



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	47K1.20
True Name	Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Leptospira Canicola-Grippyphosa-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Merck Animal Health Nobivac Canine 1-DAPPv + L4 - No distributor specified Procyon DAPPv +L4 - MSD Salud Animal Columbia S.A.S.
Date of Compilation Summary	March 18, 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>	Canine Adenovirus Type-2 (CAV-2)																		
<b>Study Purpose</b>	Efficacy against canine hepatitis virus (CAV-1)																		
<b>Product Administration</b>	Two doses administered subcutaneously, 21 days apart																		
<b>Study Animals</b>	7- to 8-week-old dogs, seronegative to CAV-1; 20 vaccinates, 5 controls																		
<b>Challenge Description</b>	All dogs were challenged with CAV-1 two weeks after the second vaccination																		
<b>Interval observed after challenge</b>	Dogs were observed daily for clinical signs, including fever, for 14 days post-challenge																		
<b>Results</b>	<p>Summary of the rectal temperatures and clinical signs after challenge are listed below.</p> <p style="text-align: center;"><b>Rectal Temperatures and Clinical Signs following Challenge:</b></p> <table style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th style="text-align: center;">Vaccinate</th> <th style="text-align: center;">Control</th> </tr> </thead> <tbody> <tr> <td>Moderate Depression</td> <td style="text-align: center;">0/20</td> <td style="text-align: center;">4/5</td> </tr> <tr> <td>Severe Depression</td> <td style="text-align: center;">0/20</td> <td style="text-align: center;">1/5</td> </tr> <tr> <td>Hemorrhaging</td> <td style="text-align: center;">0/20</td> <td style="text-align: center;">4/5</td> </tr> <tr> <td>Jaundice</td> <td style="text-align: center;">0/20</td> <td style="text-align: center;">2/5</td> </tr> <tr> <td>Fever (<math>\geq 103.4^{\circ}\text{F}</math>)</td> <td style="text-align: center;">0/20</td> <td style="text-align: center;">2/5</td> </tr> </tbody> </table> <p>Requirements for animal titer and the presence of clinical signs per 9 CFR 113.305 were met.</p> <p>See attached Table 1, 2, 3 and 4 for raw data.  Study Date (SD)  SD0 is the date of the first vaccination.  SD21 is the date of the second vaccination.  SD35 is the date of the challenge corresponding to two weeks after the second vaccination.</p>		Vaccinate	Control	Moderate Depression	0/20	4/5	Severe Depression	0/20	1/5	Hemorrhaging	0/20	4/5	Jaundice	0/20	2/5	Fever ( $\geq 103.4^{\circ}\text{F}$ )	0/20	2/5
	Vaccinate	Control																	
Moderate Depression	0/20	4/5																	
Severe Depression	0/20	1/5																	
Hemorrhaging	0/20	4/5																	
Jaundice	0/20	2/5																	
Fever ( $\geq 103.4^{\circ}\text{F}$ )	0/20	2/5																	
<b>USDA Approval Date</b>	April 01, 2010																		

**Table 1. CAV-1 Serum Neutralization Titers.**

Dog ID	Treatment Group	Study Day -1	Study Day 20	Study Day 35	Study Day 49
0923701	A Vaccinates	<2	38	609	> 4096
0923801		<2	76	512	> 4096
0923802		<2	215	1722	> 4096
0923803		<2	128	431	> 4096
0923805		<2	181	1448	> 4096
0923806		<2	1448	1448	> 4096
0923807		<2	76	256	> 4096
0923808		<2	861	2896	> 4096
0952801		<2	181	861	> 4096
0952803		<2	215	1448	N/A
0952806		<2	76	512	> 4096
0952807		<2	304	1448	> 4096
0952808		<2	215	1448	> 4096
0952901		<2	215	1024	> 4096
0952902		<2	304	1448	4096
0952903		<2	128	512	> 4096
0952905		<2	256	609	> 4096
0952906		<2	431	1448	3444
0953005		<2	128	2435	> 4096
0953006		<2	512	1448	> 4096
0953007	<2	108	1448	> 4096	
0923603	B Controls	<2	<2	<2	Dead
0923804		<2	<2	<2	> 4096
0952802		<2	<2	<2	Dead
0952904		<2	<2	<2	Dead
0953003		<2	<2	<2	Dead

GMT = Geometric Mean Titer

N/A = dog no longer in study

For purposes of calculating the GMT, > 4096 was considered to be 4096.

**Table 2. CAV-2 Serum Neutralization Titers.**

Dog ID	Treatment Group	Study Day -1	Study Day 35
0923701	A Vaccinates	<2	609
0923801		<2	1448
0923802		<2	2048
0923803		<2	2435
0923805		<2	2435
0923806		<2	1218
0923807		<2	1024
0923808		<2	> 4096
0952801		<2	2048
0952803		<2	2048
0952806		<2	1218
0952807		<2	1218
0952808		<2	1722
0952901		<2	1722
0952902		<2	1722
0952903		<2	861
0952905		<2	1218
0952906		<2	> 4096
0953005		<2	1218
0953006		<2	1448
0953007	<2	2048	
0923603	B Controls	<2	<2
0923804		<2	<2
0952802		<2	<2
0952904		<2	<2
0953003		<2	<2

GMT = Geometric Mean Titer

N/A = dog no longer in study

For purposes of calculating the GMT, > 4096 was considered to be 4096.

