



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	46D9.20
True Name	Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Borrelia Burgdorferi Bacterin-Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Duramune Lyme + Max 5-4L - Elanco US Inc. Duramune Max 5 - Elanco US Inc.
Date of Compilation Summary	December 20, 2019

**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 one 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>	<p>The study was satisfactory per the criteria in 9 CFR 113.305 (1)(ii) (A)(B)</p> <table border="1" data-bbox="582 920 1227 1115"> <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>6/6 (100%)</td> <td>6/6 (100%)</td> </tr> </tbody> </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									

<b>Canine Infectious Hepatitis Clinical Signs Observed Post Challenge</b>																			
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 Ocular Discharge				17 - Icteric Gums								* Icteric Lumbar only
	4 - Mild/Moderate Conjunctivitis										20 - Petechial Pain / Ecchymotic								** Icteric lumbar and ears
	5 - Severe Conjunctivitis						13 - Vomiting												***- 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>Raw Data: Data tables are appended to the end of this summary</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	2											
3	Control						1	1,2	1	1	1	1											
4	Control						1,2	1,2	1,2,4	1,2,	2	2											
5	Control						1	1	1,4	1	1	1											
6	Control					2		4			1	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				
9	Control						1	1	1	4	4	4											
10	Control					1	1	1	1	1	1,2			1									
11	Control					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	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															

**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															
2	Control				2	2.83	3.5	3.83	2.17								≤1.83							
3	Control				≤1.63	3.5	4.17	3.38								2.17								
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																
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				
23	SC																							
24	SC		≤1.6				2.38																	
25	SC					≤1.63																		
26	SC								2.63															≤1.63
27	SC												≤1.63											
28	SC																							
29	SC				2	≤1.83																		
30	SC																							
31	SC																							
32	SC						≤1.83	2.63	2.5															
33	SC																							
Blank - No CAV2 titer detected																								
DPC - Days Post Challenge																								

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Borrelia burgdorferi</i>
<b>Study Purpose</b>	To demonstrate effectiveness against <i>Borrelia burgdorferi</i> in dogs.
<b>Product Administration</b>	Two doses were administered subcutaneously (SC) 3 weeks apart.
<b>Study Animals</b>	<p>Study I: Eighteen (18) 8-14 week old puppies serologically negative for <i>B. burgdorferi</i> were used in the final study analysis. Animals were randomized into one group of 8 SC vaccinates and one group of 10 controls.</p> <p>Study II: Thirty (30) 8 week old puppies serologically negative for <i>B. burgdorferi</i> were used in the final study analysis. Animals were randomized into one group of 20 SC vaccinates and one group of 10 controls.</p>
<b>Challenge Description</b>	<p>Study I: Four weeks after second vaccination all animals were challenged with <i>Borrelia burgdorferi</i>.</p> <p>Study II: Three weeks after second vaccination all animals were challenged with <i>Borrelia burgdorferi</i>.</p>
<b>Interval observed after challenge</b>	<p>Study I: Dogs were observed daily for 90 days after challenge for clinical signs associated with <i>B. burgdorferi</i>.</p> <p>Study II: Dogs were observed daily for 126 days after challenge for clinical signs associated with <i>B. burgdorferi</i>.</p>
<b>Results</b>	<p>Dogs were evaluated for clinical arthritis, and the detection of <i>B. burgdorferi</i> in blood, fluids, and tissues. Clinical arthritis was defined as the number of discontinuous occurrence of limp and/or lameness for a specific limb. Blood, synovial fluid, lymph nodes, skin and urine samples were collected for <i>B. burgdorferi</i> isolation and/or detection.</p> <p>Data tables are appended to the end of this summary.</p>
<b>USDA Approval Date</b>	December 6, 1995

**Study I: Arthritic Signs Observed**

Dog	Treatment	Stiff	Lame	Limping
16	SC Vaccinate		87	
17	SC Vaccinate			
18	SC Vaccinate			
19	SC Vaccinate			
20	SC Vaccinate	78		
21	SC Vaccinate			
22	SC Vaccinate			
23	SC Vaccinate			

Dog	Treatment	Stiff	Lame	Limping
24	Control	59, 61, 87		86
25	Control	52, 62, 64, 65, 70, 71, 72, 73, 74, 75, 87	61, 77, 78	79, 80, 85
26	Control	74, 75	78, 79	80
27	Control	63, 64, 87		
28	Control	49		
29	Control	54, 58, 64, 76		
30	Control	59, 78, 80		65, 69, 70, 71, 72, 73, 75, 76, 77, 79, 87
31	Control	41, 52, 57, 59, 60, 61		58, 75, 90
32	Control	50, 55, 56, 58, 62, 70, 76	58, 59, 60, 61, 69, 73, 75, 77, 78, 85	52, 54, 56, 57, 58, 59, 60, 62, 65, 66, 68, 70, 71, 72, 74, 79, 80, 84, 86, 87, 90
33	Control	38, 41, 42, 43, 45, 50, 63, 65, 66, 69, 71, 84	54, 58, 59, 60, 61, 62, 72, 73, 76, 77, 79	38, 41, 49, 52, 53, 55, 56, 57, 65, 66, 68, 69, 70, 74, 75, 78, 80, 86, 87, 90

Number - represents the day post challenge the clinical sign was observed

Blank - No signs observed

Clinical arthritis was defined as the number of discontinuous occurrence of limp and/or lameness for a specific limb



