



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1331.23
True Name	Canine Distemper-Adenovirus Type 2-Parvovirus Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Ultra Duramune DAP - Elanco US Inc.
Date of Compilation Summary	December 19, 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.

Study Type	Efficacy									
Pertaining to	Infectious Canine Hepatitis Virus									
Study Purpose	To demonstrate effectiveness against Infectious Canine Hepatitis (ICH)									
Product Administration	Two doses were administered subcutaneously (SC) 21 days apart									
Study Animals	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.									
Challenge Description	21 days after second vaccination all dogs were challenged with Infectious Canine Hepatitis Virus.									
Interval observed after challenge	Puppies were observed for 21 days after challenge for clinical signs.									
Results	<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%)								
USDA Approval Date	March 31, 1998									

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

Study Type	Efficacy
Pertaining to	Canine Adenovirus Type II
Study Purpose	To demonstrate effectiveness against Canine Adenovirus Type II (CAV2)
Product Administration	Two doses were administered subcutaneously 21 days apart
Study Animals	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.
Challenge Description	21 days after second vaccination all dogs were challenged with CAV2
Interval observed after challenge	Puppies were observed for 21 days after challenge for clinical signs.
Results	<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>
USDA Approval Date	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	1,2			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 (TCID₅₀/100ul)

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																								

Study Type	Efficacy									
Pertaining to	Cannie Distemper Virus (CDV)									
Study Purpose	To demonstrate effectiveness against CDV									
Product Administration	Two doses were administered subcutaneously 21 days apart									
Study Animals	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.									
Challenge Description	21 days after second vaccination all dogs were challenged with CDV.									
Interval observed after challenge	Dogs were observed for 42 days after challenge for clinical signs of CDV.									
Results	<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%)								
USDA Approval Date	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																										
1 - Depression/Lethargy																						14 - Vomiting		Intermittent minor stool abnormalities observed																					
2 - Mild/Mod. Ocular Discharge																						16 - Excessive Salivation		were not considered clinical signs of CDV																					
8 - Dehydration																						17 - Chewing gum fits		infection.																					
10-Mucous stool																						18 - neuromuscular Tics																							
11-watery Stool																						20 - death																							
12-Bloody stool																						Blank - No Clinical signs observed																							

DPC – Days post-challenge

CDV Clinical Signs Observed Post Challenge - Vaccinated Dogs

Dog	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																							
24																														
25																														
26									10																					
27	11,12		10,12		10,12	10,11,12	12		10	10																				
28	11	10,12	10,12					10,12	10,12			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

Study Type	Efficacy
Pertaining to	Canine Parvovirus (CPV)
Study Purpose	To demonstrate effectiveness against CPV in 6-week-old puppies.
Product Administration	Two doses, given at an interval of 21 days, were administered subcutaneously (SC).
Study Animals	Study analysis was conducted on twenty-one 6-week-old puppies seronegative for CPV, 17 vaccinates and 4 non-vaccinated controls.
Challenge Description	Twenty-one (21) days after second vaccination puppies were challenged with CPV 2b strain.
Interval observed after challenge	Puppies were observed daily for 14 days after challenge
Results	<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>
USDA Approval Date	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	10.2	101.8	102.1	102.2	101.8	101.5	102.3	102.3	101.7	102.5	101.9	102.1	102.2
16	100.9	102.2	101.4	101.5	101.4	101.8	101.3	101.5	101.0	101.2	101.3	101.6	101.4	101.8	101.9
17	99.9	100.4	101.8	101.3	101.0	101.5	100.3	101.7	101.1	101.3	101.1	101.1	101.2	101.1	101.3
18	99.7	101.1	101.0	101.4	101.0	101.4	101.5	100.7	100.7	100.4	101.4	100.8	101.0	100.5	101.7
19	100.7	101.2	101.1	101.0	101.6	101.4	100.8	100.7	101.4	101.8	101.2	101.4	101.3	101.7	102.3
20	100.9	102.1	101.9	101.7	101.8	102.5	100.9	101.3	101.6	101.9	101.7	101.3	101.4	101.8	102.3
21	101.8	101.6	102.0	102.1	101.2	101.9	100.8	101.3	101.7	101.4	101.6	101.2	101.4	101.2	101.7

DPC = Days Post Challenge

Total White Blood Cell Counts (x1000/uL)

Non-Vaccinated Controls											
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 FAID₅₀/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

