



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	4637.24
True Name	Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola-Grippytyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Canine Imuno-Vax 9 - No distributor specified Canine Spectra 9 - Peak Marketing Solo-Jec 9 - No distributor specified
Date of Compilation Summary	September 01, 2020

**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.**

<b>Study Type</b>	Efficacy											
<b>Pertaining to</b>	Infectious Canine Hepatitis Virus											
<b>Study Purpose</b>	To demonstrate effectiveness against Infectious Canine Hepatitis (ICH)											
<b>Product Administration</b>	Two doses were administered subcutaneously (SC) 21 days apart											
<b>Study Animals</b>	Seventeen (17) 6-week-old puppies, seronegative for ICH, were randomly sorted into 1 group of 11 SC vaccinates and one group of 6 controls.											
<b>Challenge Description</b>	21 days after second vaccination all dogs were challenged with Infectious Canine Hepatitis Virus.											
<b>Interval observed after challenge</b>	Puppies were observed for 21 days after challenge for clinical signs.											
<b>Results</b>	The study was satisfactory per the criteria in 9 CFR 113.305(1)(ii) (A)(B) <table><tr><td></td><td>Mortality</td><td>Clinical Signs of CDV Infection</td></tr><tr><td>SC Vaccinates</td><td>0/11 (0%)</td><td>0/11 (0%)</td></tr><tr><td>Controls</td><td>6/6 (100%)</td><td>6/6 (100%)</td></tr></table>				Mortality	Clinical Signs of CDV Infection	SC Vaccinates	0/11 (0%)	0/11 (0%)	Controls	6/6 (100%)	6/6 (100%)
	Mortality	Clinical Signs of CDV Infection										
SC Vaccinates	0/11 (0%)	0/11 (0%)										
Controls	6/6 (100%)	6/6 (100%)										
<b>USDA Approval Date</b>	March 31, 1998											

Canine Infectious Hepatitis Clinical Signs Observed Post Challenge																		
Dog	Treatment	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC
1	Control					22	N/A	NA										
2	Control					1,4,7,20	1,3,5,6,15,17,20,22***											
3	Control				3,13,23**	1,3,23,22***	N/A											
4	Control				23**	1,3,7	1,3,6,7,17,20,22***											
5	Control			23*	3	22	N/A											
6	Control			7	7	22	N/A											
19	SC Vac																	
20	SC Vac																	
21	SC Vac																	
22	SC Vac															6		
23	SC Vac																	
24	SC Vac										6							
25	SC Vac																	
26	SC Vac																	
27	SC Vac																	
28	SC Vac																	
29	SC Vac								6							6		
	1 - Depression/Lethargy					6 - Serous ocular discharge			15 - Excessive Salivation					23 - Other				
	3- Dehydration					7 - Mild/Moderate mucopurulent			17 - Icteric Gums					* Icteric Lumbar only				
	4 - Mild/Moderate Conjunctivitis					Ocular Discharge			20 - Petechial Pain /					** Icteric lumbar and ears				
	5 - Severe Conjunctivitis					13 - Vomiting			Ecchymotic					***- moribund and euthanization				
				NO Clinical signs observed in any group after 16DPC						22 - Death				DPC – Days post challenge				

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Canine Adenovirus Type II
<b>Study Purpose</b>	To demonstrate effectiveness against Canine Adenovirus Type II (CAV2)
<b>Product Administration</b>	Two doses were administered subcutaneously 21 days apart
<b>Study Animals</b>	Twenty-two (22) 6-week-old puppies seronegative for CAV2 were randomly sorted into one group of 11 SC vaccinates and one group of 11 controls.
<b>Challenge Description</b>	21 days after second vaccination all dogs were challenged with CAV2
<b>Interval observed after challenge</b>	Puppies were observed for 21 days after challenge for clinical signs.
<b>Results</b>	<p>The study was considered satisfactory by the reduction in clinical signs and virus shedding in the vaccinates when compared to the control animals.</p> <p>See the next page for data.</p>
<b>USDA Approval Date</b>	April 3, 1998

CAV2 Clinical Signs Observed Post Challenge																									
Dog	Group	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC	17DPC	18DPC	19DPC	20DPC	21DPC		
1	Control						1	1,2		2	2														
2	Control						1	1,2	1,2	1,2	2														
3	Control						1	1,2	1	1	1	1													
4	Control						1,2	1,2	1,2,4	1,2,	2														
5	Control						1	1	1,4	1	1														
6	Control					2		4			1									1	1				
7	Control						1	1,2,4	1,2,4,5,6	1	1	2,4		1	1,2	1	1,2								
8	Control		1	1,2	1,2	1	1,2	1,6	1	1	1	1	1	1	1	1	1	1	1		1				
9	Control							1	1	4	4														
10	Control					1	1	1	1	1	1,2			1											
11	Control					2	2	1,2	1,2	1	1	1													
23	SC																								
24	SC																								
25	SC						1			1															
26	SC																								
27	SC																								
28	SC							1																	
29	SC							1	1																
30	SC		1	1	1	1	1	1	1	1		1		1	1			1		1	1	1			
31	SC						1	1	1	1	1,2														
32	SC																								
33	SC																								
		1 - Ocular Discharge				3- Sneezing				5 -Retching				7-Inappetence											
		2- Nasal Discharge				4 - Coughing				6 - depression/lethargy				Blank - No Clinical signs observed											

DPC - Days Post Challenge

### CAV2 Isolation from Nasal Swab Samples (TCID<sub>50</sub>/100ul)

Dog	Group	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC	17DPC	18DPC	19DPC	20DPC	21DPC
1	Control				2	2.5	3.63	3.5	≤1.83								≤1.83						
2	Control				2	2.83	3.5	3.83	2.17							2.17							
3	Control				≤1.63	3.5	4.17	3.38															
4	Control					2.63	3.38	4.31	2.35				≤1.63										≤1.63
5	Control				2.38	2.6	4.38	3.6	≤2.63														
6	Control				≤1.83	≤1.83	4.5	3.63	3.63														
7	Control				≤1.63	2.75	4.5	4.5	≤1.83														
8	Control				2.38	2.83	3.63	3.17															
9	Control				≤1.63	2.83	2.83	4.38													≤1.83		
10	Control				≤1.63	2.17	3.63	3.5					≤1.63	2.38	2.5	≤1.83							
11	Control				≤1.83	2.5	4.5	4.38						≤1.63	≤1.83	≤1.63	≤1.63		≤1.63		≤1.63		
23	SC																						
24	SC		≤1.6				2.38																
25	SC					≤1.63																	≤1.63
26	SC								2.63														
27	SC		≤1.63												≤1.63								
28	SC																						
29	SC				2	≤1.83									≤1.63		≤1.63						
30	SC																						
31	SC																						
32	SC		≤1.6				≤1.83	2.63	2.5						≤1.63								
33	SC																≤1.63						
Blank - No CAV2 titer detected																							
DPC - Days Post Challenge																							