**Study I: Detection of B Burgdorferi (Blood)**

Dog	Treatment	9DPC	13DPC	20DPC	24DPC	31DPC	34DPC	35DPC	38DPC
16	SC Vaccinate								
17	SC Vaccinate								
18	SC Vaccinate								
19	SC Vaccinate								
20	SC Vaccinate								
21	SC Vaccinate								
22	SC Vaccinate								
23	SC Vaccinate								

Dog	Treatment	9DPC	13DPC	20DPC	24DPC	31DPC	34DPC	35DPC	38DPC
24	Control							+	
25	Control								
26	Control								
27	Control								
28	Control	+		+		+			+
29	Control					+			
30	Control								
31	Control				+		+		
32	Control		+						
33	Control						+		

\*Samples were collected periodically from -1DPC through 90DPC, only dates with positive detection are listed. DPC is day post challenge.

"+" - Positive for Borrelia Detection

Blank - Negative for Borrelia Detection

**Study I: Detection of B Burgdorferi (Tissues and Fluid) at 90DPC**

<b>Dog</b>	<b>Treatment</b>	<b>Lymph Nodes</b>	<b>Synovial Fluid</b>	<b>Skin</b>	<b>Urine</b>
16	SC Vaccinate				
17	SC Vaccinate		+		
18	SC Vaccinate				
19	SC Vaccinate		+		
20	SC Vaccinate	+			
21	SC Vaccinate	+			
22	SC Vaccinate				
23	SC Vaccinate				

<b>Dog</b>	<b>Treatment</b>	<b>Lymph Nodes</b>	<b>Synovial Fluid</b>	<b>Skin</b>	<b>Urine</b>
24	Control			+	
25	Control		+	+	
26	Control	+		+	no sample
27	Control		+		
28	Control		+		+
29	Control		+	+	
30	Control	+			+
31	Control		+	+	+
32	Control		+		
33	Control			+	

DPC is day post challenge

"+" - Positive for Borrelia Detection

Blank - Negative for Borrelia Detection

**Study II: Arthritic Signs Observed**

<b>Dog</b>	<b>Treatment</b>	<b>Stiff</b>	<b>Lame</b>	<b>Limping</b>
1	SC Vaccinate			
2	SC Vaccinate			
3	SC Vaccinate	54, 77, 95		
4	SC Vaccinate			
5	SC Vaccinate	41, 55, 56, 58, 112		
6	SC Vaccinate			
7	SC Vaccinate	104		
8	SC Vaccinate			
9	SC Vaccinate			
10	SC Vaccinate			
11	SC Vaccinate	95, 100		28, 98, 99
12	SC Vaccinate		41	
13	SC Vaccinate	98		
14	SC Vaccinate	90		
15	SC Vaccinate	80		84
16	SC Vaccinate	42		76
17	SC Vaccinate			
18	SC Vaccinate			
19	SC Vaccinate	120		
20	SC Vaccinate	44, 45, 57	41, 52, 54	77, 79, 91, 95, 104

<b>Dog</b>	<b>Treatment</b>	<b>Stiff</b>	<b>Lame</b>	<b>Limping</b>
21	Control	30, 50, 53, 56, 58, 63, 95		78
22	Control			
23	Control	63, 65, 93, 94, 106		43, 55, 100
24	Control	65, 82		
25	Control	38, 62, 63, 75, 98, 99, 100, 103, 106		104
26	Control	56, 71, 78, 93, 99,	59, 60, 61, 72, 73, 74, 75, 80, 81, 82, 83, 89, 90, 103, 104, 105, 106, 107, 108, 120, 121, 122, 125, 126	76, 77, 84, 85, 98, 109, 110, 115
27	Control	51, 79, 103		
28	Control	57, 105	105, 125	124
29	Control			
30	Control	104	76, 77, 126	75, 78, 82, 90, 101

Number - represents the day post challenge the clinical sign was observed

Blank - No signs observed

Clinical arthritis was defined as the number of discontinuous occurrence of limp and/or lameness for a specific limb

**Study II: Detection of B Burgdorferi (Blood)**

Dog	Treatment	30DPC	34DPC	35DPC	36DPC	37DPC	41DPC	43DPC	44DPC	76DPC	103DPC
1	SC Vaccinate										
2	SC Vaccinate										
3	SC Vaccinate										
4	SC Vaccinate										
5	SC Vaccinate										
6	SC Vaccinate										
7	SC Vaccinate										
8	SC Vaccinate					+					
9	SC Vaccinate										
10	SC Vaccinate										
11	SC Vaccinate										
12	SC Vaccinate										
13	SC Vaccinate										
14	SC Vaccinate										
15	SC Vaccinate										
16	SC Vaccinate										
17	SC Vaccinate										
18	SC Vaccinate										
19	SC Vaccinate										
20	SC Vaccinate										

Dog	Treatment	30DPC	34DPC	35DPC	36DPC	37DPC	41DPC	43DPC	44DPC	76DPC	103DPC
21	Control									+	
22	Control										
23	Control										
24	Control		+	+	+	+	+		+		
25	Control	+	+								
26	Control					+	+	+			+
27	Control										
28	Control										
29	Control										
30	Control										

\*Samples were collected periodically from -1DPC through 126DPC, only dates with positive detection are listed. DPC is day post challenge.

