

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	15P5.R0
True Name	Canine Influenza Vaccine, H3, RNA Particle
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Merck Animal Health
Date of Compilation Summary	May 29, 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.

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C. I. T.	T CC							
Study Type	Efficacy Continue Influence Views (CIV) 112N2							
Pertaining to	Canine Influenza Virus (CIV) H3N2							
Study Purpose	Efficacy against CIV H3N2 in dogs							
Product Administration	Two doses administered subcutaneously, 3 weeks apart							
Study Animals		8-week-old dogs; seronegative to CIV H3N2; 20 vaccinates and 20 placebo-vaccinated controls						
Challenge Description	All dogs we second vacc			ed with	virulen	t CIV H3N	12, 3 we	eks after
Interval observed after challenge	Lungs were	score	ed 10 d	ays foll	lowing	challenge.		
Results	The percent calculated for Table 1.	or eve	ery dog	Ţ .		· Lung Con		
	Treatm	ent	N	Min	Q1	Median	Q3	Max
	Grou	р						
	Grou Vaccina		19	0	0	0	0.2	1.0
	Vaccina Contro	tes ls	20	0	2.3	7.2	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons	0 solidatio	2.3 on Scor	7.2 es, Ranked	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons Vaccina	0 solidatio	2.3 on Scor	7.2 es, Ranked ontrols	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons Vaccina 0.0	0 solidatio	2.3 on Scor	7.2 es, Ranked ontrols 0.0	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons Vaccina 0.0 0.0	0 solidatio	2.3 on Scor	7.2 es, Ranked ontrols 0.0 0.0	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons Vaccina 0.0 0.0 0.0	0 solidatio	2.3 on Scor	7.2 es, Ranked ontrols 0.0 0.0 0.2	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons Vaccina 0.0 0.0 0.0 0.0	0 solidatio	2.3 on Scor	7.2 es, Ranked ontrols 0.0 0.0 0.2 0.6	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons Vaccina 0.0 0.0 0.0 0.0 0.0	0 solidatio	2.3 on Scor	7.2 es, Ranked ontrols 0.0 0.0 0.2 0.6 0.6	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons Vaccina 0.0 0.0 0.0 0.0 0.0	0 solidatio	2.3 on Scor	7.2 es, Ranked ontrols 0.0 0.0 0.2 0.6 0.6 2.9	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons Vaccina 0.0 0.0 0.0 0.0 0.0	0 solidatio	2.3 on Scor	7.2 es, Ranked ontrols 0.0 0.0 0.2 0.6 0.6 2.9 3.5	10.7	22.6
	Vaccina Contro	tes ls Lur	20 Naccina 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0	0 solidatio	2.3 on Scor	7.2 es, Ranked ontrols 0.0 0.0 0.2 0.6 0.6 2.9	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons Vaccina 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0	0 solidatio	2.3 on Scor	7.2 es, Ranked ontrols 0.0 0.0 0.2 0.6 0.6 2.9 3.5 4.0	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons Vaccina 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.	0 solidatio	2.3 on Scor	7.2 es, Ranked ontrols 0.0 0.0 0.2 0.6 0.6 2.9 3.5 4.0 4.5	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons Vaccina 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.	0 solidatio	2.3 on Scor	7.2 es, Ranked ontrols 0.0 0.0 0.2 0.6 0.6 2.9 3.5 4.0 4.5 7.1	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons Vaccina 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.	0 solidatio	2.3 on Scor	7.2 es, Ranked ontrols 0.0 0.0 0.2 0.6 0.6 2.9 3.5 4.0 4.5 7.1 7.2 7.7 8.5	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons Vaccina 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.	0 solidatio	2.3 on Scor	7.2 es, Ranked 0.0 0.0 0.0 0.2 0.6 0.6 2.9 3.5 4.0 4.5 7.1 7.2 7.7 8.5 9.9	10.7	22.6
	Vaccina Contro	tes ls Lur	20 ng Cons Vaccina 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.	0 solidatio	2.3 on Scor	7.2 es, Ranked ontrols 0.0 0.0 0.2 0.6 0.6 2.9 3.5 4.0 4.5 7.1 7.2 7.7 8.5	10.7	22.6

*Dog removed from study prior to challenge

11.3 11.4

16.9

22.6

0.5

1.0

1.0

Raw data shown on attached page.