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira canicola</i>
<b>Study Purpose</b>	To demonstrate effectiveness against <i>Leptospira canicola</i> in 6 week old dogs.
<b>Product Administration</b>	Two doses were administered subcutaneously (SC) 3 weeks apart.
<b>Study Animals</b>	Twenty-three (23) 6-week-old puppies serologically negative <i>Leptospira</i> were randomized into one group of 11 SC vaccinates and one group of 12 controls.
<b>Challenge Description</b>	Twenty-one (21) days after second vaccination all animals were challenged with <i>Leptospira canicola</i> organisms.
<b>Interval observed after challenge</b>	Dogs were observed daily for 21 days after challenge for clinical signs associated with <i>L. canicola</i> . Blood samples were collected through 14 days after challenge.
<b>Results</b>	<p>Efficacy was determined by comparing vaccinates versus controls in clinical signs, thrombocytopenia, and leukopenia.</p> <p>A dog was considered to have thrombocytopenia if the platelet count dropped below 200 k/<math>\mu</math>L and the count was less than 50% of the baseline value.</p> <p>A dog was considered to have leukopenia if the platelet count dropped below 6 k/<math>\mu</math>L and the count was less than 50% of the baseline value.</p> <p>See the next page for data.</p>
<b>USDA Approval Date</b>	April 3, 1998





# Leptospira canicola Clinical Signs Observed Post Challenge

DPC = Day post-challenge



Leptospira canicola White Blood Cell Count Post Challenge															
Controls															
Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
23	18.3	21.7	14.2	7.4	21.7	.	.								
24	16.1	20	16.7	6.1	11.5	15.6	14.6	20.5							
25	17.1	11.3	13	8.3	10	12.6	13.6	17	26	28.1	36.6	36.7	26.2	29.4	21.9
26	9	7.9	9.6	5.6	5.7	6.7	8		11.7	13.8	16.6	9.6	11.5	12.7	13.9
27	10.4	8.9	5.5	4.1	5.2	8.6	19.4	21	16.2	7.9	11.3	13.9	15	11.5	13.3
28	9.6	18.4	6.4	3.9	7	19.4	13.2								
29	12.2	19.4	7.8	4.2	5	5.3	17.5								
30	9.5	11.9	9.5	3.2	6.1	7.9	10.6	11.1	10.4	8.7	11.4	9.2	12.69	16.7	12.2
31	8.9	10.6	6.4	4	6	10.3									
32	11.9	12.2	11.5	5.3	6	6.6	15.8								
33	11.8	17.5	6.1	2.6	5.3	4.4	8.7	13	22.8	22.8	20.5	31.5	26.3	17.4	16.9
34	7	9.6	10.1	3.4	5.6	3.8	6	12	12.6	17.3	15.3	10.9	15.7	15.9	20.2

DPC = Day post-challenge. Values reported as k/ $\mu$ L.

**Leptospira canicola Platelet Counts Post Challenge**

**SC Vaccines**

Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
12	444.3	538	480	452	473	512	531	582	478	631	512	381	483	511	470
13	551.3	679	559	573	576	539	467	636	565	470	501	616	550	510	467
14	473.3	571	452	505	444	536	497	604	693	695	567	568	508	802	640
15	459.7	407	381	543	421	503	612	633	576	497	482	560	438	463	461
16	477.3	377	409	452	456	492	555	558	655	512	519	302	428	399	390
17	318	243	247	311	324	329	389	351	314	288	270	261	232	257	278
18	425.7	331	356	381	398	453	542	247	463	483	405	480	406	554	572
19	348.7	330	353	324	403	375	376	375	379	476	381	414	418	516	524
20	555.3	494	497	530	483	523	538	706	704	662	493	601	462	464	469
21	378.3	332	354	476	447	469	441	514	650	581	501	521	429	474	583
22	469.3	413	455	581	478	576	517	469	473	597	492	500	497	495	593

DPC = Day post-challenge. Values reported as k/ $\mu$ L.

Leptospira canicola Platelet Counts Post Challenge													
Controls													
Dog	Baseline (Avg-2DPC, -1DPC, 0DPC)	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC
23	300	238	148	11	7.7	D	D	D	D	D	D	D	D
24	342	204	161	64.1	40.5	45.3	123	207	D	D	D	D	D
25	519.7	267	213	187	134	117	160	285	497	710	714	823	738
26	404.7	278	279	196	150	172	194	ND	302	441	721	648	599
27	482.7	281	225	119	55	49.9	100	157	405	455	492	552	528
28	242.3	209	60.4	45.9	3.9	11.1	11.3	D	D	D	D	D	D
29	529.7	521	305	195	37.6	15.8	42.2	D	D	D	D	D	D
30	329.3	292	167	107	61.7	81.6	122	242	412	518	697	504	632
31	432.7	327	150	80.2	38	14	D	D	D	D	D	D	D
32	395.7	329	195	103	33.3	14.2	44.1	D	D	D	D	D	D
33	563.7	409	182	115	67.1	8.5	2.4	11.4	87.1	235	417	744	701
34	232.7	174	150	64.5	41.6	8.3	6.8	82.8	142	273	310	383	479
ND= No Data													
D = dead													

DPC = Day post-challenge. Values reported as k/ $\mu$ L.

Study Type	Efficacy																																																																																																																																																										
Pertaining to	Leptospira grippotyphosa																																																																																																																																																										
Study Purpose	To demonstrate effectiveness against <i>Leptospira grippotyphosa</i> in 6-week-old dogs.																																																																																																																																																										
Product Administration	Two doses were administered subcutaneously (SC) 3 weeks apart.																																																																																																																																																										
Study Animals	Twenty (20) 6-week-old puppies were randomized into one group of 10 SC vaccinates and one group of 10 controls.																																																																																																																																																										
Challenge Description	Fifteen (15) days after second vaccination all animals were challenged with <i>Leptospira grippotyphosa</i> organisms.																																																																																																																																																										
Interval observed after challenge	Dogs were observed daily for 21 days after challenge																																																																																																																																																										
Results	<p>Efficacy was based on the reduction in spirochetemia in vaccinates when compared to controls.</p> <p>Leptospira was not isolated in any of the vaccinates receiving vaccine by SC route.</p> <p>Leptospira was isolated from blood collected from dogs in the control group after challenge, as shown in the following table for Days 0 – 14 (post-challenge):</p> <table><tr><th>Dog</th><th>0</th><th>3</th><th>4</th><th>5</th><th>6</th><th>7</th><th>8</th><th>9</th><th>10</th><th>11</th><th>12</th><th>13</th><th>14</th></tr><tr><td>1</td><td></td><td></td><td></td><td></td><td></td><td>+</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>2</td><td></td><td></td><td></td><td></td><td>+</td><td></td><td>+</td><td>+</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>3</td><td></td><td></td><td></td><td>+</td><td>+</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>4</td><td></td><td></td><td></td><td></td><td>+</td><td>+</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>5</td><td></td><td></td><td></td><td>+</td><td>+</td><td>+</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>6</td><td></td><td></td><td></td><td></td><td></td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td><td>NA</td><td>NA</td><td>NA</td></tr><tr><td>7</td><td></td><td></td><td></td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td><td>NA</td><td>NA</td><td>NA</td><td>NA</td></tr><tr><td>8</td><td></td><td></td><td></td><td></td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td><td>NA</td><td>NA</td><td>NA</td></tr><tr><td>9</td><td></td><td></td><td></td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td><td>NA</td><td>NA</td><td>NA</td></tr><tr><td>10</td><td></td><td></td><td></td><td></td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td><td>NA</td><td>NA</td><td>NA</td></tr></table> <p>NA is Animal Dead or euthanized / no sample taken + is Positive for Leptospira</p>	Dog	0	3	4	5	6	7	8	9	10	11	12	13	14	1						+								2					+		+	+						3				+	+									4					+	+								5				+	+	+								6						+	+	+	+	+	NA	NA	NA	7				+	+	+	+	+	+	NA	NA	NA	NA	8					+	+	+	+	+	+	NA	NA	NA	9				+	+	+	+	+	+	+	NA	NA	NA	10					+	+	+	+	+	+	NA	NA	NA
Dog	0	3	4	5	6	7	8	9	10	11	12	13	14																																																																																																																																														
1						+																																																																																																																																																					
2					+		+	+																																																																																																																																																			
3				+	+																																																																																																																																																						
4					+	+																																																																																																																																																					
5				+	+	+																																																																																																																																																					
6						+	+	+	+	+	NA	NA	NA																																																																																																																																														
7				+	+	+	+	+	+	NA	NA	NA	NA																																																																																																																																														
8					+	+	+	+	+	+	NA	NA	NA																																																																																																																																														
9				+	+	+	+	+	+	+	NA	NA	NA																																																																																																																																														
10					+	+	+	+	+	+	NA	NA	NA																																																																																																																																														
USDA Approval Date	January 12, 1999																																																																																																																																																										