**Table 3. Post-Challenge Rectal Temperatures (°F)**

Dog ID	Treatment Group	SD 33	SD 34	SD 35*	SD 36	SD 37	SD 38	SD 39	SD 40	SD 41	SD 42
0923701		101.2	101.3	100.2	100.8	100.8	100.4	100.5	100.4	100.4	100.3
0923801		101.7	101.4	101.6	101.3	101.5	100.8	100.7	101.0	100.6	100.7
0923802		101.1	101.1	101.3	101.4	101.0	100.6	100.3	100.6	100.8	101.7
0923803		101.7	101.6	100.4	100.2	100.6	100.7	100.5	100.0	100.5	100.3
0923805		101.2	101.3	101.2	100.7	101.0	101.0	100.9	100.4	101.1	100.9
0923806		102.2	101.7	101.3	101.5	101.0	100.8	100.7	101.1	100.9	103.0
0923807		101.6	100.5	101.2	101.1	100.6	100.5	100.8	100.6	100.6	100.6
0923808		101.6	101.2	102.0	101.8	101.0	101.0	101.0	100.8	101.0	101.7
0952801		101.4	101.2	100.8	100.9	100.7	100.8	100.3	100.3	101.0	101.0
0952806	A	101.1	100.4	100.8	101.2	100.9	100.8	100.7	100.3	100.8	101.2
0952807	Vaccinates	102.0	101.8	102.1	102.4	101.2	101.4	100.9	101.7	100.8	100.9
0952808		100.7	100.6	100.2	100.4	100.2	100.8	100.4	100.1	100.3	100.7
0952901		101.8	101.2	100.9	101.5	100.7	100.5	100.5	101.4	100.5	100.1
0952902		100.5	100.9	100.6	100.4	100.5	100.7	100.3	100.0	100.3	100.3
0952903		101.2	101.0	100.7	100.9	100.7	100.9	100.5	100.3	100.6	100.6
0952905		101.0	100.7	100.4	100.3	100.4	100.4	100.8	100.0	100.5	100.5
0952906		101.6	101.5	100.4	101.0	101.3	100.6	100.6	100.3	100.4	100.4
0953005		102.4	101.8	101.4	101.9	101.7	100.5	100.9	101.4	101.2	101.4
0953006		102.1	101.8	101.0	101.0	101.3	101.4	101.0	100.9	100.8	101.3
0953007		101.5	101.3	100.9	101.3	100.3	100.7	101.2	100.4	100.7	101.8
0923603		101.0	101.3	101.3	101.4	102.5	100.9	Dead	Dead	Dead	Dead
0923804	B	101.6	101.5	101.8	<b>103.4</b>	102.7	102.3	101.4	102.3	<b>103.4</b>	102.4
0952802	Controls	101.4	101.6	100.5	102.4	102.8	101.5	100.7	102.1	Dead	Dead
0952904		101.5	100.9	101.0	101.6	102.9	100.0*	Dead	Dead	Dead	Dead
0953003		100.6	101.2	100.5	101.1	<b>104.9</b>	101.7	Dead	Dead	Dead	Dead

SD = study day

\* Challenge

Temperatures in  $\geq 103.4^\circ\text{F}$  indicate fever

**Table 3. Post-Challenge Rectal Temperatures (°F) - continued**

Dog ID	Treatment Group	SD 43	SD 44	SD 45	SD 46	SD 47	SD 48	SD 49
0923701		100.2	100.9	100.6	101.0	101.4	101.1	101.6
0923801		100.9	100.6	100.4	100.4	101.5	101.2	101.4
0923802		100.6	101.2	101.6	101.2	101.1	101.6	101.6
0923803		100.8	101.1	100.9	100.7	100.6	100.6	101.3
0923805		101.5	100.7	100.8	100.7	100.5	101.4	101.1
0923806		100.5	101.3	102.4	101.8	100.7	101.5	101.4
0923807		100.4	101.0	102.9	101.9	100.7	101.3	100.5
0923808		101.1	101.4	101.3	101.2	101.6	100.9	101.7
0952801		101.1	100.5	100.7	101.0	101.4	101.1	100.8
0952806	A	100.1	101.1	100.8	101.0	100.7	101.0	100.7
0952807	Vaccinates	102.1	101.6	101.3	101.2	101.5	101.9	101.8
0952808		101.2	100.4	100.6	100.5	101.2	100.5	101.2
0952901		101.5	101.4	102.3	101.7	100.7	100.7	100.8
0952902		100.4	100.5	100.2	100.6	100.8	100.5	100.5
0952903		101.6	101.3	101.3	100.8	101.3	101.8	101.2
0952905		100.6	100.6	101.0	100.9	101.5	101.0	101.5
0952906		101.7	100.8	100.5	100.7	101.9	100.9	100.9
0953005		101.2	101.3	102.2	101.7	101.9	101.4	101.5
0953006		100.9	101.5	101.1	101.2	100.9	101.0	101.3
0953007		101.5	100.8	102.2	101.6	101.7	100.7	100.9
0923603		Dead	Dead	Dead	Dead	Dead	Dead	Dead
0923804	B	101.4	100.8	100.6	100.5	100.9	101.1	101.3
0952802	Controls	Dead	Dead	Dead	Dead	Dead	Dead	Dead
0952904		Dead	Dead	Dead	Dead	Dead	Dead	Dead
0953003		Dead	Dead	Dead	Dead	Dead	Dead	Dead

SD = study day

\* Challenge

Temperatures in  $\geq 103.4^{\circ}\text{F}$  indicate fever

**Table 4. Post-Challenge Clinical Observations**

Dog ID	Treatment Group	SD 33	SD 34	SD 35*	SD 36	SD 37	SD 38	SD 39	SD 40	SD 41	SD 42
0923701		-	-	-	-	-	-	-	-	-	-
0923801		-	-	-	-	-	-	-	-	-	-
0923802		-	-	-	-	-	-	-	-	-	-
0923803		-	-	-	-	-	-	-	-	-	-
0923805		-	-	-	-	-	-	-	-	-	-
0923806		-	-	-	-	-	-	-	-	-	-
0923807		-	-	-	-	-	-	-	-	-	-
0923808		-	-	-	-	-	-	-	-	-	-
0952801		-	-	-	-	-	-	-	-	-	-
0952806	A	-	-	-	-	-	-	-	-	-	-
0952807	Vaccinates	-	-	-	-	-	-	-	-	-	-
0952808		-	-	-	-	-	-	-	-	-	-
0952901		-	-	-	-	-	-	-	-	-	-
0952902		-	-	-	-	-	-	-	-	-	-
0952903		-	-	-	-	-	-	-	-	-	-
0952905		-	-	-	-	-	-	-	-	-	-
0952906		-	-	-	-	-	-	-	-	-	-
0953005		-	-	-	-	-	-	-	-	-	-
0953006		-	-	-	-	-	-	-	-	-	-
0953007		-	-	-	-	-	-	-	-	-	-
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0923603		-	-	-	-	-	L2,H	Dead	Dead	Dead	Dead
0923804	B	-	-	-	-	-	-	H	J,H	L1,H	L1,J,H
0952802	Controls	-	-	-	-	-	-	L1,H	L1,J,H	Dead	Dead
0952904		-	-	-	-	-	L1,H	Dead	Dead	Dead	Dead
0953003		-	-	-	-	L1	L1	Dead	Dead	Dead	Dead

SD = study day; \* Challenge

L1 = moderate depression; L2 = severe depression; H = Hemorrhaging; J = Jaundice

**Table 4. Post-Challenge Clinical Observations - continued**

Dog ID	Treatment Group	SD 43	SD 44	SD 45	SD 46	SD 47	SD 48	SD 49
0923701		-	-	-	-	-	-	-
0923801		-	-	-	-	-	-	-
0923802		-	-	-	-	-	-	-
0923803		-	-	-	-	-	-	-
0923805		-	-	-	-	-	-	-
0923806		-	-	-	-	-	-	-
0923807		-	-	-	-	-	-	-
0923808		-	-	-	-	-	-	-
0952801		-	-	-	-	-	-	-
0952806	A	-	-	-	-	-	-	-
0952807	Vaccinates	-	-	-	-	-	-	-
0952808		-	-	-	-	-	-	-
0952901		-	-	-	-	-	-	-
0952902		-	-	-	-	-	-	-
0952903		-	-	-	-	-	-	-
0952905		-	-	-	-	-	-	-
0952906		-	-	-	-	-	-	-
0953005		-	-	-	-	-	-	-
0953006		-	-	-	-	-	-	-
0953007		-	-	-	-	-	-	-
0923603		Dead	Dead	Dead	Dead	Dead	Dead	Dead
0923804	B	L1,J,H	H	-	-	-	-	-
0952802	Controls	Dead	Dead	Dead	Dead	Dead	Dead	Dead
0952904		Dead	Dead	Dead	Dead	Dead	Dead	Dead
0953003		Dead	Dead	Dead	Dead	Dead	Dead	Dead