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Table 1. Post-Challenge Lung Lesion Scores

Raw Scores									
Treatment Group	Dog ID	R. Cranial	R. Middle	R. Caudal	Access	L. Cr-Cr	L. Cr-Cau	L. Caudal	
	VSH3	0	0	0	0	0	0	0	
	VWG3	0	0	0	0	0	0	0	
	VXG3	0	0	0	0	0	0	0	
	WRH3	0	0	0	0	0	0	0	
	WSH3	0	0	0	0	0	0	0	
	WTG3	0	0	0	0	0	0	0	
	WYH3	0	0	0	0	0	0	0	
	WZG3	0	1	1	2	0	0	2	
	XRH3	0	0	0	0	0	0	0	
Vaccinates	XTG3	0	0	0	0	1	2	3	
	XEH3	1	0	0	0	0	2	0	
	XGG3	0	0	0	0	0	0	0	
	WCH3	0	0	0	0	0	0	2	
	WFG3	0	0	0	0	0	0	0	
	YFH3	0	0	0	0	0	0	0	
	YHH3	0	0	0	0	0	0	0	
	YIG3	0	0	0	0	0	0	0	
	VEH3	0	0	0	0	0	0	0	
	VHG3	3	0	0	0	0	0	0	

Weighted Scores

Treatment	Dog ID	R.	R.	R.	Access	L.	L.	L.	Total
Group)	Cranial	Middle	Caudal		Cr-Cr	Cr-Cau	Caudal	Score
	VSH3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	VWG3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	VXG3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	WRH3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	WSH3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	WTG3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	WYH3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	WZG3	0.0	0.10	0.25	0.18	0.0	0.0	0.52	1.0
	XRH3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Vaccinates	XTG3	0.0	0.0	0.0	0.0	0.09	0.12	0.78	1.0
	XEH3	0.15	0.0	0.0	0.0	0.0	0.12	0.0	0.3
	XGG3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	WCH3	0.0	0.0	0.0	0.0	0.0	0.0	0.52	0.5
	WFG3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	YFH3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	YHH3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	YIG3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	VEH3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	VHG3	0.46	0.0	0.0	0.0	0.0	0.0	0.0	0.5

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Table 1. Post-Challenge Lung Lesion Scores - continued