"+" - Positive for Borrelia Detection

Blank - Negative for Borrelia Detection

**Study II: Detection of B Burgdorferi (Tissues and Fluid) at 126DPC**

Dog	Treatment	Lymph Nodes	Synovial Fluid	Skin	Urine
1	SC Vaccinate	+			
2	SC Vaccinate	+			
3	SC Vaccinate		+		+
4	SC Vaccinate	+			
5	SC Vaccinate	+			+
6	SC Vaccinate				
7	SC Vaccinate	+			
8	SC Vaccinate	+		+	
9	SC Vaccinate				
10	SC Vaccinate				
11	SC Vaccinate				+
12	SC Vaccinate		+		+
13	SC Vaccinate	+			
14	SC Vaccinate	+	+	+	
15	SC Vaccinate	+			+
16	SC Vaccinate		+		+
17	SC Vaccinate	+	+	+	
18	SC Vaccinate		+		
19	SC Vaccinate				
20	SC Vaccinate	+		+	

Dog	Treatment	Lymph Nodes	Synovial Fluid	Skin	Urine
21	Control	+	+		
22	Control	+	+	+	
23	Control		+		
24	Control		+	+	+
25	Control	+	+	+	+
26	Control	+	+	+	+
27	Control	+	+		
28	Control	+	+	+	+
29	Control	+	+	+	
30	Control	+			

DPC is day post challenge

"+" - Positive for Borrelia Detection

Blank - Negative for Borrelia Detection

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Borrelia burgdorferi</i>
<b>Study Purpose</b>	To demonstrate effectiveness against <i>Borrelia burgdorferi</i> for one year duration of immunity.
<b>Product Administration</b>	Two doses were administered subcutaneously (SC) 3 to 4 weeks apart.
<b>Study Animals</b>	Study I: Twenty-four (24) dogs serologically negative for <i>B. burgdorferi</i> were used in the final study analysis. Animals were randomized into one group of 12 SC vaccinates and one group of 12 controls. Study II: Sixteen (16) dogs serologically negative for <i>B. burgdorferi</i> were used in the study. Animals were randomized into one group of 5 SC vaccinates, and one group of 11 controls.
<b>Challenge Description</b>	One year after second vaccination all animals were challenged with <i>Borrelia burgdorferi</i> .
<b>Interval observed after challenge</b>	Dogs were observed for 5 months after challenge.
<b>Results</b>	Dogs were evaluated for <i>B. burgdorferi</i> disease. Clinical disease was evaluated by clinical arthritis, the isolation of <i>B. burgdorferi</i> in skin, and detection of <i>Borrelia</i> infection by antibody profile. Clinical arthritis was defined as the number of discontinuous occurrence of limp and/or lameness for a specific limb.  Results: Study I 10/12 (83%) - Controls positive for <i>B. burgdorferi</i> disease 2/12 (17%) - SC Vaccinates positive for <i>B. burgdorferi</i> disease Data tables are appended to the end of this summary. No animals (vaccinates or controls) were observed with clinical arthritis in this study.  Study II 10/11 (91%) - Controls positive for <i>B. burgdorferi</i> disease 1/5 (20%) - SC Vaccinates positive for <i>B. burgdorferi</i> disease Data tables are appended to the end of this summary. Only one control animal was observed with clinical arthritis in this study. Dog #13 (control) was observed to be lame on 134DPC. All other animals were negative for clinical arthritis.
<b>USDA Approval Date</b>	January 2, 1997

**Study I Isolation of *B. Burgdorferi* in Skin Samples**

Animal	Treatment Group	28DPC*	63DPC	91DPC	118DPC
1	SC Vaccinate	-	+	-	+
2	SC Vaccinate	-	-	-	+
3	SC Vaccinate	-	-	-	-
4	SC Vaccinate	-	-	-	-
5	SC Vaccinate	-	-	-	-
6	SC Vaccinate	-	-	-	-
7	SC Vaccinate	-	-	-	-
8	SC Vaccinate	-	-	-	-
9	SC Vaccinate	-	-	-	-
10	SC Vaccinate	-	-	-	-
11	SC Vaccinate	-	-	-	-
12	SC Vaccinate	-	-	-	-
13	Control	-	-	-	-
14	Control	-	-	+	+
15	Control	-	+	-	+
16	Control	-	-	-	+
17	Control	-	+	+	-
18	Control	-	-	+	-
19	Control	-	+	+	+
20	Control	-	+	+	+
21	Control	-	-	-	-
22	Control	-	+	+	-
23	Control	-	+	+	+
24	Control	+	+	+	-