Study Type	Efficacy
Pertaining to	Canine Parvovirus (CPV)
Study Purpose	To demonstrate effectiveness against CPV
Product Administration	Two doses given at an interval of 28 days were administered subcutaneously (SC).
Study Animals	6-week old puppies seropositive for parvovirus, 20 vaccinates and 5 non-vaccinated controls.
Challenge Description	Fifty-six days (56) after second vaccination puppies were challenged with CPV type 2c strain.
Interval observed after challenge	Puppies were observed for clinical signs daily for 14 days after challenge
Results	<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>
USDA Approval Date	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		1													
5															
6															
7															
8		1													
10															
13															
14															
15														1	
16															1
17									1	2					
18															
20															
22															
23		1													
24															
28															

1 - Mucous Stool
2-Diarrhea (Watery stool)

3-Bloody Stool
4-Death

Blank - No clinical signs observed

DPC – Days Post Challenge

Serum Neutralization Titer								
Non-Vaccinated Controls								
Dog ID	-24DPV1	0DPV1	7PV1	28DPV1 (0DPV2)	41DPV1	56DPV1	70DPV1	84DPV1 (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 (x10³/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 log¹⁰ FAID₅₀/mL

DPC – Days Post Challenge

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

Study Type	Safety																																							
Pertaining to	ALL																																							
Study Purpose	Demonstrate safety of product under typical use conditions																																							
Product Administration	Two doses were administered subcutaneously approximately two weeks apart.																																							
Study Animals	A total of 675 dogs, privately owned and from commercial kennels were enrolled in the study. From these dogs 234 were 6 weeks of age or younger, at first vaccination. Three geographical sites were represented.																																							
Challenge Description	NA																																							
Interval observed after challenge	Animals were observed 30 minutes after each vaccination and daily for two (2) weeks after each vaccination.																																							
Results	<p>Frequency of adverse events:</p> <table border="1" data-bbox="616 887 1401 1599"> <thead> <tr> <th></th> <th>Number of Animals</th> <th>Percent of Animals</th> </tr> </thead> <tbody> <tr> <td>No observed adverse events</td> <td>628</td> <td>93.0%</td> </tr> <tr> <td>Injection Site Lesion</td> <td>1</td> <td>0.1%</td> </tr> <tr> <td>Diarrhea-one day of loose stools</td> <td>23</td> <td>3.4%</td> </tr> <tr> <td>Heavy Breathing</td> <td>1</td> <td>0.1%</td> </tr> <tr> <td>Death-Hit by Car *</td> <td>1</td> <td>0.1%</td> </tr> <tr> <td>Death-depression,decreased appetite, weight loss **</td> <td>1</td> <td>0.1%</td> </tr> <tr> <td>Lameness (leg cramp) *</td> <td>1</td> <td>0.1%</td> </tr> <tr> <td>Decreased appetite, weight loss, diarrhea, and dehydration *</td> <td>4</td> <td>0.6%</td> </tr> <tr> <td>Gastroenteritis (vomiting) *</td> <td>2</td> <td>0.3%</td> </tr> <tr> <td>Laceration *</td> <td>1</td> <td>0.1%</td> </tr> <tr> <td>Prolapsed nictitan gland *</td> <td>7</td> <td>1.0%</td> </tr> <tr> <td>Pyoderma *</td> <td>5</td> <td>0.7%</td> </tr> </tbody> </table> <p>*Affirmed by study investigator to have cause other than vaccination **Cause of death was not determined by study investigator. Signs appeared 4 days after vaccination and death 8 days later.</p> <p>The injection site lesion was detected after the second vaccination and resolved within 15 days.</p>		Number of Animals	Percent of Animals	No observed adverse events	628	93.0%	Injection Site Lesion	1	0.1%	Diarrhea-one day of loose stools	23	3.4%	Heavy Breathing	1	0.1%	Death-Hit by Car *	1	0.1%	Death-depression,decreased appetite, weight loss **	1	0.1%	Lameness (leg cramp) *	1	0.1%	Decreased appetite, weight loss, diarrhea, and dehydration *	4	0.6%	Gastroenteritis (vomiting) *	2	0.3%	Laceration *	1	0.1%	Prolapsed nictitan gland *	7	1.0%	Pyoderma *	5	0.7%
	Number of Animals	Percent of Animals																																						
No observed adverse events	628	93.0%																																						
Injection Site Lesion	1	0.1%																																						
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Death-depression,decreased appetite, weight loss **	1	0.1%																																						
Lameness (leg cramp) *	1	0.1%																																						
Decreased appetite, weight loss, diarrhea, and dehydration *	4	0.6%																																						
Gastroenteritis (vomiting) *	2	0.3%																																						
Laceration *	1	0.1%																																						
Prolapsed nictitan gland *	7	1.0%																																						
Pyoderma *	5	0.7%																																						
USDA Approval Date	13 Jan 2011																																							