	Raw Scores								
Treatment Group	Dog ID	R. Cranial	R. Middle	R. Caudal	Access	L. Cr-Cr	L. Cr-Cau	L. Caudal	
-	VRH3	7	25	3	7	15	25	8	
	VTH3	5	25	6	15	7	8	0	
	VUG3	10	25	15	20	20	0	0	
	VVG3	5	25	1	8	20	5	3	
	WUG3	0	25	0	3	7	5	1	
	WVG3	3	2	0	2	8	10	3	
	XAG3	10	30	5	5	10	5	4	
	XBG3	0	40	0	5	0	1	0	
	XQH3	10	35	15	10	8	5	0	
Controls	XSH3	35	45	15	25	20	40	10	
	XUG3	0	20	25	15	6	20	0	
	XCH3	1	0	0	0	0	0	0	
	XFG3	2	0	0	0	0	0	1	
	WAH3	0	0	0	0	0	0	0	
	WDH3	0	0	10	8	3	0	0	
	YGH3	5	25	8	7	10	3	3	
	YJG3	5	25	15	25	25	25	15	
	YKG3	0	0	0	0	5	2	0	
	VFH3	30	45	0	5	1	0	5	
	Weighted Scores								
				weighted	Scores				
Treatment	Dog ID	R.	R.	R.	Access	L.	L.	L.	Total
Treatment Group	Dog ID	R. Cranial	R. Middle			L. Cr-Cr	L. Cr-Cau	L. Caudal	Total Score
	Dog ID VRH3			R.					
		Cranial	Middle	R. Caudal	Access	Cr-Cr	Cr-Cau	Caudal	Score
	VRH3	Cranial 1.06	Middle 2.50	R. Caudal	Access	Cr-Cr 1.37	Cr-Cau 1.50	Caudal 2.07	Score 9.9
	VRH3 VTH3	1.06 0.76	Middle 2.50 2.50	R. Caudal 0.74 1.49	0.63 1.35	1.37 0.64	1.50 0.48	2.07 0.0	Score 9.9 7.2
	VRH3 VTH3 VUG3	1.06 0.76 1.52	2.50 2.50 2.50 2.50	R. Caudal 0.74 1.49 3.72	0.63 1.35 1.80	1.37 0.64 1.82	1.50 0.48 0.0	2.07 0.0 0.0	9.9 7.2 11.4
	VRH3 VTH3 VUG3 VVG3	Cranial 1.06 0.76 1.52 0.76	Middle 2.50 2.50 2.50 2.50 2.50 2.50 0.20	R. Caudal 0.74 1.49 3.72 0.25	0.63 1.35 1.80 0.72	Cr-Cr 1.37 0.64 1.82 1.82	Cr-Cau 1.50 0.48 0.0 0.30	Caudal 2.07 0.0 0.0 0.78 0.26 0.78	9.9 7.2 11.4 7.1 4.0 2.9
	VRH3 VTH3 VUG3 VVG3 WUG3	Cranial 1.06 0.76 1.52 0.76 0.0	Middle 2.50 2.50 2.50 2.50 2.50 2.50	R. Caudal 0.74 1.49 3.72 0.25 0.0	0.63 1.35 1.80 0.72 0.27	1.37 0.64 1.82 1.82 0.64	Cr-Cau 1.50 0.48 0.0 0.30 0.30	Caudal 2.07 0.0 0.0 0.78 0.26	9.9 7.2 11.4 7.1 4.0
	VRH3 VTH3 VUG3 VVG3 WUG3 WVG3	Cranial 1.06 0.76 1.52 0.76 0.0 0.46	Middle 2.50 2.50 2.50 2.50 2.50 2.50 0.20	R. Caudal 0.74 1.49 3.72 0.25 0.0	0.63 1.35 1.80 0.72 0.27 0.18	1.37 0.64 1.82 1.82 0.64 0.73	Cr-Cau 1.50 0.48 0.0 0.30 0.30 0.60	Caudal 2.07 0.0 0.0 0.78 0.26 0.78	9.9 7.2 11.4 7.1 4.0 2.9
	VRH3 VTH3 VUG3 VVG3 WUG3 WVG3 XAG3	Cranial 1.06 0.76 1.52 0.76 0.0 0.46 1.52	Middle 2.50 2.50 2.50 2.50 2.50 2.50 3.00	R. Caudal 0.74 1.49 3.72 0.25 0.0 1.24	0.63 1.35 1.80 0.72 0.27 0.18 0.45	Cr-Cr 1.37 0.64 1.82 1.82 0.64 0.73 0.91	Cr-Cau 1.50 0.48 0.0 0.30 0.30 0.60 0.30	Caudal 2.07 0.0 0.0 0.78 0.26 0.78 1.04	9.9 7.2 11.4 7.1 4.0 2.9 8.5