"+" - Positive for Borrelia Detection

" - " - Negative for Borrelia Detection

DPC is day post challenge

**Study I Detection of Borrelia infection by serum antibody profile.**

Animal	Treatment Group	-1DPC	28DPC	63DPC	89DPC	118DPC	146DPC
1	SC Vaccinate	-	-	-	+	+	+
2	SC Vaccinate	-	-	+	+	+	+
3	SC Vaccinate	-	-	-	-	-	-
4	SC Vaccinate	-	-	-	-	-	-
5	SC Vaccinate	-	-	-	-	-	-
6	SC Vaccinate	-	-	-	-	-	-
7	SC Vaccinate	-	-	-	-	-	-
8	SC Vaccinate	-	-	-	-	-	-
9	SC Vaccinate	-	-	-	-	-	-
10	SC Vaccinate	-	-	-	-	-	-
11	SC Vaccinate	-	-	-	-	-	-
12	SC Vaccinate	-	-	-	-	-	-
13	Control	-	-	-	-	-	-
14	Control	-	-	+	+	+	+
15	Control	-	-	+	+	+	+
16	Control	-	-	-	-	+	+
17	Control	-	-	-	+	+	+
18	Control	-	-	+	+	+	+
19	Control	-	-	+	+	+	+
20	Control	-	-	+	+	+	+
21	Control	-	-	-	-	-	-
22	Control	-	-	+	+	+	+
23	Control	-	-	+	+	+	+
24	Control	-	-	+	+	+	+

"+" - Antibody positive for presence of *B. burgdorferi* infection  
 "- " - Antibody negative for presence of *B. burgdorferi* infection  
 DPC is day post challenge



**Study II Isolation of *B. burgdorferi* in Skin Samples**

Animal	Treatment Group	36DPC	63DPC	91DPC	118DPC	152DPC
1	SC Vaccinate	-	-	-	-	-
2	SC Vaccinate	-	-	-	-	-
3	SC Vaccinate	-	-	-	-	-
4	SC Vaccinate	-	-	-	+	-
5	SC Vaccinate	-	-	-	-	-
6	Control	-	-	+	+	-
7	Control	-	-	-	-	-
8	Control	+	-	+	+	-
9	Control	+	-	+	+	+
10	Control	+	+	-	+	-
11	Control	-	-	+	-	-
12	Control	+	-	+	-	-
13	Control	+	+	-	+	-
14	Control	+	-	+	+	+
15	Control	-	-	+	+	-
16	Control	+	-	+	-	-

"+" - Positive for Borrelia Detection

" - " - Negative for Borrelia Detection

DPC is day post challenge

**Study II Detection of Borrelia infection by serum antibody profile.**

Animal	Treatment Group	0DPC	34DPC	62DPC	90DPC	117DPC	152DPC
1	SC Vaccinate	-	-	-	-	-	-
2	SC Vaccinate	-	-	-	-	-	-
3	SC Vaccinate	-	-	-	-	-	-
4	SC Vaccinate	-	-	+	+	+	+
5	SC Vaccinate	-	-	-	-	-	-
6	Control	-	-	+	+	+	+
7	Control	-	-	-	-	-	-
8	Control	-	-	+	+	+	+
9	Control	-	-	-	+	+	+
10	Control	-	+	+	+	+	+
11	Control	-	-	+	+	+	+
12	Control	-	-	+	+	+	+
13	Control	-	-	+	+	+	+
14	Control	-	-	+	+	+	+
15	Control	-	-	-	+	+	+
16	Control	-	-	-	+	+	+

"+" - Antibody positive for presence of *B. burgdorferi* infection

" - " - Antibody negative for presence of *B. burgdorferi* infection

DPC is day 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 for <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>Data tables are appended to the end of this summary.</p>
<b>USDA Approval Date</b>	April 3, 1998

**Leptospira canicola 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	
12																							
13		A																				G	
14		A														A					B	BJ	
15		G	D				G				A					AG	G						
16		D	D	G																			
17					G																		
18		G			A										A	A		AG					
19																							
20		G		G	G	G		G		G													
21		G	A	AD	G	G	A											H					
22																							
		DPC = Day post-challenge																					
A-inappetance					G - Ocular Discharge	Mucoid																	
B-Vomiting					H - Nasal Discharge	Serous																	
C-Labored Breathing					I - Nasal Discharge	Mucoid																	
D - Depression/Lethagy					J - Diarrhea	Mild (loose stool)																	
E1 - Conjunctivitis Mild/Moderate					K - Diarrhea	Severe (bloody stool)																	
E2 - Conjunctivitis Severe					L - Bloody Urine																		
F- Ocular Discharge Serous					M - Icterus																		

**Leptospira canicola Clinical Signs Observed Post Challenge**

Dog	Controls																							
	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC	17DPC	18DPC	19DPC	20DPC	21DPC		
23					A,D,K,M,N4																			
24			D,G,N3		A,D,G,J	A,D,G	A,D,K	C,D,G,L,N4																
25			N2	B	G		A,K	A,G	A	D		A,D,N1	D	G										
26		A,G	D,G,N1	D,G,N1	G	D	A,D,J	A,G,K	A,D,K	A,D		G	D,G										B	
27			N1	A	A	A,N1	A,K	A,D,G								A		A,G						
28		A	GN2	A	A,G,L	A,D,G,K,L,M,N4	A,D,E2,M,N4																	
29			D,N2	J,K	A,B,D,G,L	D,G,K,L,N4	A,D,E1,K,L,M,N4																	
30		G	N2			G,K	A,D,G,K	G	G,K				G		G	G								
31	H		N2	G,K	B,D,X,L	D,G,K,L,N4																		
32			N1	G	G,L	D,X,L	A,D,G,K,L,M,N4																	
33	G	G	G,N2	A,G,N1	A,G	A,B,J	A,D,G,K,L	A,D,G,K,L	A,D,G,K,L	A,D,G,K,L	A,K	G	G			G,L		A,G	G					
34			A,N1	A,G,N2		G	A,D,G,K,L				A,K	G,K	G,K											
A-inappetance					G - Ocular Discharge	Mucoid																		
B-Vomiting					H - Nasal Discharge	Serous																		
C-Labored Breathing					I - Nasal Discharge	Mucoid																		
D - Depression/Lethargy					J - Diarrhea	Mild (loose stool)																		
E1 - Conjunctivitis Mild/Moderate					K - Diarrhea	Severe (bloody stool)																		
E2 - Conjunctivitis Severe					L - Bloody Urine																			
F - Ocular Discharge Serous					M - Icterus																			

