	-
	5	-	-	-	-	-	-	-	-	-
	6	-	-	-	-	CS	-	-	-	-
	7	-	-	-	-	-	-	-	-	-
	8	-	-	-	-	-	-	-	-	-
	9	-	-	-	-	-	-	-	-	-
	10	-	-	-	-	-	-	-	-	-
	11	-	-	-	-	-	-	-	-	-
	12	-	-	-	-	-	-	-	-	-
	13	-	-	-	-	-	-	-	-	-
	14	-	-	-	-	-	-	-	-	-
	15	-	-	-	-	-	-	-	-	-
	16	-	-	-	-	-	-	-	-	-
	17	-	-	-	-	-	-	-	-	-
	18	-	-	-	-	-	-	-	-	-
	19	-	-	-	-	-	-	-	-	-
	20	-	-	-	-	-	-	-	-	-
	21	-	-	-	-	-	-	-	-	-
	22	-	-	-	-	-	-	-	-	-
	23	-	-	-	-	-	-	-	-	-
B Placebo-vaccinated Controls	24	-	-	-	-	-	-	-	-	-
	25	-	-	-	-	-	-	-	-	-
	26	-	-	-	-	-	-	-	-	-
	27	-	-	-	-	-	-	-	-	-
	28	-	-	-	-	-	-	-	-	-
	29	-	-	-	-	-	-	-	-	-
	30	-	-	-	-	-	-	-	-	-
	31	-	-	-	-	-	-	-	-	-
	32	-	-	-	-	-	-	-	-	-
	33	-	-	-	-	-	-	-	-	-
	34	-	-	-	-	-	-	-	-	-
	35	-	-	-	-	-	-	-	-	-
	36	-	-	-	-	-	-	-	-	-
	37	-	-	-	-	-	-	-	-	-
	38	-	-	-	-	-	-	-	-	-
	39	-	-	-	-	-	-	-	-	-
	40	-	-	-	-	-	-	-	-	-
	41	-	-	-	-	-	-	-	-	-
	42	-	-	-	-	-	-	-	-	-
	43	-	-	-	-	-	-	-	-	-
	44	-	-	-	-	-	-	-	-	-
	45	-	-	-	-	-	-	-	-	-
	46	-	-	-	-	-	-	-	-	-

PC = post-challenge

(-) = No clinical signs present

CS = Spontaneous coughing

Post-Challenge Clinical Observations - continued

Treatment Group	Dog ID	Day 8 PC	Day 9 PC	Day 10 PC	Day 11 PC	Day 12 PC	Day 13 PC	Day 14 PC
A Vaccinates	1	-	-	-	-	-	-	-
	2	-	-	-	-	-	-	-
	3	-	-	-	-	-	-	-
	4	-	-	-	-	-	-	-
	5	-	-	-	-	-	-	-
	6	-	-	-	-	CS	-	-
	7	-	-	-	-	-	-	-
	8	-	-	-	-	-	-	-
	9	-	-	-	-	-	-	-
	10	-	-	-	-	-	-	-
	11	-	-	-	-	-	-	-
	12	-	-	-	-	-	-	-
	13	-	-	-	-	-	-	-
	14	-	-	-	-	-	-	-
	15	-	-	-	-	-	-	-
	16	-	-	-	-	-	-	-
	17	-	-	-	-	-	-	-
	18	-	-	-	-	-	-	-
	19	-	-	-	-	-	-	-
	20	-	-	-	-	-	-	-
	21	-	-	-	-	-	-	-
	22	-	-	-	-	-	-	-
	23	-	-	-	-	-	-	-
B Placebo-vaccinated Controls	24	-	-	-	-	-	-	-
	25	-	-	-	-	-	-	-
	26	-	-	-	-	-	-	-
	27	-	-	-	-	-	-	-
	28	-	-	-	-	-	-	-
	29	-	-	-	-	-	-	-
	30	-	-	-	-	-	-	-
	31	-	-	-	-	-	-	-
	32	-	-	-	-	-	-	-
	33	-	-	-	-	-	-	-
	34	-	-	-	-	-	-	-
	35	-	-	-	-	-	-	-
	36	-	-	-	-	-	-	-
	37	-	-	-	-	-	-	-
	38	-	-	-	-	-	-	-
	39	-	-	-	-	-	-	-
	40	-	-	-	-	-	-	-
	41	-	-	-	-	-	-	-
	42	-	-	-	-	-	-	-
	43	-	-	-	-	-	-	-
	44	-	-	-	-	-	-	-
	45	-	-	-	-	-	-	-
	46	-	-	-	-	-	-	-