	VRH3 VTH3 VUG3 VVG3 WUG3 WVG3 XAG3 XBG3	Cranial 1.06 0.76 1.52 0.76 0.0 0.46 1.52 0.0	Middle 2.50 2.50 2.50 2.50 2.50 2.50 3.00 4.00	R. Caudal 0.74 1.49 3.72 0.25 0.0 0.0 1.24 0.0	0.63 1.35 1.80 0.72 0.27 0.18 0.45	Cr-Cr 1.37 0.64 1.82 1.82 0.64 0.73 0.91	Cr-Cau 1.50 0.48 0.0 0.30 0.30 0.60 0.30 0.06	Caudal 2.07 0.0 0.0 0.78 0.26 0.78 1.04 0.0	Score 9.9 7.2 11.4 7.1 4.0 2.9 8.5 4.5
Group	VRH3 VTH3 VUG3 VVG3 WUG3 WVG3 XAG3 XAG3 XBG3 XQH3	Cranial 1.06 0.76 1.52 0.76 0.0 0.46 1.52 0.0 1.52	Middle 2.50 2.50 2.50 2.50 2.50 2.50 3.00 4.00 3.50	R. Caudal 0.74 1.49 3.72 0.25 0.0 0.0 1.24 0.0 3.72	0.63 1.35 1.80 0.72 0.27 0.18 0.45 0.45	1.37 0.64 1.82 1.82 0.64 0.73 0.91 0.0 0.73	Cr-Cau 1.50 0.48 0.0 0.30 0.30 0.60 0.30 0.06 0.30	Caudal 2.07 0.0 0.0 0.78 0.26 0.78 1.04 0.0	9.9 7.2 11.4 7.1 4.0 2.9 8.5 4.5
Group	VRH3 VTH3 VUG3 VVG3 WUG3 WVG3 XAG3 XBG3 XQH3 XSH3	Cranial 1.06 0.76 1.52 0.76 0.0 0.46 1.52 0.0 1.52 5.32	Middle 2.50 2.50 2.50 2.50 2.50 2.50 3.00 4.00 3.50 4.50	R. Caudal 0.74 1.49 3.72 0.25 0.0 0.0 1.24 0.0 3.72 3.72	0.63 1.35 1.80 0.72 0.27 0.18 0.45 0.90 2.25	Cr-Cr 1.37 0.64 1.82 1.82 0.64 0.73 0.91 0.0 0.73 1.82	Cr-Cau 1.50 0.48 0.0 0.30 0.30 0.60 0.30 0.06 0.30 2.40	Caudal 2.07 0.0 0.0 0.78 0.26 0.78 1.04 0.0 0.0 2.59	9.9 7.2 11.4 7.1 4.0 2.9 8.5 4.5 10.7 22.6
Group	VRH3 VTH3 VUG3 VVG3 WVG3 WVG3 XAG3 XBG3 XQH3 XSH3 XUG3	Cranial 1.06 0.76 1.52 0.76 0.0 0.46 1.52 0.0 1.52 0.0 1.52 5.32 0.0	Middle 2.50 2.50 2.50 2.50 2.50 3.00 4.00 3.50 4.50 2.00	R. Caudal 0.74 1.49 3.72 0.25 0.0 0.0 1.24 0.0 3.72 3.72 6.20	0.63 1.35 1.80 0.72 0.27 0.18 0.45 0.45 0.90 2.25 1.35	Cr-Cr 1.37 0.64 1.82 1.82 0.64 0.73 0.91 0.0 0.73 1.82 0.55	Cr-Cau 1.50 0.48 0.0 0.30 0.30 0.60 0.30 0.06 0.30 1.20	Caudal 2.07 0.0 0.0 0.78 0.26 0.78 1.04 0.0 0.0 2.59	Score 9.9 7.2 11.4 7.1 4.0 2.9 8.5 4.5 10.7 22.6 11.3
Group	VRH3 VTH3 VUG3 VVG3 WUG3 WVG3 XAG3 XBG3 XQH3 XSH3 XUG3 XCH3	Cranial 1.06 0.76 1.52 0.76 0.0 0.46 1.52 0.0 1.52 5.32 0.0 0.15	Middle 2.50 2.50 2.50 2.50 2.50 2.50 3.00 4.00 3.50 4.50 2.00 0.0	R. Caudal 0.74 1.49 3.72 0.25 0.0 0.0 1.24 0.0 3.72 3.72 6.20 0.0	0.63 1.35 1.80 0.72 0.27 0.18 0.45 0.45 0.90 2.25 1.35 0.0	Cr-Cr 1.37 0.64 1.82 1.82 0.64 0.73 0.91 0.0 0.73 1.82 0.55 0.0	Cr-Cau 1.50 0.48 0.0 0.30 0.30 0.60 0.30 0.06 0.30 2.40 1.20 0.0	Caudal 2.07 0.0 0.0 0.78 0.26 0.78 1.04 0.0 0.0 2.59 0.0	Score 9.9 7.2 11.4 7.1 4.0 2.9 8.5 4.5 10.7 22.6 11.3 0.2