DPC = Day post-challenge

**Leptospira canicola 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
12	22.1	25.8	15.1	17	20.3	19.3	20	20.7	16.5	19.4	19.3	10.7	17.2	19.6	16.6
13	12.3	12.4	9.3	9.6	10.5	9	8	12.5	11.8	10.4	8.8	12.7	10.2	9.7	9.1
14	21.7	19.8	12.3	12.9	14	15.5	13.6	17.4	19.2	19.3	16.9	15.3	14	23.2	15.7
15	13.3	8.8	9.6	12.7	8.2	11.5	12.2	13.1	11.8	8.5	8.5	13.1	9.2	10.2	9.4
16	14	13.2	9.5	7.6	8.4	10.1	10.2	9.4	11.4	9.7	11.3	9.3	10.1	10.8	10.5
17	14.3	16.1	12.8	11.8	12.2	10.7	13.2	12.5	9.8	7.3	8.8	9.5	10.3	9.9	12.3
18	11	11.4	10.6	10.1	10.2	9.4	11.7	9.7	9.3	9.3	9.1	11.6	11.7	17.2	17.6
19	8.9	8.4	8	9.1	8.4	6.6	7.2	7.5	6.4	8.2	7	8.8	7.3	12.3	13.4
20	11.2	15.8	10.7	9.1	7.6	8	9	9.2	10.5	11.4	7	13	9.3	7.6	12.7
21	11	10.5	9.5	15.1	14.6	14.1	13.9	13.4	20.7	14.9	11.7	16.5	13.2	14.7	21.7
22	10.2	15.6	9.4	12.1	9.5	12.7	11	7.3	8.3	11.7	7.7	10.2	9.2	11	11.5

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

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

Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	Controls																	
		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 Vaccinates

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**

Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	Controls														
		1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	
23	300	238	148	11	7.7	D	D	D	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	D	D	D
25	519.7	267	213	187	134	117	160	285	497	710	714	823	738	810	717	
26	404.7	278	279	196	150	172	194	ND	302	441	721	648	599	590	588	
27	482.7	281	225	119	55	49.9	100	157	405	455	492	552	528	428	435	
28	242.3	209	60.4	45.9	3.9	11.1	11.3	D	D	D	D	D	D	D	D	D
29	529.7	521	305	195	37.6	15.8	42.2	D	D	D	D	D	D	D	D	D
30	329.3	292	167	107	61.7	81.6	122	242	412	518	697	504	632	596	551	
31	432.7	327	150	80.2	38	14	D	D	D	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	D	D	D
33	563.7	409	182	115	67.1	8.5	2.4	11.4	87.1	235	417	744	701	726	714	
34	232.7	174	150	64.5	41.6	8.3	6.8	82.8	142	273	310	383	479	475	564	
ND= No Data																
D = dead																

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

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira grippotyphosa</i>
<b>Study Purpose</b>	To demonstrate effectiveness against <i>Leptospira grippotyphosa</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 were randomized into one group of 10 SC vaccinates and one group of 10 controls.
<b>Challenge Description</b>	Fifteen (15) days after second vaccination all animals were challenged with <i>Leptospira grippotyphosa</i> organisms.
<b>Interval observed after challenge</b>	Dogs were observed daily for 21 days after challenge
<b>Results</b>	<p>Efficacy was based on the reduction in spirochetemia in vaccinates when compared to controls.</p> <p>A data table is appended to the end of this summary.</p>
<b>USDA Approval Date</b>	January 12, 1999

### Isolation of Leptospira from Blood Collected from Dogs Post Challenge

Control Animals													
Dog	0DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
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

NA - Animal Dead or euthanized / no sample taken

+ - Positive for Leptospira

\*Leptospira was not isolated in any of the SC vaccinates

<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>Data tables are appended to the end of this summary.</p>
<b>USDA Approval Date</b>	March 31, 1998

**Leptospira Ictero Clinical Signs Observed Post Challenge**

Dog	SC Vaccinates																						
	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		A,E							E														
16																							
17																							
18																							
19																							
20			D	D		D	D							E									
A-inappetance																							
B-Vomiting																							
C-Depression/Lethargy																							
D-Ocular Discharge Serous																							
E-Ocular Discharge Mucoïd																							
F-Nasal Discharge Serous																							
G-Nasal Discharge Mucoïd																							
H-Diarrhea Mild (loose stool)																							
I-Diarrhea Moderate (Watery stool)																							
J-Diarrhea Severe (bloody stool)																							