PC = post-challenge

(-) = No clinical signs present

CS = Spontaneous coughing

Post-Challenge Rectal Temperatures (°F)

Treatment Group	Dog ID	Day -1 PC	Day 0 PC	Day 1 PC	Day 2 PC	Day 3 PC	Day 4 PC	Day 5 PC	Day 6 PC	Day 7 PC
A Vaccinates	1	102.3	103.3	103.6	103.2	102.4	102.9	101.1	102.4	101.8
	2	102.0	102.3	102.5	102.2	101.4	102.1	102.0	102.4	101.2
	3	101.6	102.3	101.2	101.8	102.2	102.1	101.4	101.7	101.0
	4	101.7	101.6	101.1	102.3	102.1	102.4	102.1	101.4	101.7
	5	102.1	100.0	100.8	102.0	100.7	100.9	101.9	101.9	100.4
	6	102.4	101.5	101.6	101.9	101.8	102.5	101.8	101.9	102.0
	7	102.6	102.5	102.0	102.4	103.2	102.8	102.0	100.9	102.2
	8	101.7	101.8	101.2	103.0	102.3	102.8	102.7	102.5	102.7
	9	102.4	102.2	102.4	102.5	100.4	102.0	102.0	102.1	102.5
	10	102.5	101.7	101.5	102.0	101.1	101.4	103.0	102.2	101.7
	11	102.2	101.9	102.1	101.4	102.5	101.9	-	101.5	102.0
	12	102.3	101.4	101.1	102.9	102.6	102.6	101.4	102.1	101.6
	13	104.0/103.6*	103.5/102.6*	103.1	102.2	103.4	103.2	102.2	102.7	102.6
	14	101.3	102.9	101.8	102.7	102.6	101.7	102.1	100.9	103.3
	15	101.5	101.3	101.8	101.5	102.1	101.1	101.6	102.2	101.3
	16	101.5	101.1	101.2	102.5	102.6	100.6	101.7	101.4	102.0
	17	99.3	102.2	101.1	102.0	102.6	102.2	101.7	101.7	101.9
	18	101.3	101.1	100.6	101.6	101.9	100.8	101.1	100.9	100.5
	19	102.0	100.8	101.8	101.9	101.4	101.1	101.2	100.0	101.9
	20	102.0	101.7	102.0	101.5	101.5	101.1	101.1	101.6	101.5
	21	101.3	101.4	101.6	101.3	101.6	100.9	101.9	102.1	101.6
	22	100.3	102.3	101.6	101.0	102.1	102.4	101.8	101.9	101.4
	23	101.1	102.1	101.8	101.6	102.3	101.8	101.6	101.8	102.4
B Placebo-vaccinated Controls	24	102.1	102.1	102.9	101.9	101.7	102.3	102.1	101.9	101.9
	25	101.1	101.4	101.9	102.1	101.2	102.3	103.0	101.2	101.8
	26	100.3	102.6	100.8	101.8	101.2	101.2	101.7	101.9	101.5
	27	101.4	101.5	101.3	101.4	100.9	101.5	101.3	102.1	101.5
	28	102.3	101.5	100.5	101.6	101.1	100.4	101.5/101.2*	100.8	100.8
	29	101.2	101.7	100.7	101.4	99.7	100.8	101.5	101.0	102.0
	30	101.7	100.9	100.8	100.3	101.7	102.4	101.8	100.0	101.1
	31	102.1	101.3	102.3	102.1	101.9	101.8	102.7	102.2	101.7
	32	101.1	100.7	101.1	99.8	100.6	101.4	100.4	101.6	101.3
	33	101.6	102.6	102.2	101.3	101.7	102.6	102.3	102.4	102.3
	34	101.5	100.6	100.9	100.6	100.9	101.5	101.0	101.1	101.3
	35	101.6	101.1	100.5	101.6	101.6	102.0	101.9	102.4	101.3
	36	101.4	100.4	101.5	101.3	101.5	101.6	102.0	102.0	101.2
	37	101.7	101.2	101.5	101.7	101.2	101.7	101.8	101.6	102.3
	38	100.8	102.6	101.2	100.8	101.8	100.9	101.9	101.7	101.8
	39	102.1	101.1	102.2	101.2	102.1	101.0	101.9	101.6	100.8
	40	101.2	102.1	101.5	101.9	102.6	101.6	101.6	102.2	102.4
	41	100.7	101.5	102.4	103.3	102.1	102.7	102.0	103.5**	103.3
	42	101.4	101.5	102.0	101.3	101.3	101.1	101.2	100.8	100.6
	43	102.3	102.1	102.4	101.3	101.9	101.5	102.2	102.4	101.8
	44	100.7	101.0	101.7	100.7	102.4	100.5	101.1	101.2	101.2
	45	101.4	101.2	101.5	101.8	102.5	102.4	101.8	101.9	101.0
	46	101.2	102.1	101.2	101.1	100.3	101.6	101.3	101.8	101.2