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira icterohaemorrhagiae</i>
<b>Study Purpose</b>	To demonstrate effectiveness against <i>Leptospira icterohaemorrhagiae</i> in 6 week old dogs.
<b>Product Administration</b>	Two doses were administered subcutaneously (SC) 3 weeks apart.
<b>Study Animals</b>	Twenty-two (22) 6-week-old puppies serologically negative for <i>Leptospira icterohaemorrhagiae</i> were randomized into one group of 10 SC vaccinates and one group of 12 controls.
<b>Challenge Description</b>	Twenty-one (21) days after second vaccination all animals were challenged with <i>Leptospira icterohaemorrhagiae</i> organisms.
<b>Interval observed after challenge</b>	Dogs were observed daily for 21 days after challenge for clinical signs associated with <i>L. icterohaemorrhagiae</i> . Blood samples were collected through 14 days after challenge.
<b>Results</b>	<p>Efficacy was determined by comparing vaccinates versus controls in clinical signs, thrombocytopenia, and leukopenia.</p> <p>A dog was considered to have thrombocytopenia if the platelet count dropped below 200 k/<math>\mu</math>L and the count was less than 50% of the baseline value.</p> <p>A dog was considered to have leukopenia if the platelet count dropped below 6 k/<math>\mu</math>L and the count was less than 50% of the baseline value.</p> <p>See the next page for data.</p>
<b>USDA Approval Date</b>	March 31, 1998

Leptospira Ictero Clinical Signs Observed Post Challenge																						
SC Vaccinates																						
Dog	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC	17DPC	18DPC	19DPC	20DPC	21DPC
11							A															
12																						
13				E		D							E					E	D		E	
14				E			E		F										D	E		
15		AE							E				D								E	
16																				A		
17																						
18																			D			
19							E															
20			D	D		D	D					D		E			E					
A-Inappetance						F - Nasal Discharge Serous																
B-Vomiting						G - Nasal Discharge Mucoid																
C- Depression/Lethargy						H- Diarrhea Mild (loose stool)																
D- Ocular Discharge Serous						I- Diarrhea Moderate (Watery stool)																
E - Ocular Discharge Mucoid						J - Diarrhea Severe (bloody stool)																
											</											

DPC = Day post-challenge



## Leptospira Ictero Clinical Signs Observed Post Challenge

[illegible]

DPC = Day post-challenge

**Leptospira ictero White Blood Cell Count Post Challenge**

Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	SC Vaccinates													
		1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
11	7.2	7.3	12.4	7.9	6.8	10.1	6.4	6.4	6.4	8.5	8.9	9.7	9.6	7.2	6.4
12	10	13.9	10.4	8.9	9.1	12.4	15.2	8.2	11.1	8.6	7.7	10.2	9	9.1	12.3
13	7.6	15.4	9.6	13.2	9.1	14.2	8.8	9.2	9.6	8.3	10.6	6.7	7.8	7.8	8.4
14	13.4	7.6	12.6	8.2	12.6	11.3	9.3	7.3	11.8	8	13.2	9.8	10	12.8	9.1
15	9.8	11.4	9.8	9	8	8.3	11.2	10.2	8	7.5	10.4	7.7	11.1	7.5	10.9
16	9.1	8.8	9.5	6.8	8.1	9.1	9.4	8.4	10.1	7.7	8.7	9.5	10	8.3	8.3
17	9.1	7.1	7.8	8.1	7.5	7.2	10.5	9.4	11.4	7.6	11.7	7.1	10.2	7.5	7.3
18	7.2	7.7	10.5	9.1	6.6	7.3	7.1	8.4	7.4	8	9	8.1	6.5	7.8	6.4
19	9.5	13.8	8.4	11.7	11.7	8.7	6.7	10.5	7.5	8.2	7.7	7.8	7	8.8	6.7
20	13.1	9.9	5.3	9.1	11.9	14.8	14.4	6.4	9.1	8.7	12.5	12.6	7.6	8.1	8.9

DPC = Day post-challenge. Values reported as k/ $\mu$ L.

Leptospira ictero White Blood Cell Count Post Challenge																	
Controls																	
Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC		
21	7.4	6.6	9.6	6.7	8.2	6.2	8.6	6.7	6.5	8.1	10.4	6.4	8.5	6.5	6.2		
22	7.4	8.5	9.3	8.2	6.5	7.3	13.4	9.4	7.2	8.2	13.4	10.1	7.7	7.6	9.4		
23	9.3	12.2	9.4	11.6	7.1	9	10	7	6.5	7.1	11.9	7	9.6	11	11.8		
24	13.7	19.6	10.6	7.8	11.8	15.3	16.7	19.8	16	13.7	19.2	24.9	13.3	24.4	12.3		
25	10	13.9	8.5	6.9	9.1	7	10.9	12.8	9.6	10	13.9	9.4	8.3	9	7.1		
26	8.4	8.6	9	3.9	11.8	12.2	15.4	11.3	11.8	9	10.2	13.3	8.6	8.9	10.5		
27	7.8	7.5	9.4	15.8	14.6	10.7	9.8	7.5	8.6	12.1	8.6	8.3	11.4	7.4	9.5		
28	7.8	8.8	6.7	4.5	7.3	7.3	8.8	14.7	10	11.6	11.7	14	8.3	7.8	7.7		
29	7.8	6.7	5.8	4.1	26.4	D											
30	8.8	7.6	5	7.2	7.8	7.5	7.8	6.2	9.9	8	10.3	10.1	9.9	9.4	9.6		
31	11	8.1	8.3	4.2	19	D											
32	8.3	9.3	6.2	5	10.7	12.6	10.6	13.5	14.5	9.6	14.1	9.9	10	10.1	9.3		
D = dead																	

DPC = Day post-challenge. Values reported as k/ $\mu$ L.