DPC = Day post-challenge

**Leptospira Ictero Clinical Signs Observed Post Challenge**

		Controls																													
Dog	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC	17DPC	18DPC	19DPC	20DPC	21DPC									
21					F		A																								
22					F					B											E										
23			L	L								E			E	E	E	E													
24			L	L																											
25																															
26																															
27			L	D	D	E		J	A				E			D															
28			L,E	K	A,C,D,J						M																				
29			L			D																									
30				L,D	A,E						M																				
31			L	E			A					E					E														
32							E																								
	A-inappetance																														
	B-Vomiting																														
	C-Depression/Lethargy																														
	D-Ocular Discharge Serous																														
	E-Ocular Discharge Mucoid																														
	F - Nasal Discharge Serous																														
	G - Nasal Discharge Mucoid																														
	H- Diarrhea Mild (loose stool)																														
	I- Diarrhea Moderate (Watery stool)																														
	J- Diarrhea Severe (bloody stool)																														
	K - Bloody Urine																														
	L - Fever >103.0°F																														
	M - Death																														
	Blank - no clinical sign observed																														

DPC = Day post-challenge

**Leptospira ictero White Blood Cell Count 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	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**

Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	Controls													
		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**

Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	SC Vaccinates													
		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.

**Leptospira ictero Platelet Counts Post Challenge**

Controls															
Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
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										
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										
32	267	184	55	7.7	88.8	196	257	347	525	430	529	360	337	287	301
<b>D = Dead</b>															

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 for <i>Leptospira</i> were randomized into 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>A Data table is appended to the end of this summary.</p>
<b>USDA Approval Date</b>	January 12, 1999

**Isolation of Leptospira from Blood Collected from Dogs Post Challenge**

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

DPC= Day post challenge

\*Leptospira was not isolated from blood in any of the SC vaccinates

<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>Raw Data: Data tables are appended to the end of this summary</p>
<b>USDA Approval Date</b>	March 16, 1998

### CPI Serum Neutralization Antibody Titers

#### Control Animals

Dog	ODPV1	14DPV1	ODPV2	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

#### SC Vaccinates

Dog	ODPV1	14DPV1	ODPV2	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

<b>Controls</b>															
Do g	0DP C	1DP C	2DP C	3DP C	4DP C	5DP C	6DP C	7DP C	8DP C	9DP C	10DP C	11DP C	12DP C	13DP C	14DP C
1	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-
2	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-
3	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
4	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
5	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
6	-	+	+	+	+	+	+	+	+	-	-	-	-	-	-
<b>SC Vaccinates</b>															
Do g	0DP C	1DP C	2DP C	3DP C	4DP C	5DP C	6DP C	7DP C	8DP C	9DP C	10DP C	11DP C	12DP C	13DP C	14DP C
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>	Cannie 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 one 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>	<p>The study was satisfactory per the criteria in 9 CFR 113.306 (b)(3) (i-ii)</p> <table border="1" data-bbox="582 884 1228 1075"> <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> <p>Raw Data: Data tables are appended to the end of this summary</p>		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	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	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		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						
2- Mild/Mod. Ocular Discharge Mucoïd					16 - Excessive Salivation					Intermittent minor stool abnormalities observed were not considered clinical signs of CDV infection.	
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																			14				10,12	
19																								
20																			10					
21																								
22																								
23					10																			
24																								
25																								
26																								
27																		10,12	11,12	11,12	12	12	12	
28																		10,12	10,12					
	Intermittent minor stool abnormalities observed were not considered clinical signs of CDV infection.																							
	1 - Depression/Lethargy																							
	2 - Mild/Mod. Ocular Discharge																							
	8 - Dehydration																							
	10-Mucous stool																							
	11-watery Stool																							
	12-Bloody stool																							
		14 - Vomiting																						
		16 - Excessive Salivation																						
		17 - Chewing gum fits																						
		18 - neuromuscular Tics																						
		20 - death																						
		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 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 9CFR 113.317</p> <p>Number affected by challenge according to 9CFR 113.317:  Vaccinates: 0/17 (0%)  Controls: 2/4 (50%)</p> <p>Raw data:  Data table are appended to the end of this summary.</p>
<b>USDA Approval Date</b>	August 31, 2001

CPV Post Challenge Daily Observations

Non-Vaccinated Controls															
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	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							

Vaccinates															
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	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  
 C - Dehydration  
 D - Mucous Stool  
 E - Watery Stool  
 F - Bloody Stool  
 G - Anorexia  
 H - Vomiting  
 I - Death  
 DPC = Days Post Challenge

**Daily Rectal Temperature (°F)**

Non-Vaccinated Controls															
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	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	101.4	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	102.4	102.0
3	101.2	101.6	102.5	101.3	104.5	101.3	100.0	Na	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	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	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											
CatID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
1	12.3	10.7	13.2	11.5	11.2	13.9	8.2	9.0	9.7	10.5	10.3
2	9.9	12.3	14.4	11.7	17.0	12.7	13.0	7.5	10.0	9.0	12.9
3	20.6	18.0	23.0	Na	30.2	15.6	13.7	Na	Na	Na	Na
4	14.7	18.4	17.4	17.4	19.9	6.3	0.3	Na	Na	Na	Na