**SD** = study day; \* Challenge

**L1** = moderate depression; **L2** = severe depression; **H** = Hemorrhaging; **J** = Jaundice



<b>Study Type</b>	Safety
<b>Pertaining to</b>	Canine Adenovirus Type-2 (CAV-2)
<b>Study Purpose</b>	To demonstrate the 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 were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	1980

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira canicola</i>
<b>Study Purpose</b>	Efficacy against leptospirosis due to <i>L.canicola</i> .
<b>Product Administration</b>	Two doses were administered subcutaneously (SC) 21 days apart.
<b>Study Animals</b>	7-8 week old dogs, sero-negative for antibodies specific to <i>Leptospira</i> ; 20 vaccinates and 10 controls
<b>Challenge Description</b>	All animals were challenged with <i>L. canicola</i> Day 21 and Day 22 after the last vaccination.
<b>Interval observed after challenge</b>	Clinical signs, including fever, were monitored daily for 21 days post-challenge. Tissues were examined on day 21 post challenge or on the day when the dog died if earlier than day 21.
<b>Results</b>	<p><b>Summary of Results:</b></p> <p><u>Summary of Mortality after Challenge</u>  Vaccinates            0/20  Controls                7/10</p> <p><u>Summary of Isolation from Tissues</u>  Vaccinates            1/20  Controls                10/10</p> <p><b>See the attached tables for raw data for this study:</b></p> <p>Table 1. Mortality  Table 2. <i>Leptospira</i> Isolation from Tissues Collected at End of Study  Table 3. Number of Times Clinical Signs Were Observed in 21 Days Post Challenge  Table 4. Clinical Observations Post-Challenge</p>
<b>USDA Approval Date</b>	September 22, 2008

**Table 1. Mortality**

<b>Treatment Group</b>	<b>Dog ID</b>	<b>Mortality</b>
A	AWK-7	No
A	RGL-7	No
A	SBL-7	No
A	SQK-7	No
A	TRL-7	No
A	UQL-7	No
A	URL-7	No
A	XCL-7	No
A	XSL-7	No
A	YHL-7	No
A	PUK-7	No
A	QEL-7	No
A	RRL-7	No
A	TAL-7	No
A	UJL-7	No
A	UXL-7	No
A	VZL-7	No
A	WDL-7	No
A	WIL-7	No
A	XGL-7	No
B	PSL-7	Yes
B	QSK-7	No
B	RFL-7	Yes
B	ROL-7	Yes
B	SYL-7	No
B	XUK-7	Yes
B	SPL-7	No
B	TEK-7	Yes
B	TVK-7	Yes
B	TWL-7	Yes

**Group A – Vaccinates; Group B - Controls**

**Table 2. Leptospira Isolation from Tissues Collected at End of Study**

Treatment Group	Dog ID	Tissue Collection Date* (Study Day)	Kidney	Liver	Urine/Bladder
A	AWK-7	63	0	0	0
A	RGL-7	63	0	0	0
A	SBL-7	63	0	0	0
A	SQK-7	63	1	0	2
A	TRL-7	63	0	0	0
A	UQL-7	63	0	0	0
A	URL-7	63	0	0	0
A	XCL-7	63	0	0	0
A	XSL-7	63	0	0	0
A	YHL-7	63	0	0	0
A	PUK-7	63	0	0	0
A	QEL-7	63	0	0	0
A	RRL-7	63	0	0	0
A	TAL-7	63	0	0	0
A	UJL-7	63	0	0	0
A	UXL-7	63	0	0	0
A	VZL-7	63	0	0	0
A	WDL-7	63	0	0	0
A	WIL-7	63	0	0	0
A	XGL-7	63	0	0	0
B	PSL-7 <sup>b</sup>	46	2	2	2
B	QSK-7	63	2	0	0
B	RFL-7 <sup>a</sup>	45	2	2	2
B	ROL-7 <sup>b</sup>	46	2	2	2
B	SYL-7	63	1	0	0
B	XUK-7 <sup>b</sup>	46	2	2	2
B	SPL-7	63	1	0	0
B	TEK-7 <sup>c</sup>	47	2	2	2
B	TVK-7 <sup>b</sup>	46	2	2	2
B	TWL-7 <sup>d</sup>	48	2	2	2

**Group A - Vaccinates**

**Group B - Controls**

**(2) = Leptospira isolated from tissue.**

**(1) = Leptospira isolated from tissue only after subculture.**

**(0) = Leptospira not isolated from tissue.**

**\* Several dogs in the control group died prior to the end of study (Study Day 63, 21 days post challenge) and the tissue collection date was earlier than Study Day 63.**

<sup>a</sup> Dog died on study day 45 (3 days after challenge)

<sup>b</sup> Dogs died on study day 46 (4 days after challenge)

<sup>c</sup> Dog died on study day 47 (5 days after challenge)

<sup>d</sup> Dog died on study day 48 (6 days after challenge)

**Table 3. Number of Times Clinical Signs Were Observed in 21 Days Post-Challenge.**

Dog ID	Group	High or Low Rectal Temp.	Ocular Congestion	Inappetence	Depression	Vomiting
AWK-7	A	0	0	0	0	1
RGL-7	A	0	0	0	0	0
SBL-7	A	0	6	0	0	3
SQK-7	A	0	0	0	0	0
TRL-7	A	0	0	0	0	0
UQL-7	A	0	0	0	0	1
URL-7	A	0	0	0	0	0
XCL-7	A	0	0	0	0	0
XSL-7	A	0	0	0	0	2
YHL-7	A	0	2	0	0	0
PUK-7	A	0	4	0	0	1
QEL-7	A	0	0	0	0	1
RRL-7	A	0	0	0	0	0
TAL-7	A	0	0	0	0	3
UJL-7	A	0	3	0	0	0
UXL-7	A	0	5	0	0	0
VZL-7	A	0	0	0	0	1
WDL-7	A	0	0	0	0	0
WIL-7	A	0	0	0	0	1
XGL-7	A	0	0	0	0	1
<b>Total</b>		<b>0</b>	<b>20</b>	<b>0</b>	<b>0</b>	<b>15</b>
PSL-7	B	3	3	3	4	2
QSK-7	B	0	5	2	0	3
RFL-7	B	0	2	2	2	1
ROL-7	B	1	3	3	4	2
SYL-7	B	1	5	2	0	0
XUK-7	B	1	2	2	2	1
SPL-7	B	1	8	6	2	5
TEK-7	B	2	2	2	3	2
TVK-7	B	2	3	3	4	2
TWL-7	B	2	5	5	3	4
<b>Total</b>		<b>13</b>	<b>38</b>	<b>30</b>	<b>24</b>	<b>22</b>