Leptospira ictero Platelet Counts Post Challenge															
SC Vaccinates															
Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
11	449.7	432	619	476	440	667	457	447	488	442	591	586	536	471	359
12	518.3	475	456	447	428	526	645	435	480	505	487	453	473	461	517
13	489.3	595	425	560	424	580	445	517	416	508	522	415	347	337	349
14	451.7	258	413	349	457	374	344	335	376	331	431	330	263	351	281
15	357.7	380	297	286	275	282	435	400	314	285	388	288	401	290	369
16	369	264	298	217	264	278	308	268	281	253	316	258	286	284	294
17	473.7	407	400	386	332	214	542	457	513	436	529	417	498	373	381
18	506	482	569	392	397	351	393	419	327	424	406	388	283	391	287
19	477	467	386	552	529	417	459	500	378	489	356	383	331	406	352
20	502.3	412	506	483	525	515	555	352	392	358	488	501	325	340	378

DPC = Day post-challenge. Values reported as k/ $\mu$ L.

DPC = Day post-challenge. Values reported as k/ $\mu$ L.

### Leptospira ictero Platelet Counts Post Challenge

Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	Controls													14DPC	
		1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC		
21	534.3	291	315	207	301	341	545	506	529	537	575	434	399	414	410	
22	428.7	238	250	168	126	184	261	288	340	412	520	421	369	386	367	
23	411.3	374	307	265	289	362	393	361	369	447	546	444	422	583	535	
24	344.7	251	130	99.5	116	189	312	497	440	480	618	635	461	658	451	
25	566	401	220	146	189	288	483	611	458	466	660	519	427	432	409	
26	392	302	213	94.9	84.5	210	361	381	421	444	467	578	513	452	388	
27	475.7	399	423	483	413	335	386	437	465	575	469	461	540	372	474	
28	411.7	214	93.5	60.5	128	213	307	332	467	612	622	618	495	467	383	
29	332	136	101	6.7	11.2	D										
30	421.9	204	80.9	53.9	119	231	379	512	549	516	642	494	411	421	427	
31	319.3	163	94.4	36.7	11.9	D										
32	267	184	55	7.7	88.8	196	257	347	525	430	529	360	337	287	301	
D = Dead																

DPC = Day post-challenge. Values reported as k/ $\mu$ L.

<b>Study Type</b>	Efficacy																																																																																																																																																																																
<b>Pertaining to</b>	<i>Leptospira pomona</i>																																																																																																																																																																																
<b>Study Purpose</b>	To demonstrate effectiveness against <i>Leptospira pomona</i> in 6 week old dogs.																																																																																																																																																																																
<b>Product Administration</b>	Two doses were administered subcutaneously (SC) 3 weeks apart.																																																																																																																																																																																
<b>Study Animals</b>	Twenty (20) 6-week-old puppies serologically negative to <i>Leptospira</i> were randomized into one group of one group of 10 SC vaccinates and one group of 10 controls.																																																																																																																																																																																
<b>Challenge Description</b>	Twenty-five (25) days after second vaccination all animals were challenged with <i>Leptospira pomona</i> organisms.																																																																																																																																																																																
<b>Interval observed after challenge</b>	Dogs were observed daily for 21 days after challenge. Blood samples were collected through 14 days after challenge.																																																																																																																																																																																
<b>Results</b>	<p>Efficacy was based on the reduction in spirochetemia in vaccinates when compared to controls.</p> <p><i>Leptospira</i> was not isolated from blood in any of the vaccinates receiving vaccine by SC route.</p> <p><i>Leptospira</i> was isolated from blood collected from dogs in the control group after challenge, as shown in the following table for Days 0 – 14 (post-challenge):</p> <table><tr><th>Dog</th><th>0</th><th>1</th><th>2</th><th>3</th><th>4</th><th>5</th><th>6</th><th>7</th><th>8</th><th>9</th><th>10</th><th>11</th><th>12</th><th>13</th><th>14</th></tr><tr><td>1</td><td></td><td></td><td>+</td><td>+</td><td>+</td><td>+</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>2</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>3</td><td></td><td></td><td>+</td><td>+</td><td>+</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>4</td><td></td><td></td><td></td><td>+</td><td>+</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>5</td><td></td><td></td><td>+</td><td>+</td><td>+</td><td>+</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>6</td><td></td><td></td><td>+</td><td>+</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>7</td><td></td><td>+</td><td>+</td><td>+</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>8</td><td></td><td></td><td>+</td><td>+</td><td>+</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>9</td><td></td><td>+</td><td>+</td><td>+</td><td>+</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>10</td><td></td><td>+</td><td></td><td>+</td><td>+</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> <p>+ is Positive for <i>Leptospira</i></p>	Dog	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	1			+	+	+	+										2																3			+	+	+											4				+	+											5			+	+	+	+										6			+	+												7		+	+	+												8			+	+	+											9		+	+	+	+											10		+		+	+										
Dog	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14																																																																																																																																																																		
1			+	+	+	+																																																																																																																																																																											
2																																																																																																																																																																																	
3			+	+	+																																																																																																																																																																												
4				+	+																																																																																																																																																																												
5			+	+	+	+																																																																																																																																																																											
6			+	+																																																																																																																																																																													
7		+	+	+																																																																																																																																																																													
8			+	+	+																																																																																																																																																																												
9		+	+	+	+																																																																																																																																																																												
10		+		+	+																																																																																																																																																																												
<b>USDA Approval Date</b>	January 12, 1999																																																																																																																																																																																

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Canine Parainfluenza Virus
<b>Study Purpose</b>	To demonstrate effectiveness against Canine Parainfluenza Virus (CPI)
<b>Product Administration</b>	Two doses were administered by the subcutaneous (SC) route three (3) weeks apart
<b>Study Animals</b>	Nineteen (19) 6-week-old puppies seronegative for CPI were randomly sorted into one group of 13 SC vaccinates and one group of 6 controls.
<b>Challenge Description</b>	21 days after second vaccination all dogs were challenged with CPI
<b>Interval observed after challenge</b>	Puppies were observed for 21 days after challenge for clinical signs. Blood and nasal swabs were collected during this period.
<b>Results</b>	<p>The study was considered satisfactory based on the serologic response in vaccinates and the decrease in the number of days of virus shedding in vaccinates when compared to controls.</p> <p>See the next page for data.</p>
<b>USDA Approval Date</b>	March 16, 1998

**CPI Serum Neutralization  
Antibody Titers**

<b>Controls</b>										
Dog	0DPV1	14DPV1	0DPV2	7DPV2	14DPV2 (w)	14DPV2	21DPV2	7DPC	14DPC	21DPC
1	<2	<2	<2	<2	<2	<2	<2	2	28	65
2	<2	<2	<2	<2	<2	<2	<2	1	99	182
3	<2	<2	<2	<2	<2	<2	<2	1	81	280
4	<2	<2	2	<2	<2	<2	<2	3	46	221
5	<2	<2	<2	<2	<2	<2	<2	2	71	289
6	<2	<2	<2	<2	<2	<2	<2	4	64	182