**Vaccinates**

CatID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
5	10.2	11.8	11.8	8.4	10.3	12.7	9.18	9.1	9.8	10.3	10.7
6	11.0	10.2	12.7	11.0	9.3	10.1	9.61	9.8	10.3	9.3	10.0
7	13.5	9.0	9.3	9.1	9.4	10.2	8.73	8.9	10.9	10.0	8.4
8	11.9	10.4	10.2	10.0	9.0	9.3	8.40	8.6	8.2	8.4	9.7
9	12.5	12.8	12.8	10.3	9.7	9.3	8.17	8.1	8.2	7.3	7.3
10	12.7	13.7	15.1	12.3	9.9	10.0	8.00	10.2	20.3	12.0	9.9
11	11.3	11.7	9.8	Na	9.4	8.8	7.71	10.7	18.9	8.8	14.9
12	27.2	18.5	21.8	15.3	13.9	10.4	10.70	12.1	11.2	10.8	10.1
13	7.8	17.6	16.1	15.1	11.0	11.2	11.80	11.5	14.1	13.9	9.5
14	20.4	21.6	17.6	Na	20.4	14.0	17.10	14.1	11.4	10.0	10.3
15	16.7	17.6	14.5	12.6	10.6	10.9	11.0	10.4	10.3	14.2	23.2
16	21.6	18.5	16.0	16.0	16.0	14.7	12.6	15.4	12.0	12.8	13.1
17	13.6	10.8	9.1	Na	9.3	12.7	7.8	9.9	11.0	14.4	8.5
18	12.4	14.8	11.0	14.6	14.7	14.9	11.8	9.4	9.4	10.0	8.8
19	37.0	28.2	27.7	20.0	21.9	28.6	17.2	20.3	16.3	17.7	16.2
20	19.0	21.3	18.7	17.4	18.9	28.2	14.1	19.6	18.3	19.6	16.2
21	16.7	11.6	14.3	15.9	12.8	14.4	12.9	14.5	10.1	12.1	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>	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 9CFR 113.317(c)(3)(i)</p> <p>Number affected:  Vaccinates: 1/20 (5%)  Controls: 4/5 (80%)</p> <p>Requirements of 9CFR 113.317 (c)(3)(i) were met.</p> <p>Raw data:  Data tables are appended to the end of this summary.</p>
<b>USDA Approval Date</b>	January 31, 2012

**CPV Post challenge Clinical Observations**

Non-Vaccinated Controls															
Dog ID	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															
4															
5															
6															
7															
8															
8															
10															
13															
14															
15														1	
16															1
17									1	2					
18															
20															
22															
23															
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 (ODPC)
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 (ODPC)
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      ODPC - Days post challenge  
 DPV2 - Days Post Second Vaccination

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

Controls														
CatID	-2DPC	-1DPC	0DPC	Average	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
9	1.24	1.20	1.38	1.27	1.71	1.45	0.80	0.30	0.28	0.74	0.27	Na	Na	Na
11	2.24	2.59	2.07	2.30	2.28	2.36	1.82	0.29	0.58	0.69	1.04	1.17	1.27	2.13
19	1.57	2.14	1.87	1.86	2.32	2.26	2.42	1.42	0.70	1.59	1.66	1.52	2.11	2.70
21	1.67	2.19	2.52	2.13	2.68	1.92	2.31	1.17	0.67	1.75	2.03	1.52	2.09	3.35
27	2.68	2.26	2.30	2.41	2.29	2.37	2.25	0.92	1.00	1.09	2.04	1.74	2.08	2.60

**Vaccinates**

CatID	-2DPC	-1DPC	0DPC	Average	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
1	3.05	3.06	2.74	2.95	2.05	2.25	2.42	2.39	2.66	3.31	2.57	3.01	2.64	3.14
2	2.45	2.50	2.34	2.43	3.32	3.05	3.27	3.03	2.73	3.20	3.23	2.92	3.28	1.67
3	2.09	2.40	2.34	2.28	2.42	2.46	2.32	1.65	1.73	2.38	2.16	2.42	2.52	2.10
4	1.10	1.59	2.46	1.72	3.23	2.45	2.91	2.03	2.75	2.34	2.41	2.87	2.66	3.12
5	0.62	0.96	1.16	0.91	1.23	1.32	1.14	1.26	1.19	1.57	1.49	1.36	1.09	1.98
6	1.43	1.84	1.73	1.67	1.84	1.55	1.16	1.79	1.62	2.44	1.97	2.32	2.24	2.77
7	1.23	1.22	1.18	1.21	1.18	1.51	1.53	1.68	1.52	1.81	0.22	1.67	1.91	2.33
8	2.07	1.89	2.00	1.99	1.81	1.93	1.78	1.52	1.64	2.52	2.23	2.51	2.59	2.38
10	2.74	2.80	3.27	2.94	1.93	2.43	2.56	3.01	2.65	2.44	2.65	2.64	2.83	2.76
13	1.26	2.25	2.24	1.92	2.43	1.88	2.57	2.39	2.57	3.09	3.22	3.24	3.17	2.72
14	2.17	2.24	3.02	2.48	3.57	3.62	3.76	3.28	3.07	3.66	4.10	4.18	4.57	4.83
15	2.21	2.30	2.66	2.39	3.10	2.81	3.04	2.85	2.98	3.29	2.51	0.93	2.71	2.59
16	1.68	2.54	2.06	2.09	2.56	2.08	3.35	2.83	2.35	3.13	2.90	2.27	3.24	3.30
17	2.25	2.14	2.11	2.17	2.42	2.84	2.62	2.93	2.69	3.04	2.78	1.34	2.59	3.28
18	2.06	2.82	2.50	2.46	2.97	2.48	2.62	3.05	3.04	3.98	3.27	2.26	3.98	4.78
20	1.83	2.11	2.05	2.00	2.58	2.22	2.39	2.50	1.73	1.98	2.12	2.28	2.35	3.26
22	3.80	3.05	3.35	3.40	3.96	3.18	3.38	3.75	2.36	2.42	3.93	3.23	3.34	4.33
23	0.84	1.46	1.51	1.27	1.63	1.35	1.47	1.45	1.29	1.72	1.53	1.44	1.14	1.22
24	0.97	2.04	2.32	1.78	2.09	2.24	2.67	2.03	2.03	2.70	2.46	2.68	2.86	3.54
28	2.43	2.68	2.15	2.42	2.68	2.89	3.56	3.56	2.52	2.46	3.57	3.61	3.50	0.92