**Group A - Vaccinates; Group B - Controls**

**Table 3 continued on next page**

**Table 3 continued. Number of Times Clinical Signs Were Observed in 21 Days Post-Challenge.**

Dog ID	Group	Jaundice	Dehydration	Hematuria	Petechiae	Melena	Total Score
AWK-7	A	0	0	0	0	0	1
RGL-7	A	0	0	0	0	0	0
SBL-7	A	0	0	0	0	1	10
SQK-7	A	0	0	0	0	1	1
TRL-7	A	0	0	0	0	0	0
UQL-7	A	0	0	0	0	0	1
URL-7	A	0	0	0	0	0	0
XCL-7	A	0	0	0	0	0	0
XSL-7	A	0	0	0	0	2	4
YHL-7	A	0	0	0	0	2	4
PUK-7	A	0	0	0	0	0	5
QEL-7	A	0	0	0	0	0	1
RRL-7	A	0	0	0	0	0	0
TAL-7	A	0	0	0	0	2	5
UJL-7	A	0	0	1	0	2	6
UXL-7	A	0	0	0	0	0	5
VZL-7	A	0	0	0	0	0	1
WDL-7	A	0	0	0	0	2	2
WIL-7	A	0	0	1	0	0	2
XGL-7	A	0	0	0	0	2	3
<b>Total</b>		<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>14</b>	
PSL-7	B	0	2	1	1	4	23
QSK-7	B	0	2	1	0	7	20
RFL-7	B	0	1	1	0	1	10
ROL-7	B	1	1	2	1	2	20
SYL-7	B	0	0	1	0	2	11
XUK-7	B	0	2	1	0	3	14
SPL-7	B	0	7	0	4	7	40
TEK-7	B	0	2	1	2	3	19
TVK-7	B	1	2	1	1	2	21
TWL-7	B	0	2	1	2	4	28
<b>Total</b>		<b>2</b>	<b>21</b>	<b>10</b>	<b>11</b>	<b>35</b>	

**Group A - Vaccinates; Group B - Controls**

**Table 4. Clinical Observations Post-Challenge.**

Treatment Group	Dog ID	SD# 40	SD 41	SD 42*	SD 43*	SD 44	SD 45
A	AWK-7	-	-	-	-	-	-
A	RGL-7	-	-	-	-	-	-
A	SBL-7	-	-	-	-	C	-
A	SQK-7	-	-	-	M	-	-
A	TRL-7	-	-	-	-	-	-
A	UQL-7	-	-	-	-	-	V
A	URL-7	-	-	-	-	-	-
A	XCL-7	-	-	-	-	-	-
A	XSL-7	-	-	-	-	-	-
A	YHL-7	-	-	-	-	C	-
A	PUK-7	-	-	-	-	C	C
A	QEL-7	-	-	-	-	-	-
A	RRL-7	-	-	-	-	-	-
A	TAL-7	-	-	-	-	-	V
A	UJL-7	-	-	-	-	-	C
A	UXL-7	-	-	-	-	C	-
A	VZL-7	-	-	-	-	-	-
A	WDL-7	-	-	-	-	-	-
A	WIL-7	-	-	-	-	-	-
A	XGL-7	-	-	-	-	-	-
B	PSL-7	-	-	-	M	I,C,L1,M	I,C,L1,V,D,H,M
B	QSK-7	-	-	-	-	-	I,M
B	RFL-7	-	-	-	-	I,C	I,C,L2,V,D,H,M
B	ROL-7	-	-	-	-	I,C,L1,H	I,C,L1,V,M
B	SYL-7	-	-	-	H	-	I,M
B	XUK-7	-	-	-	-	I,C,L1,D,M	I,C,L1,V,D,H,M
B	SPL-7	-	-	-	-	V,C	I,V,M
B	TEK-7	-	-	-	-	-	I,H,M
B	TVK-7	-	-	-	-	I,C	I,C,L2,V,D,H,M
B	TWL-7	-	-	-	-	I,C,M	I,C,V,H

**Group A - Vaccinates; Group B – Controls;**

**#SD = Study Day**

**\* Challenge**

**(-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice; D = Dehydration; H = Hematuria; P = Petechiae; M = Melena; I = Inappetence**

**Table 4 continued next page**

**Table 4 continued. Clinical Observations Post-Challenge.**

Treatment Group	Dog ID	SD 46	SD 47	SD 48	SD 49
A	AWK-7	-	-	-	-
A	RGL-7	-	-	-	-
A	SBL-7	-	-	-	C
A	SQK-7	-	-	-	-
A	TRL-7	-	-	-	-
A	UQL-7	-	-	-	-
A	URL-7	-	-	-	-
A	XCL-7	-	-	-	-
A	XSL-7	-	-	-	-
A	YHL-7	C	-	-	M
A	PUK-7	C	-	-	-
A	QEL-7	-	-	-	-
A	RRL-7	-	-	-	-
A	TAL-7	-	-	-	-
A	UJL-7	C	-	-	-
A	UXL-7	C	-	C	C
A	VZL-7	-	V	-	-
A	WDL-7	-	-	-	-
A	WIL-7	V	-	-	-
A	XGL-7	-	M	-	-
B	PSL-7	I,C,L2,V,D,P,M	Dead	Dead	Dead
B	QSK-7	-	-	V,M	I,C,V,D,M
B	RFL-7	Dead	Dead	Dead	Dead
B	ROL-7	I,C,L2,V,J,D,H,P,M	Dead	Dead	Dead
B	SYL-7	I,M	-	C	C
B	XUK-7	M, Dead	Dead	Dead	Dead
B	SPL-7	C,V,D,M	I,C,L1,V,D,P,M	I,C,L1,D,P,M	I,C,D,P,M
B	TEK-7	I,C,L1,V,D,P,M	C,L2,V,D,P,M	Dead	Dead
B	TVK-7	I,C,L2,V,J,D,P,M	Dead	Dead	Dead
B	TWL-7	I,C,V,M	I,C,L2,V,D,P,M	I,C,L1,V,D,P,M	Dead

**Group A - Vaccinates; Group B – Controls;**

**# SD = Study Day**

**(-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice; D = Dehydration; H = Hematuria; P = Petechiae; M = Melena; I = Inappetence**