<b>SQ Vaccinates</b>										
Dog	0DPV1	14DPV1	0DPV2	7DPV2	14DPV2 (w)	14DPV2	21DPV2	7DPC	14DPC	21DPC
20	<2	<2	<2	<2	10	36	42	1248	7281	6295
21	<2	<2	<2	<2	3	16	6	2892	5880	4742
22	<2	<2	<2	<2	<2	18	6	1446	7037	3622
23	<2	<2	<2	<2	4	46	10	1152	10809	4581
24	<2	<2	<2	<2	<2	3	3	1579	4562	4096
25	<2	<2	<2	<2	<2	<2	<2	811	2884	10139
26	<2	<2	<2	<2	<2	<2	<2	227	793	661
27	<2	<2	<2	<2	<2	27	12	789	7079	5754
28	<2	<2	<2	<2	<2	<2	4	878	2253	2655
29	<2	<2	<2	<2	<2	16	5	1330	9462	7228
30	<2	<2	<2	<2	<2	3	3	373	1151	724
31	<2	<2	<2	<2	<2	<2	<2	2048	2281	2586
32	<2	<2	<2	2.2	<2	<2	3	1833	1193	880

DPV - Days Post Vaccination

DPC - Days Post Challenge

A titer of <2 is considered seronegative



### CPI Virus Isolation from Nasal Swabs

Controls															
Dog	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-
2	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-
3	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
4	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
5	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
6	-	+	+	+	+	+	+	+	+	-	-	-	-	-	-

SC Vaccinates															
Dog	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
20	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
21	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
22	-	+	+	+	+	+	-		+	-	-	-	-	-	-
23	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
24	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
25	-	+	+	+	+	+	-	-	+	-	-	-	-	-	-
26	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
27	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
28	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
29	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
30	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
31	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-
32	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-

- means CPI virus was not detected

+ means CPI virus was detected

<b>Study Type</b>	Efficacy											
<b>Pertaining to</b>	Canine Distemper Virus (CDV)											
<b>Study Purpose</b>	To demonstrate effectiveness against CDV											
<b>Product Administration</b>	Two doses were administered subcutaneously 21 days apart											
<b>Study Animals</b>	Seventeen (17) 6-week-old puppies seronegative for CDV were randomly sorted into 1 group of 11 SC vaccinates and one group of 6 controls.											
<b>Challenge Description</b>	21 days after second vaccination all dogs were challenged with CDV.											
<b>Interval observed after challenge</b>	Dogs were observed for 42 days after challenge for clinical signs of CDV.											
<b>Results</b>	<div>The study was satisfactory per the criteria in 9 CFR 113.306 (b)(3) (i-ii)</div> <table><thead><tr><th></th><th>Mortality</th><th>Clinical Signs of CDV Infection</th></tr></thead><tbody><tr><td>SC Vaccinates</td><td>0/11 (0%)</td><td>0/11 (0%)</td></tr><tr><td>Controls</td><td>5/6 (83%)</td><td>6/6 (100%)</td></tr></tbody></table> <div>See the next page for data.</div>				Mortality	Clinical Signs of CDV Infection	SC Vaccinates	0/11 (0%)	0/11 (0%)	Controls	5/6 (83%)	6/6 (100%)
	Mortality	Clinical Signs of CDV Infection										
SC Vaccinates	0/11 (0%)	0/11 (0%)										
Controls	5/6 (83%)	6/6 (100%)										
<b>USDA Approval Date</b>	April 6, 1998											

## CDV Clinical Signs Observed Post Challenge - Control Dogs

Dog	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
1			10,12,18	10,12,18	10,11,12	10	2,12	10,12,16,17,Euth	20	20	20
2				2,10,12	10	2,10,12	1,2,10,12	14	8,10,12,14,16,17,18, Euth	20	20
3				2,10,12		10,12	12	14	8,10,11,14	1,8,10,11,12	2,8,10,12
4				2,10,12		2,10,12	10	10,12	1,2,8,10,12	2,8,17	20
5							10,12		10,11	2,10,12	10,12
6					2,12	2,10,12	2,10,12	11,12	12,2	2,10,12	2,8,10,12

  

Dog	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC-26DPC	27DPC	28-29DPC	30DPC	31-42DPC
1	20	20	20	20	20	20	20	20	20	20
2	20	20	20	20	20	20	20	20	20	20
3	8,10,12	1,8,10	8,10,11	1,8,9,10,12	20	20	20	20	20	20
4	20	20	20	20	20	20	20	20	20	20
5	8,10,12,14		2,11		11,12		10,12		10,12	
6	1,2,8,10,12	1,2,8,12	20	20	20	20	20	20	20	20

  

	1 - Depression/lethargy	14 - Vomiting	Intermittent minor stool abnormalities observed were not considered clinical signs of CDV infection.
2- Mild/Mod. Ocular Discharge Mucoïd	16 - Excessive Salivation		
8 - Dehydration	17 - Chewing gum fits		
10-Mucous stool	18 - neuromuscular Tics		
11-watery Stool	20 - death		
12-Bloody stool	Blank - No Clinical signs observed		

DPC – Days Post Challenge

# CDV Clinical Signs Observed Post Challenge - Vaccinated Dogs

SC Vaccinates																							
Dog	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC	17DPC	18DPC	19DPC	20DPC	21DPC	
18																						10,12	
19																		14					
20																				10			
21																							
22																							
23					10																		
24																							
25																							
26																					12		
27																		10,12	11,12	11,12	12	12	
28																		10,12		10,12			
	1 - Depression/Lethargy										14 - Vomiting										Intermittent minor stool abnormalities observed		
	2- Mild/Mod. Ocular Discharge Muroid										16 - Excessive Salivation										were not considered clinical signs of CDV		
	8 - Dehydration										17 - Chewing gum fits										infection.		
	10-Mucous stool										18 - neuromuscular Tics												
	11-watery Stool										20 - death												
	12-Bloody stool										Blank - No Clinical signs observed												

DPC – Days Post Challenge

## CDV Clinical Signs Observed Post Challenge - Vaccinated Dogs

Dog	22DPC	23DPC	24DPC	25DPC	26DPC	27DPC	28DPC	29DPC	30DPC	31DPC	32DPC	33DPC	34DPC	35DPC	36DPC	37DPC	38DPC	39DPC	40DPC	41DPC	42DPC
18	11																				
19																					
20																					
21																					
22				10,12													14				
23	10				10	10	10		12												
24																					
25																					
26						10		10	10												
27	11,12		10,12		10,12	10,11,12	12														
28	11	10,12	10,12					10,12				12	12	12	12	12			12		
1 - Depression/Lethargy								14 - Vomiting								Intermittent minor stool abnormalities observed were not considered clinical signs of CDV infection.					
2- Mild/Mod. Ocular Discharge Muroid								16 - Excessive Salivation													
8 - Dehydration								17 - Chewing gum fits													
10-Mucous stool								18 - neuromuscular Tics													
11-watery Stool								20 - death													
12-Bloody stool								Blank - No Clinical signs observed													