Body Temperature Post Challenge °F												
Non-Vaccinated Controls												
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	
9	102.0	102.0	102.6	102.9	103.2	104.6	103.2	100.9	Na	Na	Na	
11	102.6	102.9	102.6	102.6	103.1	103.4	102.8	102.2	101.3	101.5	102.2	
19	102.5	102.8	102.1	102.3	101.9	103.8	102.3	102.4	101.6	102.1	101.9	
21	102.2	102.3	101.3	101.4	102.0	103.4	102.0	101.8	101.5	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	101.9	
Vaccinates												
Dog ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	
1	101.9	102.0	101.9	101.9	101.7	102.0	101.5	101.9	101.3	101.6	101.7	
2	102.7	103.5	103.1	103.1	103.5	102.3	103.1	102.9	102.4	102.6	102.6	
3	103.0	103.0	102.5	102.2	102.7	102.7	103.1	103.0	102.1	102.5	101.9	
4	101.6	102.4	102.3	102.1	102.4	102.1	103.4	102.7	102.1	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	102.7	
6	102.7	102.6	101.7	102.8	102.4	102.4	102.8	102.7	102.2	102.4	102.1	
7	101.7	102.5	102.5	103.3	103.0	103.1	103.1	103.1	102.9	102.6	102.1	
8	102.7	102.9	102.5	102.4	102.6	102.2	102.2	102.5	101.7	101.2	102.2	
10	103.1	103.3	102.3	102.8	103.0	102.5	102.2	102.7	102.8	101.9	101.9	
13	103.0	102.5	102.8	102.2	103.2	102.6	102.7	103.0	102.4	102.9	102.7	
14	102.3	102.8	102.4	102.4	102.7	102.4	102.6	102.4	102.0	101.9	102.1	
15	102.5	102.7	102.3	102.0	102.8	102.2	102.4	102.4	101.9	102.2	101.7	
16	101.7	102.5	102.8	101.9	102.5	102.1	102.1	101.9	101.5	101.1	101.6	
17	101.9	102.8	102.3	102.6	102.7	102.1	102.0	101.9	102.0	101.7	102.1	
18	102.2	102.5	102.1	101.5	102.3	102.6	102.0	102.0	101.9	101.8	102.0	
20	102.2	101.9	101.9	102.0	102.2	101.8	101.8	101.9	101.6	101.4	101.9	
22	102.7	102.9	102.4	101.8	102.8	102.5	102.5	102.8	102.0	102.0	101.9	
23	102.5	102.8	102.7	102.7	103.2	102.4	102.7	103.1	102.1	102.4	102.2	
24	103.3	103.1	102.6	102.2	102.5	102.4	102.2	102.2	102.1	101.8	102.3	
28	102.2	102.1	102.0	102.4	102.2	102.2	102.0	102.0	101.8	101.5	101.6	

### Fecal Virus Isolation Titer Post Challenge

Controls											
CatID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
9	≤1.5	≤1.5	≤1.5	≤1.5	≤2.5	6.6	7.6	5.2	≥9.2	Na	Na
11	≤1.5	≤1.8	≤1.5	≤1.5	5.5	7.2	7.5	≥8.5	≥8.6	≥7.6	6.6
19	≤1.5	≤1.5	≤1.5	≤1.5	2.5	4.2	7.5	7.6	4.2	4	≤1.5
21	≤1.5	≤1.5	≤1.5	≤1.8	4.3	4.7	6.3	6.8	≤2.8	4.5	3.6
27	≤1.5	≤1.5	≤1.5	≤1.5	≤2.8	5.2	7.4	6.6	5.2	≤3.0	≤1.5

Vaccinates											
CatID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC
1	≤1.5	≤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	≤1.5
3	≤1.5	≤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	≤1.5
5	≤1.5	≤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	≤1.5
7	≤1.5	≤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	≤1.5
10	≤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	≤1.6	≤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
20	≤1.5	≤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	≤1.5
23	≤1.5	≤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	≤1.5
28	≤1.5	≤1.5	≤1.5	≤1.5	≤1.5	≤2.5	≤1.5	≤2.5	≤1.5	≤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
<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>	NA
<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>	Frequency of events is appended to the end of this summary.
<b>USDA Approval Date</b>	November 15, 2002

### Summary of Reactions:

Reaction Type	Puppies up to 6 weeks of age				Dogs > 6 Weeks of Age				Sum of Doses	Reaction Rate
	<24hr	>24hrs	Total Reactions by dose	%	<24hr	>24hrs	Total Reactions by dose	%		
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.