**Table 4 continued on next page**



**Table 4 continued. Clinical Observations Post-Challenge**

Treatment Group	Dog ID	SD# 50	SD 51	SD 52	SD 53	SD 54	SD 55	SD 56
A	AWK-7	-	-	-	-	-	V	-
A	RGL-7	-	-	-	-	-	-	-
A	SBL-7	C	M	C,V	C,V	C,V	-	-
A	SQK-7	-	-	-	-	-	-	-
A	TRL-7	-	-	-	-	-	-	-
A	UQL-7	-	-	-	-	-	-	-
A	URL-7	-	-	-	-	-	-	-
A	XCL-7	-	-	-	-	-	-	-
A	XSL-7	-	-	-	-	V	V,M	-
A	YHL-7	M	-	-	-	-	-	-
A	PUK-7	V	C	-	-	-	-	-
A	QEL-7	-	-	-	-	V	-	-
A	RRL-7	-	-	-	-	-	-	-
A	TAL-7	M	M	-	-	V	-	-
A	UJL-7	-	C	-	-	-	-	-
A	UXL-7	C	-	-	-	-	-	-
A	VZL-7	-	-	-	-	-	-	-
A	WDL-7	-	-	M	M	-	-	-
A	WIL-7	-	-	-	-	-	-	-
A	XGL-7	-	-	-	-	V	-	-
B	PSL-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	QSK-7	C,M	C,D,M	C,M	C,V,M	-	H	-
B	RFL-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	ROL-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	SYL-7	C	C	C	-	-	-	-
B	XUK-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	SPL-7	I,C,D,P,M	I,C,D,M	C,D	-	-	V	-
B	TEK-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	TVK-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	TWL-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead

**Group A - Vaccinates; Group B – Controls;**

**# SD = Study Day**

**(-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice; D = Dehydration; H = Hematuria; P = Petechiae; M = Melena; I = Inappetence**

**Table 4 contined on next page**

**Table 4 continued. Clinical Observations Post-Challenge**

Treatment Group	Dog ID	SD 57	SD 58	SD 59	SD 60	SD 61	SD 62	SD 63
A	AWK-7	-	-	-	-	-	-	-
A	RGL-7	-	-	-	-	-	-	-
A	SBL-7	-	-	-	-	-	-	-
A	SQK-7	-	-	-	-	-	-	-
A	TRL-7	-	-	-	-	-	-	-
A	UQL-7	-	-	-	-	-	-	-
A	URL-7	-	-	-	-	-	-	-
A	XCL-7	-	-	-	-	-	-	-
A	XSL-7	M	-	-	-	-	-	-
A	YHL-7	-	-	-	-	-	-	-
A	PUK-7	-	-	-	-	-	-	-
A	QEL-7	-	-	-	-	-	-	-
A	RRL-7	-	-	-	-	-	-	-
A	TAL-7	-	-	-	-	V	-	-
A	UJL-7	-	H,M	M	-	-	-	-
A	UXL-7	-	-	-	-	-	-	-
A	VZL-7	-	-	-	-	-	-	-
A	WDL-7	-	-	-	-	-	-	-
A	WIL-7	-	-	H	-	-	-	-
A	XGL-7	M	-	-	-	-	-	-
B	PSL-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	QSK-7	-	-	-	-	-	-	-
B	RFL-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	ROL-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	SYL-7	-	-	-	-	-	-	-
B	XUK-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	SPL-7	-	-	-	-	-	-	-
B	TEK-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	TVK-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	TWL-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead

**Group A - Vaccinates; Group B – Controls;**

**# SD = Study Day**

**(-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice; D = Dehydration; H = Hematuria; P = Petechiae; M = Melena; I = Inappetence**

<b>Study Type</b>	Efficacy				
<b>Pertaining to</b>	<i>Leptospira canicola</i>				
<b>Study Purpose</b>	To evaluate urinary shedding in vaccinated dogs following challenge with <i>L. canicola</i> .				
<b>Product Administration</b>	Two doses administered subcutaneously 21 days apart.				
<b>Study Animals</b>	36 dogs, sero-negative to all 4 Leptospira serovars, 8 weeks of age. 24 vaccinates, 12 controls.				
<b>Challenge Description</b>	All animals were challenged with <i>L. canicola</i> 14 days after the last vaccination.				
<b>Interval observed after challenge</b>	Animals were observed daily for 14 days post-challenge for clinical signs of leptospirosis. Urine samples were collected on days 10, 14, 17, 21, 24, 28, 31, and 35 post-challenge.				
<b>Results</b>	<p><b>Summary of Results</b> (See Table 1 for raw data)</p> <p><u>Urine Culture Results</u></p> <table> <tr> <td>Vaccinates</td> <td>0/24</td> </tr> <tr> <td>Controls*</td> <td>11/11</td> </tr> </table> <p>* One dog in the Control group died 4 days post-challenge due to severe clinical signs after challenge and data is not available.</p>	Vaccinates	0/24	Controls*	11/11
Vaccinates	0/24				
Controls*	11/11				
<b>USDA Approval Date</b>	October 28, 2011				

**Table 1. Leptospira Isolation from Urine**

Treatment Group	Dog ID	Day Post-Challenge							
		10	14	17	21	24	28	31	35
A (Vaccinates)	KFJ-0	o	o	o	o	o	o	o	o
	KGJ-0	o	o	o	o	o	o	o	o
	KII-0	o	o	o	o	o	o	o	o
	KJI-0	o	o	o	o	o	o	o	o
	KYJ-0	o	o	o	+	o	o	o	o
	KZI-0	o	o	o	o	o	o	o	o
	LBI-0	o	o	o	o	o	o	o	o
	LCJ-0	o	o	o	o	o	o	o	o
	LFJ-0	o	o	o	o	o	o	o	o
	LHJ-0	o	o	o	o	o	o	o	o
	LII-0	o	o	o	o	o	o	o	o
	LOJ-0	o	o	o	o	o	o	o	o
	LPJ-0	o	o	o	o	o	o	o	o
	LYI-0	o	o	o	o	o	o	o	o
	OBI-0	o	o	o	o	o	o	o	o
	OCI-0	o	o	o	o	o	o	o	o
	PII-0	o	o	o	o	o	o	o	+
	PZJ-0	o	o	o	o	o	o	o	o
	QCJ-0	o	o	o	o	o	o	o	o
	SBJ-0	o	o	o	o	o	o	o	o
SCJ-0	o	o	o	o	o	o	o	o	
SFI-0	o	o	o	o	o	o	o	o	
SGL-0	o	o	o	o	o	o	o	o	
SHK-0	o	o	o	o	o	o	o	o	
B (Controls)	KHI-0	+	+	+	+	+	+	+	+
	KXJ-0	+	+	+	+	+	o	+	+
	LAI-0	o	+	+	+	+	+	+	+
	LDJ-0	+	+	+	o	+	o	o	o
	LGI-0	+	+	o	+	+	+	o	o
	LZI-0	o	+	+	+	o	+	o	+
	OAJ-0	+	+	+	o	+	+	+	+
	QAJ-0	+	+	+	+	+	+	+	o
	QBJ-0	+	+	o	+	+	+	+	+
	SDJ-0	+	+	+	o	+	+	+	+
SEI-0	+	+	+	+	+	+	+	+	