DPC – Days Post Challenge

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Canine Parvovirus (CPV)
<b>Study Purpose</b>	To demonstrate effectiveness against CPV in 6-week-old puppies.
<b>Product Administration</b>	Two doses, given at an interval of 21 days, were administered subcutaneously (SC).
<b>Study Animals</b>	Study analysis was conducted on twenty-one (21) 6-week-old puppies seronegative for CPV, 17 vaccinates and 4 non-vaccinated controls.
<b>Challenge Description</b>	Twenty-one (21) days after second vaccination puppies were challenged with CPV 2b strain.
<b>Interval observed after challenge</b>	Puppies were observed daily for 14 days after challenge
<b>Results</b>	<p>The data were analyzed according to 9 CFR 113.317.</p> <p>Number affected by challenge according to 9 CFR 113.317:</p> <p>Vaccinates: 0/17 (0%)</p> <p>Controls: 2/4 (50%)</p> <p>See the next page for data.</p>
<b>USDA Approval Date</b>	August 31, 2001

CPV Post Challenge Daily Observations

Dog ID	Non-Vaccinated Controls													
	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	14DPC
1		D					E,H							
2							B,C,H	C	C					
3					H	D	B,G,H	I						
4						G,H	B,C,D,F,G,H	I						

Dog ID	Vaccinates													
	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	14DPC
1														
2														
3	D						H				E			
4														
5											D			
6														
7										E				
8														
9														
10										D				
11		D				D								
12														
13			D											
14														
15														
16														
17														

B - Lethargy      E - Watery Stool      H - Vomiting      DPC = Days Post Challenge  
 C - Dehydration      F - Bloody Stool      I - Death  
 D - Mucous Stool      G - Anorexia

# Daily Rectal Temperature (°F)

Non-Vaccinated Controls														
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	14DPC
1	100.4	101.3	101.3	101.1	102.1	101.9	100.7	101.3	101.3	101.0	100.8	101.4	100.6	101.2
2	99.7	101.2	101.7	100.9	103.0	102.6	99.3	101.0	101.0	101.0	101.5	101.6	101.3	102.0
3	101.2	101.6	102.5	101.3	104.5	101.3	100.0	Na	Na	Na	Na	Na	Na	Na
4	100.4	101.2	101.4	101.2	104.1	101.7	93.4	Na	Na	Na	Na	Na	Na	Na

## Vaccinates

Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
5	101.1	101.9	101.2	101.3	101.7	101.5	101.0	101.0	101.5	101.7	101.1	101.8	101.7	101.3	101.8
6	101.1	100.5	101.5	101.3	101.1	101.5	101.5	101.3	101.7	101.6	101.4	101.7	101.7	101.3	102.1
7	101.0	100.5	101.0	100.8	101.3	101.1	100.6	100.5	101.4	101.2	100.9	101.0	101.3	101.4	100.8
8	100.7	100.9	101.4	101.7	101.4	101.1	101.3	101.3	101.7	101.4	101.3	101.4	101.2	100.9	102.3
9	101.0	101.0	101.4	101.5	101.2	101.0	101.3	101.1	101.3	101.5	101.6	101.7	101.5	101.3	101.8
10	101.3	101.9	102.1	101.5	102.0	101.6	101.1	101.4	101.5	101.8	102.3	102.4	102.5	102.7	102.0
11	100.5	100.8	101.0	101.2	100.9	100.8	100.8	101.2	101.3	101.0	101.2	101.0	101.3	101.1	101.6
12	99.7	100.7	101.5	101.1	101.1	101.3	100.9	101.0	101.1	101.1	101.1	101.3	101.0	101.3	101.2
13	100.5	101.6	102.1	101.0	101.2	101.0	101.1	100.9	101.5	101.3	101.7	102.3	101.4	101.8	102.1
14	101.3	100.8	101.6	101.4	101.2	101.2	100.6	100.9	101.1	101.1	101.1	101.2	101.1	101.0	101.6
15	101.3	101.5	102.2	101.8	102.1	102.2	101.8	101.5	102.3	102.3	101.7	102.5	101.9	102.1	102.2
16	100.9	102.2	101.4	101.5	101.4	101.8	101.3	101.5	101.0	101.2	101.3	101.6	101.4	101.8	101.9
17	99.9	100.4	101.8	101.3	101.0	101.5	100.3	101.7	101.1	101.3	101.1	101.1	101.2	101.1	101.3
18	99.7	101.1	101.0	101.4	101.0	101.4	101.5	100.7	100.7	100.4	101.4	100.8	101.0	100.5	101.7
19	100.7	101.2	101.1	101.0	101.6	101.4	100.8	100.7	101.4	101.8	101.2	101.4	101.3	101.7	102.3
20	100.9	102.1	101.9	101.7	101.8	102.5	100.9	101.3	101.6	101.9	101.7	101.3	101.4	101.8	102.3
21	101.8	101.6	102.0	102.1	101.2	101.9	100.8	101.3	101.7	101.4	101.6	101.2	101.4	101.2	101.7

DPC = Days Post Challenge



# Total White Blood Cell Counts (x1000/uL)

Non-Vaccinated Controls										
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	10DPC
1	12.3	10.7	13.2	11.5	11.2	13.9	8.2	9.0	9.7	10.3
2	9.9	12.3	14.4	11.7	17.0	12.7	13.0	7.5	10.0	12.9
3	20.6	18.0	23.0	Na	30.2	15.6	13.7	Na	Na	Na
4	14.7	18.4	17.4	17.4	19.9	6.3	0.3	Na	Na	Na

Vaccinates										
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	10DPC
5	10.2	11.8	11.8	8.4	10.3	12.7	9.18	9.1	9.8	10.7
6	11.0	10.2	12.7	11.0	9.3	10.1	9.61	9.8	10.3	10.0
7	13.5	9.0	9.3	9.1	9.4	10.2	8.73	8.9	10.9	8.4
8	11.9	10.4	10.2	10.0	9.0	9.3	8.40	8.6	8.2	9.7
9	12.5	12.8	12.8	10.3	9.7	9.3	8.17	8.1	8.2	7.3
10	12.7	13.7	15.1	12.3	9.9	10.0	8.00	10.2	20.3	9.9
11	11.3	11.7	9.8	Na	9.4	8.8	7.71	10.7	18.9	14.9
12	27.2	18.5	21.8	15.3	13.9	10.4	10.70	12.1	11.2	10.1
13	7.8	17.6	16.1	15.1	11.0	11.2	11.80	11.5	14.1	9.5
14	20.4	21.6	17.6	Na	20.4	14.0	17.10	14.1	11.4	10.3
15	16.7	17.6	14.5	12.6	10.6	10.9	11.0	10.4	10.3	23.2
16	21.6	18.5	16.0	16.0	16.0	14.7	12.6	15.4	12.0	13.1
17	13.6	10.8	9.1	Na	9.3	12.7	7.8	9.9	11.0	8.5
18	12.4	14.8	11.0	14.6	14.7	14.9	11.8	9.4	9.4	8.8
19	37.0	28.2	27.7	20.0	21.9	28.6	17.2	20.3	16.3	16.2
20	19.0	21.3	18.7	17.4	18.9	28.2	14.1	19.6	18.3	16.2
21	16.7	11.6	14.3	15.9	12.8	14.4	12.9	14.5	10.1	14.3