Group	VRH3 VTH3 VUG3 VVG3 WUG3 WVG3 XAG3 XBG3 XQH3 XSH3 XUG3 XCH3 XFG3	Cranial 1.06 0.76 1.52 0.76 0.0 0.46 1.52 0.0 1.52 0.0 1.52 5.32 0.0 0.15 0.30	Middle 2.50 2.50 2.50 2.50 2.50 3.00 4.00 3.50 4.50 2.00 0.0	R. Caudal 0.74 1.49 3.72 0.25 0.0 0.0 1.24 0.0 3.72 3.72 6.20 0.0 0.0	0.63 1.35 1.80 0.72 0.27 0.18 0.45 0.90 2.25 1.35 0.0 0.0	Cr-Cr 1.37 0.64 1.82 1.82 0.64 0.73 0.91 0.0 0.73 1.82 0.55 0.0 0.0	Cr-Cau 1.50 0.48 0.0 0.30 0.30 0.60 0.30 0.06 0.30 2.40 1.20 0.0	Caudal 2.07 0.0 0.0 0.78 0.26 0.78 1.04 0.0 2.59 0.0 0.26	Score 9.9 7.2 11.4 7.1 4.0 2.9 8.5 4.5 10.7 22.6 11.3 0.2 0.6
Group	VRH3 VTH3 VUG3 VVG3 WVG3 WVG3 XAG3 XBG3 XQH3 XSH3 XCH3 XFG3 WAH3	Cranial 1.06 0.76 1.52 0.76 0.0 0.46 1.52 0.0 1.52 5.32 0.0 0.15 0.30 0.0	Middle 2.50 2.50 2.50 2.50 2.50 3.00 4.00 3.50 4.50 2.00 0.0 0.0	R. Caudal 0.74 1.49 3.72 0.25 0.0 0.0 1.24 0.0 3.72 3.72 6.20 0.0 0.0 0.0	0.63 1.35 1.80 0.72 0.27 0.18 0.45 0.45 0.90 2.25 1.35 0.0 0.0	Cr-Cr 1.37 0.64 1.82 1.82 0.64 0.73 0.91 0.0 0.73 1.82 0.55 0.0 0.0	Cr-Cau 1.50 0.48 0.0 0.30 0.30 0.60 0.30 2.40 1.20 0.0 0.0	Caudal 2.07 0.0 0.0 0.78 0.26 0.78 1.04 0.0 0.0 2.59 0.0 0.0 0.26 0.0	Score 9.9 7.2 11.4 7.1 4.0 2.9 8.5 4.5 10.7 22.6 11.3 0.2 0.6 0.0
Group	VRH3 VTH3 VUG3 VVG3 WUG3 WVG3 XAG3 XAG3 XBG3 XQH3 XSH3 XCH3 XFG3 WAH3 WDH3	Cranial 1.06 0.76 1.52 0.76 0.0 0.46 1.52 0.0 1.52 5.32 0.0 0.15 0.30 0.0 0.0	Middle 2.50 2.50 2.50 2.50 2.50 3.00 4.00 3.50 4.50 2.00 0.0 0.0 0.0 0.0 0.0	R. Caudal 0.74 1.49 3.72 0.25 0.0 1.24 0.0 3.72 3.72 6.20 0.0 0.0 0.0 2.48	0.63 1.35 1.80 0.72 0.27 0.18 0.45 0.90 2.25 1.35 0.0 0.0 0.72	Cr-Cr 1.37 0.64 1.82 1.82 0.64 0.73 0.91 0.0 0.73 1.82 0.55 0.0 0.0 0.0	Cr-Cau 1.50 0.48 0.0 0.30 0.30 0.60 0.30 0.06 0.30 2.40 1.20 0.0 0.0 0.0	Caudal 2.07 0.0 0.0 0.78 0.26 0.78 1.04 0.0 2.59 0.0 0.0 0.26 0.0 0.0	Score 9.9 7.2 11.4 7.1 4.0 2.9 8.5 4.5 10.7 22.6 11.3 0.2 0.6 0.0 3.5
Group	VRH3 VTH3 VUG3 VVG3 WUG3 WVG3 XAG3 XAG3 XBG3 XQH3 XSH3 XCH3 XCH3 XFG3 WAH3 WDH3 YGH3	Cranial 1.06 0.76 1.52 0.76 0.0 0.46 1.52 0.0 1.52 5.32 0.0 0.15 0.30 0.0 0.76	Middle 2.50 2.50 2.50 2.50 2.50 3.00 4.00 3.50 4.50 2.00 0.0 0.0 0.0 2.50	R. Caudal 0.74 1.49 3.72 0.25 0.0 0.0 1.24 0.0 3.72 6.20 0.0 0.0 0.0 2.48 1.98	0.63 1.35 1.80 0.72 0.27 0.18 0.45 0.90 2.25 1.35 0.0 0.0 0.72 0.63	Cr-Cr 1.37 0.64 1.82 1.82 0.64 0.73 0.91 0.0 0.73 1.82 0.55 0.0 0.0 0.0 0.0 0.27 0.91	Cr-Cau 1.50 0.48 0.0 0.30 0.30 0.60 0.30 0.06 0.30 2.40 1.20 0.0 0.0 0.0 0.18	Caudal 2.07 0.0 0.0 0.78 0.26 0.78 1.04 0.0 2.59 0.0 0.0 0.26 0.0 0.78	Score 9.9 7.2 11.4 7.1 4.0 2.9 8.5 4.5 10.7 22.6 11.3 0.2 0.6 0.0 3.5 7.7