**o = culture negative**  
**+ = culture positive**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira grippotyphosa</i>
<b>Study Purpose</b>	Pivotal efficacy against leptospirosis due to <i>L. grippotyphosa</i>
<b>Product Administration</b>	Two doses were administered subcutaneously (SC) 21 days apart.
<b>Study Animals</b>	7- to 8-week-old dogs, sero-negative for antibodies specific to <i>Leptospira</i> ; 20 vaccinates and 10 controls
<b>Challenge Description</b>	All animals were challenged with <i>L. grippotyphosa</i> Day 35, Day 36, and Day 37 after the last vaccination.
<b>Interval observed after challenge</b>	Clinical signs, including fever, were monitored daily for 21 days post-challenge. Tissues were examined on day 21 post challenge or on the day when the dog died if earlier than day 21.
<b>Results</b>	<p><b>Summary of Results:</b></p> <p><u>Summary of Mortality after Challenge</u>  Vaccinates            0/20  Controls                4/10</p> <p><u>Summary of Isolation from Tissues</u>  Vaccinates            0/20  Controls                9/10</p> <p><b>See the attached tables for raw data for this study:</b></p> <p>Table 1. Mortality  Table 2. <i>Leptospira</i> Isolation from Tissues Collected at End of Study  Table 3. Number of Times Clinical Signs Were Observed in 21 Days Post-Challenge  Table 4. Clinical Observations Post-Challenge</p>
<b>USDA Approval Date</b>	September 22, 2008

**Table 1. Mortality**

<b>Treatment Group</b>	<b>Dog ID</b>	<b>Mortality</b>
A	KTO-7	No
	KWP-7	No
	LBP-7	No
	LSO-7	No
	LYP-7	No
	PAP-7	No
	PJO-7	No
	PPP-7	No
	PWO-7	No
	QKO-7	No
	QSP-7	No
	QWP-7	No
	RCP-7	No
	RHP-7	No
	RYP-7	No
	SFP-7	No
	SLP-7	No
	THP-7	No
	TQP-7	No
TVP-7	No	
B	LPP-7	No
	OA0-7	Yes
	PGP-7	Yes
	PSP-7	No
	QHP-7	No
	QUO-7	No
	SAO-7	No
	SYP-7	No
	TEP-7	Yes
	TRO-7	Yes

**Group A – Vaccinates; Group B - Controls**

**Table 2. Leptospira Isolation from Tissues Collected at End of Study**

Treatment Group	Dog ID	Kidney	Liver	Urine/ Bladder
A	KTO-7	0	0	0
	KWP-7	0	0	0
	LBP-7	0	0	0
	LSO-7	0	0	0
	LYP-7	0	0	0
	PAP-7	0	0	0
	PJO-7	0	0	0
	PPP-7	0	0	0
	PWO-7	0	0	0
	QKO-7	0	0	0
	QSP-7	0	0	0
	QWP-7	0	0	0
	RCP-7	0	0	0
	RHP-7	0	0	0
	RYP-7	0	0	0
	SFP-7	0	0	0
	SLP-7	0	0	0
	THP-7	0	0	0
	TQP-7	0	0	0
	TVP-7	0	0	0
B	LPP-7	2	0	0
	OAO-7	2	2	0
	PGP-7	2	2	2
	PSP-7	2	0	1
	QHP-7	0	0	0
	QUO-7	2	0	0
	SAO-7	2	0	0
	SYP-7	2	0	2
	TEP-7	2	2	2
	TRO-7	2	2	2

**Group A - Vaccinates**  
**Group B - Controls**

**2 = Isolated from the original culture**  
**1 = Isolated from subculture**  
**0 = Negative culture**

**Table 3. Number of Times Clinical Signs Were Observed in 21 Days Post-Challenge**

Treatment Group	Dog ID	Low/High Rectal Temps.	Inappetance	Ocular Congestion	Depression/ Lethargy	Vomiting
A	KTO-7	1	1	1	0	0
	KWP-7	1	0	2	1	1
	LBP-7	0	0	1	0	1
	LSO-7	0	1	1	0	0
	LYP-7	0	0	0	0	1
	PAP-7	0	0	0	0	0
	PJO-7	1	0	0	0	0
	PPP-7	0	0	1	0	0
	PWO-7	1	2	2	1	1
	QKO-7	0	0	1	0	0
	QSP-7	0	0	0	0	0
	QWP-7	0	1	0	0	0
	RCP-7	2	1	0	1	0
	RHP-7	0	1	0	0	1
	RYP-7	0	1	0	1	0
	SFP-7	1	0	1	1	0
	SLP-7	1	2	4	0	3
	THP-7	1	1	0	1	0
	TQP-7	0	1	0	1	0
TVP-7	0	3	1	1	1	
<b>Total</b>		<b>9</b>	<b>15</b>	<b>15</b>	<b>8</b>	<b>9</b>
B	LPP-7	3	5	5	7	0
	OAO-7	3	4	3	5	2
	PGP-7	1	5	2	5	1
	PSP-7	2	5	4	0	2
	QHP-7	2	6	4	3	0
	QUO-7	5	13	5	14	0
	SAO-7	4	10	5	9	1
	SYP-7	2	3	7	5	1
	TEP-7	2	2	0	4	2
TRO-7	1	3	0	4	2	
<b>Total</b>		<b>25</b>	<b>56</b>	<b>35</b>	<b>56</b>	<b>11</b>

**Group A - Vaccinates; Group B – Controls**

Table 3 continued on next page



**Table 3 continued. Number of Times Clinical Signs Were Observed in 21 Days Post-Challenge**

Treatment Group	Dog ID	Jaundice	Dehydration	Hematuria	Melena	Petechiae	Total Score
A	KTO-7	0	0	0	2	0	5
	KWP-7	0	0	0	1	0	6
	LBP-7	0	0	0	0	0	2
	LSO-7	0	0	0	0	0	2
	LYP-7	0	0	0	1	0	2
	PAP-7	0	0	0	0	0	0
	PJO-7	0	0	0	0	0	1
	PPP-7	0	0	0	0	0	1
	PWO-7	0	0	0	1	0	8
	QKO-7	0	0	0	0	0	1
	QSP-7	0	0	0	0	0	0
	QWP-7	0	0	0	0	0	1
	RCP-7	0	0	0	0	0	4
	RHP-7	0	1	0	1	0	4
	RYP-7	0	0	0	0	0	2
	SFP-7	0	0	0	0	0	3
	SLP-7	0	0	1	2	0	14
	THP-7	0	0	0	0	0	3
	TQP-7	0	0	0	1	0	3
	TVP-7	0	0	0	0	2	0
<b>Total</b>		<b>0</b>	<b>1</b>	<b>1</b>	<b>11</b>	<b>0</b>	
B	LPP-7	0	4	3	3	1	31
	OAO-7	1	3	1	3	3	28
	PGP-7	1	3	3	2	1	24
	PSP-7	0	0	3	2	1	19
	QHP-7	0	0	1	4	0	20
	QUO-7	6	13	3	7	1	66
	SAO-7	6	11	4	3	0	53
	SYP-7	0	0	0	1	0	19
	TEP-7	0	1	1	2	0	14
	TRO-7	0	1	0	2	0	13
<b>Total</b>		<b>14</b>	<b>36</b>	<b>19</b>	<b>29</b>	<b>7</b>	