DPC = Days Post Challenge

CPV Titer From Fecal Material (Log FAID <sub>50</sub> /mg Feces)											
Non-Vaccinated Controls											
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
1	<1.5	<1.5	<1.5	<1.5	2.4	4.2	5.8	5.5	5.2	2.0	1.5
2	<1.5	<1.5	<1.5	<1.5	1.5	3.8	5.6	5.4	4.5	3.5	3.4
3	<1.5	<1.5	<1.5	<1.5	3.2	5.5	NS	NS	NS	NS	NS
4	<1.5	<1.5	<1.5	<1.5	3.5	NS	6.2	NS	NS	NS	NS

Vaccinates											
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
5	<1.5	<1.5	<1.5	<1.5	<1.5	NS	<1.5	<1.5	<1.5	<1.5	<1.5
6	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
7	<1.5	<1.5	<1.5	<1.5	<1.5	NS	<1.5	<1.5	<1.5	<1.5	<1.5
8	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
9	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
10	<1.5	<1.5	<1.5	<1.5	<1.5	NS	<1.5	<1.5	<1.5	<1.5	<1.5
11	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
12	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
13	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
14	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
15	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
16	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
17	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
18	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
19	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5
20	<1.5	<1.5	<1.5	<1.5	<1.5	NS	<1.5	<1.5	<1.5	<1.5	<1.5
21	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5

<1.5 is considered negative

NS = No sample

DPC = Days Post Challenge

C

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Canine Parvovirus (CPV)
<b>Study Purpose</b>	To demonstrate effectiveness against CPV
<b>Product Administration</b>	Two doses given at an interval of 28 days were administered subcutaneously (SC).
<b>Study Animals</b>	Twenty-five (25) 6-week-old puppies seropositive for parvovirus; 20 vaccinates and 5 non-vaccinated controls.
<b>Challenge Description</b>	Fifty-six days (56) after second vaccination puppies were challenged with CPV type 2c strain.
<b>Interval observed after challenge</b>	Puppies were observed for clinical signs daily for 14 days after challenge
<b>Results</b>	<p>Dogs were determined affected by the criteria of 9 CFR 113.317(c)(3)(i).</p> <p>Number affected:</p> <p>Vaccinates: 1/20 (5%) Controls: 4/5 (80%)</p> <p>See the next page for data.</p>
<b>USDA Approval Date</b>	January 31, 2012

### CPV Post challenge Clinical Observations

Non-Vaccinated Controls															
DogID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
9						1,2,3	1,2,3	1,2,3	2,3,4	Na	Na	Na	Na	Na	Na
11						1,2,3	1,2,3	1,2,3	2,3						
19							1	1	1						
21								2,3	1,3						
27															

Vaccinates															
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1														1,3	
2															
3											1				
4	1														
5															
6															
7															
8	1														
10															
13															
14															
15														1	
16															1
17									1	2					
18															
20															
22															
23	1														
24															
28															

1 - Mucous Stool  
 2-Diarrhea (Watery stool)  
 3-Bloody Stool  
 4 -Death  
 Blank - No clinical signs observed

DPC – Days post challenge

Serum Neutralization Titer								
Non-Vaccinated Controls								
Dog ID	-24DPV1	0DPV1	7PV1	28DPV1 (0DPV2)	41DPV1	56DPV1	70DPV1	84DPV1 (0DPC)
9	724	8	4	<2	<2	<2	<2	<2
11	91	4	3	<2	<2	<2	<2	<2
19	23	64	23	<2	<2	<2	<2	<2
21	<2	11	10	<2	<2	<2	<2	<2
27	10	8	6	<2	<2	<2	<2	<2

  

Vaccinates								
Dog ID	-24DPV1	0DPV1	7PV1	28DPV1 (0DPV2)	41DPV1	56DPV1	70DPV1	84DPV1 (0DPC)
1	91	32	8	<2	1024	11585	11585	=>23170
2	64	32	23	<2	362	6871	16384	16384
3	54	45	23	2	1024	5793	5793	6871
4	153	64	23	<2	724	19534	23170	=>46341
5	2048	45	16	<2	45	4096	8192	23170
6	1024	23	23	<2	<2	512	2896	9767
7	1448	6	4	<2	1024	8192	8192	=>23170
8	512	32	8	<2	<2	2896	11585	=>46341
10	128	45	64	2	<2	11585	11585	11585
13	181	6	6	<2	45	2048	5793	8192
14	32	8	16	2	<2	2896	4884	11585
15	23	6	2	<2	512	11585	11585	16384
16	8	11	11	2	<2	9767	11585	23170
17	32	32	23	5	<2	11585	8192	16384
18	16	23	19	<2	512	23170	11585	11585
20	45	11	4	<2	724	8192	16384	11585
22	<2	11	8	<2	4	8192	11585	8192
23	2	8	11	<2	1448	NO TEST	16384	11585
24	4	11	4	<2	1024	16384	23170	16384
28	128	32	16	<2	1448	4096	11585	9767

  

DPV1 - Days post first Vaccination

DPV2 - Days Post Second Vaccination

0DCP - Days post challenge

### Lymphocyte Counts Post Challenge (x10<sup>3</sup>/μl)

Controls											
Cat ID	-2DPC	-1DPC	0DPC	Average	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	10DPC
9	1.24	1.20	1.38	1.27	1.71	1.45	0.80	0.30	0.28	0.74	Na
11	2.24	2.59	2.07	2.30	2.28	2.36	1.82	0.29	0.58	0.69	1.27
19	1.57	2.14	1.87	1.86	2.32	2.26	2.42	1.42	0.70	1.59	2.11
21	1.67	2.19	2.52	2.13	2.68	1.92	2.31	1.17	0.67	1.75	2.09
27	2.68	2.26	2.30	2.41	2.29	2.37	2.25	0.92	1.00	1.09	2.08

Vaccinates											
Cat ID	-2DPC	-1DPC	0DPC	Average	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	10DPC
1	3.05	3.06	2.74	2.95	2.05	2.25	2.42	2.39	2.66	3.31	2.64
2	2.45	2.50	2.34	2.43	3.32	3.05	3.27	3.03	2.73	3.20	3.28
3	2.09	2.40	2.34	2.28	2.42	2.46	2.32	1.65	1.73	2.38	2.52
4	1.10	1.59	2.46	1.72	3.23	2.45	2.91	2.03	2.75	2.34	2.87
5	0.62	0.96	1.16	0.91	1.23	1.32	1.14	1.26	1.19	1.57	1.09
6	1.43	1.84	1.73	1.67	1.84	1.55	1.16	1.79	1.62	2.44	2.32
7	1.23	1.22	1.18	1.21	1.18	1.51	1.53	1.68	1.52	1.81	1.67
8	2.07	1.89	2.00	1.99	1.81	1.93	1.78	1.52	1.64	2.52	2.51
10	2.74	2.80	3.27	2.94	1.93	2.43	2.56	3.01	2.65	2.44	2.83
13	1.26	2.25	2.24	1.92	2.43	1.88	2.57	2.39	2.57	3.09	3.17
14	2.17	2.24	3.02	2.48	3.57	3.62	3.76	3.28	3.07	3.66	4.18
15	2.21	2.30	2.66	2.39	3.10	2.81	3.04	2.85	2.98	3.29	0.93
16	1.68	2.54	2.06	2.09	2.56	2.08	3.35	2.83	2.35	3.13	2.27
17	2.25	2.14	2.11	2.17	2.42	2.84	2.62	2.93	2.69	3.04	1.34
18	2.06	2.82	2.50	2.46	2.97	2.48	2.62	3.05	3.04	3.98	2.59
20	1.83	2.11	2.05	2.00	2.58	2.22	2.39	2.50	1.73	1.98	3.27
22	3.80	3.05	3.35	3.40	3.96	3.18	3.38	3.75	2.36	2.42	2.28
23	0.84	1.46	1.51	1.27	1.63	1.35	1.47	1.45	1.29	1.72	3.93
24	0.97	2.04	2.32	1.78	2.09	2.24	2.67	2.03	2.03	2.70	1.53
28	2.43	2.68	2.15	2.42	2.68	2.89	3.56	3.56	2.52	2.46	2.46
											3.57
											3.61
											3.50
											0.92