(-) = Data not available

* = Temperature taken twice due to dog overexcitement

** = Dog was noted as jumping around excessively during clinical observations

Post-Challenge Rectal Temperatures (°F) - continued

Treatment Group	Dog ID	Day 8 PC	Day 9 PC	Day 10 PC	Day 11 PC	Day 12 PC	Day 13 PC	Day 14 PC
A Vaccinates	1	99.6	102.2	102.7	100.6	103.6	102.4	102.2
	2	100.9	101.4	101.8	101.5	102.9	99.8	102.2
	3	101.9	100.5	99.4	100.9	101.8	101.3	101.4
	4	101.8	101.0	101.5	101.2	101.8	102.1	101.9
	5	101.5	101.7	102.1	101.5	102.7	101.9	100.9
	6	102.7	102.6	102.7	102.4	103.8	102.0	-
	7	101.1	102.9	102.6	101.2	102.3	102.5	-
	8	102.5	102.6	102.0	101.8	102.8	102.2	102.8
	9	101.9	101.8	101.0	101.3	103.9	102.0	102.5
	10	100.8	101.9	102.5	102.5	102.4	101.6	-
	11	101.6	101.2	102.1	101.5	101.9	101.0	-
	12	100.3	101.8	101.6	101.8	102.0	101.1	-
	13	102.9	102.1	103.1	103.0	102.5	103.3	-
	14	100.8	101.9	102.3	102.8	103.8	103.2	102.1
	15	102.1	100.5	101.9	100.9	101.4	101.9	100.9
	16	101.3	102.4	102.4	101.9	102.4	102.4	101.6
	17	101.8	102.4	100.9	101.5	101.8	101.0	101.3
	18	101.6	101.1	101.7	101.0	102.4	101.4	101.9
	19	101.2	102.0	102.3	101.3	102.7	101.9	102.4
	20	101.4	101.7	102.3	101.7	102.6	101.8	101.1
	21	101.2	100.6	102.5	101.0	101.6	101.3	100.8
	22	101.6	101.1	102.3	101.6	102.1	102.3	101.0
	23	102.0	102.5	102.5	101.6	102.9	101.6	102.0
B Placebo-vaccinated Controls	24	101.5	100.6	102.4	101.4	101.4	102.5	100.6
	25	101.2	101.3	102.0	101.4	102.2	101.4	102.3
	26	102.3	102.0	102.6	101.4	102.9	100.0	100.2
	27	100.7	100.8	103.3	101.0	102.7	100.6	101.1
	28	100.9	101.9	101.7	100.6	102.3	102.0	-
	29	101.0	101.6	101.6	101.9	102.3	101.3	-
	30	101.7	101.7	102.1	101.5	101.3	101.7	100.3
	31	101.7	102.1	102.4	100.1	102.2	102.4	-
	32	101.3	100.2	101.3	101.3	101.7	101.6	-
	33	101.9	102.3	101.8	101.8	102.3	101.2	-
	34	100.7	101.7	101.3	101.5	101.7	101.8	-
	35	102.0	101.5	101.9	101.4	101.9	101.9	101.7
	36	100.8	101.4	101.1	101.8	100.9	102.2	101.5
	37	101.8	102.1	102.0	102.0	101.7	101.9	100.5
	38	101.3	102.0	102.3	101.9	101.9	102.2	100.6
	39	101.8	102.0	101.2	102.5	100.2	102.2	101.6
	40	102.3	102.4	102.0	101.9	102.4	101.9	101.7
	41	103.3**	101.6	103.7**	102.6	103.0	101.7	101.8
	42	100.5	101.3	101.9	100.9	100.8	100.9	100.0
	43	101.8	102.2	103.0	102.2	102.8	102.6	102.6
	44	101.0	100.2	102.7	101.1	101.6	100.9	101.3
	45	100.4	100.6	101.9	101.5	101.0	101.8	101.7
	46	101.0	101.0	101.2	102.2	102.2	101.2	101.5