**Group A - Vaccinates; Group B - Controls**

**Table 4. Clinical Observations Post-Challenge**

Treatment Group	Dog ID	SD# 54	SD 55	SD 56	SD 57*	SD 58*	SD 59
A	KTO-7	-	-	-	-	-	I,M
	KWP-7	-	-	-	-	-	-
	LBP-7	-	-	-	-	-	-
	LSO-7	-	-	-	-	-	I,C
	LYP-7	-	-	-	-	-	-
	PAP-7	-	-	-	-	-	-
	PJO-7	-	-	-	-	-	-
	PPP-7	-	-	-	-	-	-
	PWO-7	-	-	-	-	-	-
	QKO-7	-	-	-	-	-	-
	QSP-7	-	-	-	-	-	-
	QWP-7	-	-	-	-	-	I
	RCP-7	-	-	-	-	-	-
	RHP-7	-	-	-	-	-	-
	RYP-7	-	-	-	-	-	-
	SFP-7	-	-	-	-	-	-
	SLP-7	-	-	-	-	-	-
THP-7	-	-	-	-	I,L1	-	
TQP-7	-	-	-	-	I,L1	-	
TVP-7	-	-	-	-	-	-	
B	LPP-7	-	-	-	-	I,L1	I,C,L2,D,M
	OAO-7	-	-	-	-	-	I,L1,V,M
	PGP-7	-	-	-	-	I	I
	PSP-7	-	-	-	-	-	I
	QHP-7	-	-	-	-	L1	I,L1,M
	QUO-7	-	-	-	-	I,L1	I,L1
	SAO-7	-	-	-	-	-	I,L1,D
	SYP-7	-	-	-	-	L1	I,C,L1,V
	TEP-7	-	-	-	-	L1	I,L1,V,M
TRO-7	-	-	-	-	I,L1	I,L1,V,M	

Group A - Vaccinates; Group B – Controls; # SD = Study Day; \* = Challenge administration days  
 (-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice; D = Dehydration; H = Hematuria; P = Petechiae; M = Melena; I = Inappetence

Table 4 continued on next page

Table 4 continued. Clinical Observations Post-Challenge

Treatment Group	Dog ID	SD 60	SD 61	SD 62	SD 63	SD 64
A	KTO-7	C	-	-	-	-
	KWP-7	-	C,L1,V,M	C	-	-
	LBP-7	-	-	-	C,V	-
	LSO-7	-	-	-	-	-
	LYP-7	-	V,M	-	-	-
	PAP-7	-	-	-	-	-
	PJO-7	-	-	-	-	-
	PPP-7	C	-	-	-	-
	PWO-7	I,C,L1,V,M	I,C	-	-	-
	QKO-7	C	-	-	-	-
	QSP-7	-	-	-	-	-
	QWP-7	-	-	-	-	-
	RCP-7	I,L1	-	-	-	-
	RHP-7	-	-	I,V,D,M	-	-
	RYP-7	I,L1	-	-	-	-
	SFP-7	C,L1	-	-	-	-
	SLP-7	I,C,V,M	I,C,V,H,M	C	C	-
THP-7	-	-	-	-	-	
TQP-7	-	M	-	-	-	
TVP-7	I,C,L1,V,M	I,M	-	-	-	
B	LPP-7	I,C,L2,D,H,M	I,C,L1,D,H,P,M	I,C,L1,D,H	C	-
	OAO-7	I,C,L1,V,D,P,M	I,C,L1,D,P	I,C,L2,J,D,H,P,M	Dead	Dead
	PGP-7	I,L2,V,D,H,M	I,C,L1,D,H,M	I,C,L2,J,D,H,P	Dead	Dead
	PSP-7	I,V	I,C,P	I,C,V,H,M	I,C,H,M	C,H
	QHP-7	I,L1	I,C,H,M	I,C,M	I,C,M	I,C
	QUO-7	I,C,L2,D,M	I,C,L1,D,M	I,C,L1,J,D,H,P	I,C,L1,J,D,H,M	I,C,J,D,H
	SAO-7	I,C,L2,V,D,M	I,C,L1,J,D,H,M	I,C,L2,J,D,H,M	I,C,L1,J,D	I,C,L1,J,D,H
	SYP-7	I,C,L2,M	I,C,L1	C	C	C
	TEP-7	I,L2,V,D,H,M	Dead	Dead	Dead	Dead
	TRO-7	I,L2,V,D,M	Dead	Dead	Dead	Dead

Group A - Vaccinates; Group B – Controls; # SD = Study Day; \* = Challenge administration days  
 (-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice; D = Dehydration; H = Hematuria; P = Petechiae; M = Melena; I = Inappetence

Table 4 continued on next page

**Table 4 continued. Clinical Observations Post-Challenge**

Treatment Group	Dog ID	SD# 65	SD 66	SD 67	SD 68	SD 69	SD 70
A	KTO-7	-	M	-	-	-	-
	KWP-7	-	-	-	-	-	-
	LBP-7	-	-	-	-	-	-
	LSO-7	-	-	-	-	-	-
	LYP-7	-	-	-	-	-	-
	PAP-7	-	-	-	-	-	-
	PJO-7	-	-	-	-	-	-
	PPP-7	-	-	-	-	-	-
	PWO-7	-	-	-	-	-	-
	QKO-7	-	-	-	-	-	-
	QSP-7	-	-	-	-	-	-
	QWP-7	-	-	-	-	-	-
	RCP-7	-	-	-	-	-	-
	RHP-7	-	-	-	-	-	-
	RYP-7	-	-	-	-	-	-
	SFP-7	-	-	-	-	-	-
	SLP-7	-	-	-	-	-	-
	THP-7	-	-	-	-	-	-
TQP-7	-	-	-	-	-	-	
TVP-7	-	I	-	-	-	-	
B	LPP-7	-	-	-	-	-	-
	OAD-7	Dead	Dead	Dead	Dead	Dead	Dead
	PGP-7	Dead	Dead	Dead	Dead	Dead	Dead
	PSP-7	-	-	-	-	-	-
	QHP-7	-	-	-	-	-	-
	QUO-7	I,L1,D	I,L1,D,M	I,J,D,M	I,J,D,M	I,L1,J,D,M	L1,D
	SAO-7	I,L1,D,H	I	I,J,D	I,J,D	D	D
	SYP-7	-	C	-	-	-	-
	TEP-7	Dead	Dead	Dead	Dead	Dead	Dead
	TRO-7	Dead	Dead	Dead	Dead	Dead	Dead