DPC – Days post challenge

# **Body Temperature Post Challenge °F**

Non-Vaccinated Controls										
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	10DPC
9	102.0	102.0	102.6	102.9	103.2	104.6	103.2	100.9	Na	Na
11	102.6	102.9	102.6	102.6	103.1	103.4	102.8	102.2	101.3	101.5
19	102.5	102.8	102.1	102.3	101.9	103.8	102.3	102.4	101.6	102.1
21	102.2	102.3	101.3	101.4	102.0	103.4	102.0	101.8	101.5	101.4
27	102.2	102.1	102.1	102.7	102.5	102.8	103.0	102.4	100.9	101.6

Vaccinates										
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	10DPC
1	101.9	102.0	101.9	101.9	101.7	102.0	101.5	101.9	101.3	101.6
2	102.7	103.5	103.1	103.1	103.5	102.3	103.1	102.9	102.4	102.6
3	103.0	103.0	102.5	102.2	102.7	102.7	103.1	103.0	102.1	102.5
4	101.6	102.4	102.3	102.1	102.4	102.1	103.4	102.7	102.1	102.1
5	103.5	103.4	103.2	103.3	103.5	102.6	102.8	103.4	102.8	103.1
6	102.7	102.6	101.7	102.8	102.4	102.4	102.8	102.7	102.2	102.4
7	101.7	102.5	102.5	103.3	103.0	103.1	103.1	103.1	102.9	102.6
8	102.7	102.9	102.5	102.4	102.6	102.2	102.2	102.5	101.7	101.2
10	103.1	103.3	102.3	102.8	103.0	102.5	102.2	102.7	102.8	101.9
13	103.0	102.5	102.8	102.2	103.2	102.6	102.7	103.0	102.4	102.9
14	102.3	102.8	102.4	102.4	102.7	102.4	102.6	102.4	102.0	101.9
15	102.5	102.7	102.3	102.0	102.8	102.2	102.4	102.4	101.9	102.2
16	101.7	102.5	102.8	101.9	102.5	102.1	102.1	101.9	101.5	101.1
17	101.9	102.8	102.3	102.6	102.7	102.1	102.0	101.9	102.0	102.1
18	102.2	102.5	102.1	101.5	102.3	102.6	102.0	102.0	101.9	101.8
20	102.2	101.9	101.9	102.0	102.2	101.8	101.8	101.9	101.6	101.4
22	102.7	102.9	102.4	101.8	102.8	102.5	102.5	102.8	102.0	102.0
23	102.5	102.8	102.7	102.7	103.2	102.4	102.7	103.1	102.1	102.4
24	103.3	103.1	102.6	102.2	102.5	102.4	102.2	102.2	102.1	101.8
28	102.2	102.1	102.0	102.4	102.2	102.2	102.0	102.0	101.8	101.5

DPC – Days post challenge

### Fecal Virus Isolation Titer Post Challenge

CatID	Controls									
	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	10DPC
9	≤1.5	≤1.5	≤1.5	≤1.5	≤2.5	6.6	7.6	5.2	≥9.2	Na
11	≤1.5	≤1.8	≤1.5	≤1.5	5.5	7.2	7.5	≥8.5	≥8.6	6.6
19	≤1.5	≤1.5	≤1.5	≤1.5	2.5	4.2	7.5	7.6	4.2	4
21	≤1.5	≤1.5	≤1.5	≤1.8	4.3	4.7	6.3	6.8	≤2.8	4.5
27	≤1.5	≤1.5	≤1.5	≤1.5	≤2.8	5.2	7.4	6.6	5.2	≤3.0

CatID	Vaccinates									
	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	10DPC
1	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
2	≤1.5	≤1.8	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
3	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
4	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
6	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
7	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
8	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
10	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
13	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
14	≤1.5	≤1.6	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
15	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
16	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
17	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
18	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
20	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
22	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
23	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
24	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5
28	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤2.5	≤1.5	≤2.5	≤1.5	≤1.5

Positive For CPV >1.5 log<sup>10</sup> FAID<sub>50</sub>/mL

DPC – Days post challenge



<b>Study Type</b>	Safety
<b>Pertaining to</b>	Canine Adenovirus Type-2 (CAV-2)
<b>Study Purpose</b>	Development of corneal opacity is not associated with the use of this product
<b>Product Administration</b>	
<b>Study Animals</b>	
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data are not available.

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All fractions
<b>Study Purpose</b>	Demonstrate safety of product under typical use conditions
<b>Product Administration</b>	Either one or two doses of vaccine 2-4 weeks apart by the subcutaneous route. A total of 1231 doses were administered.
<b>Study Animals</b>	A total of 621 dogs, 358 under 6 weeks of age and 263 greater than 6 weeks of age, privately owned and from commercial kennels were enrolled in the study.
<b>Challenge Description</b>	Not applicable
<b>Interval observed after challenge</b>	No challenge. Observed for 30 minutes after vaccination and then daily for 2 weeks after each vaccination.
<b>Results</b>	Results are summarized below.
<b>USDA Approval Date</b>	November 15, 2002

### Summary of Reactions:

	Puppies up to 6 weeks of age				Dogs > 6 Weeks of Age					
Reaction Type	<24hr	>24hrs	Total Reactions by dose	%	<24hr	>24hrs	Total Reactions by dose	%	Sum of Doses	Reaction Rate
None	NA	NA	696	97.21%	NA	NA	506	98.25%	1202	97.64%
Salivation	0	0	0	0.00%	1	0	1	0.19%	1	0.08%
Lethargy	3	6	9	1.26%	0	0	0	0.00%	9	0.73%
Anorexia	3	10	13	1.82%	0	0	0	0.00%	13	1.06%
Injection Site Swelling	0	4	4	0.56%	0	1	1	0.19%	5	0.41%
Injection Site Pain	3	0	3	0.42%	5	0	5	0.97%	8	0.65%
Facial Swelling	0	0	0	0.00%	1	0	1	0.19%	1	0.08%
Vomiting or Diarrhea	3	0	3	0.42%	1	0	1	0.19%	4	0.32%
Mortality*	0	0	0	0.00%	2	0	2	0.39%	2	0.16%
<b>Total Doses</b>	<b>716</b>				<b>515</b>				<b>1231</b>	

\*Confirmed by cooperator to be due to causes other than vaccination.

Some dogs had more than one adverse event, so total events do not agree with doses administered.