(-) = Data not available

**Dog was noted as jumping around excessively during clinical observations.

Nasal Swab CPI Titrations (log₁₀FAID₅₀/mL)

Treatment Group	Dog ID	Day 0 PC	Day 1 PC	Day 2 PC	Day 3 PC	Day 4 PC	Day 5 PC	Day 6 PC	Day 7 PC	Day 8 PC	Day 9 PC	Day 10 PC	Duration of Shedding (days)
A Vaccinates	1	-	-	-	≤ 0.75	≤ 0.75	≤ 0.75	3.25	2.00	1.00	1.00	-	7
	2	-	-	1.00	-	-	-	-	≤ 0.75	-	-	-	6
	3	-	-	≤ 0.75	-	-	-	-	-	-	-	-	1
	4	-	-	-	-	-	-	-	-	-	-	-	0
	5	-	-	-	-	-	-	-	-	-	-	-	0
	6	-	-	-	-	-	-	1.00	2.75	-	-	-	2
	7	-	-	-	-	-	-	-	-	-	-	-	0
	8	-	-	-	-	-	-	-	-	-	-	-	0
	9	-	-	-	-	1.25	1.50	-	-	-	-	-	2
	10	-	-	-	-	-	-	-	-	-	-	-	0
	11	-	-	-	-	-	-	-	-	-	-	-	0
	12	-	-	-	-	-	-	-	1.00	1.00	-	-	2
	13	-	-	-	1.00	≤ 0.75	1.25	-	-	-	-	-	3
	14	-	-	-	-	-	-	-	-	-	-	-	0
	15	-	-	-	-	-	-	-	-	-	-	-	0
	16	-	-	3.00	2.25	1.50	1.25	-	≤ 0.75	-	-	-	6
	17	-	-	-	-	-	-	-	-	-	-	-	0
	18	-	-	-	-	-	≤ 0.75	-	-	1.25	-	-	4
	19	-	-	-	-	1.00	-	-	-	-	-	-	1
	20	-	-	-	-	-	-	-	-	-	-	-	0
	21	-	-	1.00	3.50	2.75	2.50	2.25	1.50	-	-	-	6
	22	-	-	-	-	-	-	-	-	1.50	-	-	1
	23	-	-	-	-	-	1.00	-	-	-	1.00	-	5
B Placebo-vaccinated Controls	24	-	-	≤ 0.75	-	≤ 0.75	-	-	-	-	-	-	3
	25	-	-	1.50	1.75	2.25	2.50	4.25	2.25	2.00	-	-	7
	26	-	-	1.75	3.00	≤ 0.75	3.75	3.75	4.25	2.25	1.00	-	8
	27	-	-	-	-	-	-	≤ 0.75	-	-	-	-	1
	28	-	-	1.25	2.75	3.50	3.25	3.50	3.75	3.25	2.00	-	8
	29	-	-	1.00	3.00	3.00	2.75	2.50	1.75	1.50	≤ 0.75	-	8
	30	-	-	-	-	-	-	-	≤ 0.75	-	≤ 0.75	-	3
	31	-	-	-	-	1.25	-	-	1.75	2.75	2.00	-	6
	32	-	-	-	-	-	≤ 0.75	-	-	-	-	-	1
	33	-	-	1.00	1.75	3.00	2.75	3.25	3.00	2.50	≤ 0.75	-	8
	34	-	-	3.50	4.25	4.00	3.25	2.75	2.50	1.75	≤ 0.75	-	8
	35	-	-	-	-	1.00	1.75	2.00	2.00	3.25	3.00	-	6
	36	-	-	2.50	2.75	2.75	3.00	3.25	2.25	1.25	-	1.50	9
	37	-	-	1.75	3.00	3.75	4.00	3.50	1.00	-	-	-	6
	38	-	-	-	-	-	-	≤ 0.75	-	1.25	1.00	-	4
	39	-	-	-	-	-	-	-	1.25	2.50	2.50	-	3
	40	-	-	1.00	2.50	3.75	4.00	3.50	3.00	2.00	-	-	7
	41	-	-	-	-	≤ 0.75	1.00	-	-	-	-	-	2
	42	-	-	≤ 0.75	2.25	2.75	2.75	3.25	3.25	1.50	-	-	7
	43	-	-	3.00	3.50	3.50	3.75	3.75	3.25	2.50	-	-	7
	44	-	-	-	-	≤ 0.75	1.00	-	2.00	2.50	-	-	5
	45	-	-	-	-	-	-	-	1.50	2.00	-	-	2
	46	-	-	-	-	-	-	-	-	-	-	-	0

