



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	18M1.29
True Name	Parvovirus Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Duramune Max Pv - Elanco US Inc.
Date of Compilation Summary	November 09, 2018

**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>	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	0DDPC	1DDPC	2DDPC	3DDPC	4DDPC	5DDPC	6DDPC	7DDPC	8DDPC	9DDPC	10DDPC	11DDPC	12DDPC	13DDPC	14DDPC
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	0DDPC	1DDPC	2DDPC	3DDPC	4DDPC	5DDPC	6DDPC	7DDPC	8DDPC	9DDPC	10DDPC	11DDPC	12DDPC	13DDPC	14DDPC
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



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

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

DPV1 - Days post first Vaccination      0DCP - 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

<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>	A total of 621 dogs, 358 under 6 weeks of age and 263 greater than 6 weeks of age, were administered 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>	Privately owned and commercial kennel canines
<b>Challenge Description</b>	NA
<b>Interval observed after challenge</b>	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.