



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	13D1.24
True Name	Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	June 02, 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>	<p>The study was satisfactory per the criteria in 9 CFR 113.305(1)(ii) (A)(B)</p> <table border="1" data-bbox="587 920 1230 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									

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											
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				
9	Control						1	1	1	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															

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															
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																							
28	SC											≤1.63												
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>	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	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

<b>SQ Vaccinates</b>										
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>															
Dog	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-
2	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-
3	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
4	-	+	+	+	+	+	+	-	+	-	-	-	-	-	-
5	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-
6	-	+	+	+	+	+	+	+	+	-	-	-	-	-	-

<b>SC Vaccinates</b>															
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>	<p>The study was satisfactory per the criteria in 9 CFR 113.306 (b)(3) (i-ii)</p> <table border="1" data-bbox="587 887 1230 1079"> <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>See the next page for data.</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	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						
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						
Intermittent minor stool abnormalities observed were not considered clinical signs of CDV infection.											

DPC – Days Post Challenge

**CDV Clinical Signs Observed Post Challenge - Vaccinated Dogs**

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	
18																							10,12
19																			14				
20																				10			
21																							
22																							
23					10																		
24																							
25																							
26																							
27																		10,12	11,12	11,12	12	12	12
28																		10,12	10,12	10,12			
<b>1 - Depression/Lethargy</b> <b>2 - Mild/Mod. Ocular Discharge Mucoïd</b> <b>8 - Dehydration</b> <b>10 - Mucous stool</b> <b>11 - watery Stool</b> <b>12 - Bloody stool</b> <b>14 - Vomiting</b> <b>16 - Excessive Salivation</b> <b>17 - Chewing gum fits</b> <b>18 - neuromuscular Tics</b> <b>20 - death</b> <b>Blank - No Clinical signs observed</b>																							
Intermittent minor stool abnormalities observed were not considered clinical signs of CDV infection.																							

DPC – Days Post Challenge

### CDV Clinical Signs Observed Post Challenge - Vaccinated Dogs

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

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%)  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

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															
14						D									
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											
Cat ID	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											
Cat ID	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>	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															
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	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 Neutritization 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    0DCP - Days post challenge  
 DPV2 - Days Post Second Vaccination

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

CatID	Controls													
	-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

CatID	Vaccinates													
	-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

DPC – Days post challenge

**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

DPC – Days post challenge

### Fecal Virus Isolation Titer Post Challenge

CatID	Controls										
	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

CatID	Vaccinates										
	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 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:

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.