PC = Post-challenge
(-) = No virus detected

Study Type	Safety																																																		
Pertaining to	All																																																		
Study Purpose	To demonstrate safety under field conditions																																																		
Product Administration	One dose administered by the oral route																																																		
Study Animals	637 dogs represented six geographic locations. 211 dogs were 7 weeks of age, which is the recommended minimum age; 426 dogs ranged in age from 8 weeks to 16 years.																																																		
Challenge Description	Not applicable																																																		
Interval observed after challenge	Dogs were observed daily for 14 days for any adverse events.																																																		
Results	There were no immediate reactions following administration of the test product. <u>Summary of Adverse Events:</u> <table> <tr> <th>VeDDRA Code for Adverse Events Related to the Test Vaccine</th><th>Number of Adverse Events in 637 doses</th></tr> <tr><td>Cough</td><td>13 (2.0%)</td></tr> <tr><td>Sneezing</td><td>5 (0.8%)</td></tr> <tr><td>Emesis</td><td>4 (0.6%)</td></tr> <tr><td>Lethargy</td><td>3 (0.5%)</td></tr> <tr><td>Anorexia</td><td>2 (0.3%)</td></tr> <tr><td>Diarrhea</td><td>1 (0.2%)</td></tr> <tr><td>Gastritis</td><td>1 (0.2%)</td></tr> <tr><td>Gastroenteritis</td><td>1 (0.2%)</td></tr> <tr><td>Colitis</td><td>1 (0.2%)</td></tr> <tr><td>Anxiety</td><td>1 (0.2%)</td></tr> <tr><td>Bronchitis</td><td>1 (0.2%)</td></tr> <tr><td>Enteritis</td><td>1 (0.2%)</td></tr> <tr><td>Eye Disorder NOS</td><td>1 (0.2%)</td></tr> <tr><td>Respiratory tract disorder NOS</td><td>1 (0.2%)</td></tr> <tr><td>Retching</td><td>1 (0.2%)</td></tr> <tr><td>Total</td><td>37 (5.8%)</td></tr> </table> <table> <tr> <th>VeDDRA Code for Adverse Events Not Related to the Test Vaccine</th><th>Number of Adverse