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Study Type	Safety					
Pertaining to	All					
	To demonstrate safety under field conditions					
Study Purpose						
Product Administration	Two doses administered 3-4 weeks apart by the subcutaneous route					
Study Animals	654 dogs represented five geograph: 217 dogs were 8 weeks of age, which age; 437 dogs ranged in age from 9	ch is the recommende	ed minimum			
Challenge Description	Not applicable					
Interval observed after challenge	Dogs were observed daily for 14 day adverse events.	ys after each vaccina	tion for any			
Results	Summary of Adverse Events:					
	VeDDRA Code for Adverse Events Related to	Number of Adverse Events				
	the Test Vaccine	in 1,301 doses				
	Lethargy	21 (1.6%)				
	Diarrhea	4 (0.3%)				
	Polydipsia	3 (0.2%)				
	Anorexia	1 (0.1%)				
	Injection Site Oedema	1 (0.1%)				
	Anaphylaxis	1 (0.1%)				
	Injection site pain	1 (0.1%)				
	Total	32 (2.5%)				
	VeDDRA Code for	Number of	7			
	Adverse Events Not Related to	Adverse Events				
	the Test Vaccine	in 1,301 doses				
	Diarrhea	14 (1.1%)	-			
	Emesis	13 (1.0%)	_			
	Cough	12 (0.9%)				
	Respiratory Tract Disorder NOS	6 (0.5%)				
	Lethargy	5 (0.4%)				
	Lack of Efficacy* (Parvovirus disease)	4 (0.3%)				
	Joint Pain NOS	3 (0.2%)				
	Hyperthermia	3 (0.2%)	_			
	Dermatitis and Eczema	3 (0.2%)	_			
	Gastroenteritis	2 (0.2%)	1			
	Sneezing	2 (0.2%)	_			
	Muscle tremor	2 (0.2%)	_			
	Anxiety Disorder NOS	2 (0.2%)	-			
	Anorexia	1 (0.1%)	-			
	Polydipsia Hypersalivation	1 (0.1%) 1 (0.1%)	-			
	Nausea	1 (0.1%)	_			
	Injection site hemorrhage	1 (0.1%)	-			

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	Dermal Mass	1 (0.1%)
	Otitis externa	1 (0.1%)
	Pneumonia	1 (0.1%)
	Ocular discharge	1 (0.1%)
	Pruritus	1 (0.1%)
	Regurgitation	1 (0.1%)
	Digestive Tract Hypermotility	1 (0.1%)
	Alopecia	1 (0.1%)
	Trauma NOS	1 (0.1%)
	Total	85 (6.5%)
	*Lack of expected effectiveness of the vacc	ine due to concurrent disease
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