Events in 637 doses</th></tr> <tr><td>Emesis (chewed up hose, eating grass, eating armadillo)</td><td>11 (1.7%)</td></tr> <tr><td>Lethargy</td><td>7 (1.0%)</td></tr> <tr><td>Diarrhea</td><td>7 (1.0%)</td></tr> <tr><td>Cough</td><td>2 (0.3%)</td></tr> <tr><td>Anorexia</td><td>2 (0.3%)</td></tr> <tr><td>Gastritis</td><td>2 (0.3%)</td></tr> <tr><td>Gastroenteritis</td><td>2 (0.3%)</td></tr> </table>	VeDDRA Code for Adverse Events Related to the Test Vaccine	Number of Adverse Events in 637 doses	Cough	13 (2.0%)	Sneezing	5 (0.8%)	Emesis	4 (0.6%)	Lethargy	3 (0.5%)	Anorexia	2 (0.3%)	Diarrhea	1 (0.2%)	Gastritis	1 (0.2%)	Gastroenteritis	1 (0.2%)	Colitis	1 (0.2%)	Anxiety	1 (0.2%)	Bronchitis	1 (0.2%)	Enteritis	1 (0.2%)	Eye Disorder NOS	1 (0.2%)	Respiratory tract disorder NOS	1 (0.2%)	Retching	1 (0.2%)	Total	37 (5.8%)	VeDDRA Code for Adverse Events Not Related to the Test Vaccine	Number of Adverse Events in 637 doses	Emesis (chewed up hose, eating grass, eating armadillo)	11 (1.7%)	Lethargy	7 (1.0%)	Diarrhea	7 (1.0%)	Cough	2 (0.3%)	Anorexia	2 (0.3%)	Gastritis	2 (0.3%)	Gastroenteritis	2 (0.3%)
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	Polydipsia	2 (0.3%)
	Colitis	1 (0.2%)
	Aggression	1 (0.2%)
	Corneal edema (due to trauma)	1 (0.2%)
	Death*	1 (0.2%)
	Dehydration	1 (0.2%)
	Digestive tract hypermotility (Borborygmus)	1 (0.2%)
	Horner's Syndrome	1 (0.2%)
	Hypersensitivity reaction (stung by a bee)	1 (0.2%)
	Hypoglycemia	1 (0.2%)
	Increased appetite	1 (0.2%)
	Muscle tremor	1 (0.2%)
	Nausea	1 (0.2%)
	Oral discomfort (grass burr stuck under tongue)	1 (0.2%)
	Otitis externa	1 (0.2%)
	Skin and tissue infection NOS (skin infection on abdomen and thighs)	1 (0.2%)
	Tendon injury (soft tissue strain to left rear leg)	1 (0.2%)
	Trauma NOS (skin scratch from trauma)	1 (0.2%)
	Total	52 (8.2%)
	*Dog was euthanized due to difficulty swallowing, lack of eating, and decline in quality of life following a hypoglycemic event.	
USDA Approval Date	June 27, 2022	