**Group A - Vaccinates; Group B – Controls; # SD = Study Day**

**(-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice; D = Dehydration; H = Hematuria; P = Petechiae; M = Melena; I = Inappetence**

**Table 4 continued on next page**

**Table 4 continued. Clinical Observations Post-Challenge**

Treatment Group	Dog ID	SD 71	SD 72	SD 73	SD 74	SD 75	SD 76	SD 77
A	KTO-7	-	-	-	-	-	-	-
	KWP-7	-	-	-	-	-	-	-
	LBP-7	-	-	-	-	-	-	-
	LSO-7	-	-	-	-	-	-	-
	LYP-7	-	-	-	-	-	-	-
	PAP-7	-	-	-	-	-	-	-
	PJO-7	-	-	-	-	-	-	-
	PPP-7	-	-	-	-	-	-	-
	PWO-7	-	-	-	-	-	-	-
	QKO-7	-	-	-	-	-	-	-
	QSP-7	-	-	-	-	-	-	-
	QWP-7	-	-	-	-	-	-	-
	RCP-7	-	-	-	-	-	-	-
	RHP-7	-	-	-	-	-	-	-
	RYP-7	-	-	-	-	-	-	-
	SFP-7	-	-	-	-	-	-	-
	SLP-7	-	-	-	-	-	V	-
THP-7	-	-	-	-	-	-	-	
TQP-7	-	-	-	-	-	-	-	
TVP-7	-	-	-	-	-	-	-	
B	LPP-7	-	-	-	-	-	-	-
	OAD-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
	PGP-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
	PSP-7	-	-	-	-	-	-	-
	QHP-7	-	-	-	-	-	-	-
	QUO-7	-	-	-	-	-	L2,D	I,L1,D
	SAO-7	-	-	-	-	-	-	-
	SYP-7	-	-	-	-	-	-	-
	TEP-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
TRO-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead	

**Group A - Vaccinates; Group B – Controls; # SD = Study Day**  
**(-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice; D = Dehydration; H = Hematuria; P = Petechiae; M = Melena; I = Inappetence**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira grippotyphosa</i>
<b>Study Purpose</b>	To evaluate urinary shedding in vaccinated dogs following challenge with <i>L. grippotyphosa</i> ..
<b>Product Administration</b>	Two doses administered subcutaneously 21 days apart.
<b>Study Animals</b>	35 dogs, sero-negative to all 4 Leptospira serovars, 7-8 weeks of age. 23 vaccinates, 12controls.
<b>Challenge Description</b>	All animals were challenged with <i>L. grippotyphosa</i> 14 days after the last vaccination.
<b>Interval observed after challenge</b>	Animals were observed daily for 14 days post-challenge for clinical signs of leptospirosis. Urine samples were collected on days 9, 13, 16, 20, 23, 27, 29, and 35 postchallenge.
<b>Results</b>	<p><b>Summary of Results (See Table 1 for raw data)</b></p> <p><u>Urine Culture Results</u></p> <p>Vaccinates    0/23</p> <p>Controls*     11/11</p> <p>* One in the Control group died 6 days post-challenge due to severe clinical signs after challenge and data is not available.</p>
<b>USDA Approval Date</b>	October 28, 2011

**Table 1. Leptospira Isolation from Urine**

Treatment Group	Dog ID	Day Post-Challenge							
		9	13	16	20	23	27	29	35
A (Vaccinates)	CBPEAH	0	0	0	0	0	0	0	0
	CBPEAZ	0	0	0	0	0	0	0	0
	CBPEBA	0	0	0	0	0	0	0	0
	CBPEBI	0	0	0	0	0	0	0	0
	CBPEBJ	0	0	0	0	0	0	0	0
	CBPEBK	0	0	0	0	0	0	0	0
	CBPEBM	0	0	0	0	0	0	0	0
	CBPEBW	0	0	0	0	0	0	0	0
	CBPEBZ	0	0	0	0	0	0	0	0
	CBPECC	0	0	0	0	0	0	0	0
	CBPECE	0	0	0	0	0	0	0	0
	CBPECN	0	0	0	0	0	0	0	0
	CBPECS	0	0	0	0	0	0	0	0
	CBPECV	0	0	0	0	0	0	0	0
	CBPEDA	0	0	0	0	0	0	0	0
	CBPEDF	0	0	0	0	0	0	0	0
	CBPEDG	0	0	0	0	0	0	0	0
	CBPEDK	0	0	0	0	0	0	0	0
	CBPEDT	0	0	0	0	0	0	0	0
	CBPEEC	0	0	0	0	0	0	0	0
CBPEEM	0	0	0	0	0	0	0	0	
CBPEFE	0	0	0	0	0	0	0	0	
CBPEFF	0	0	0	0	0	0	0	0	
B (Controls)	CBPEAN	0	+	0	+	+	+	+	0
	CBPEBE	0	+	+	+	0	+	+	0
	CBPEBP	0	0	+	+	+	+	+	+
	CBPEBX	0	0	0	0	+	0	+	0
	CBPEBY	+	+	+	0	+	+	+	0
	CBPECB	0	+	+	0	0	0	0	0
	CBPECG	0	0	0	+	+	0	0	0
	CBPECR	0	0	+	+	+	+	+	0
	CBPEDH	0	0	+	+	0	+	+	0
	CBPEDJ	0	0	0	+	0	+	0	0
CBPEFC	+	+	0	+	+	+	0	0	

**0 = culture negative**  
**+ = culture positive**

<b>Study Type</b>	Efficacy								
<b>Pertaining to</b>	<i>Leptospira icterohaemorrhagiae</i>								
<b>Study Purpose</b>	Pivotal efficacy against leptospirosis due to <i>L. icterohaemorrhagiae</i>								
<b>Product Administration</b>	Two doses were administered subcutaneously (SC) 21 days apart.								
<b>Study Animals</b>	7- to 8-week-old dogs, sero-negative for antibodies specific to <i>Leptospira</i> ; 20 vaccinates and 10 controls.								
<b>Challenge Description</b>	All animals were challenged with <i>L. grippityphosa</i> on Day 28 and 29 after the last vaccination.								
<b>Interval observed after challenge</b>	Clinical signs, including fever, were monitored daily until 21 days after challenge. Tissues were examined on day 21 post challenge or on the day when the dog died if earlier than day 21.								
<b>Results</b>	<p><b>Summary of Results:</b></p> <p><u>Summary of Mortality after Challenge</u></p> <table> <tr> <td>Vaccinates</td> <td>0/20</td> </tr> <tr> <td>Controls</td> <td>6/10</td> </tr> </table> <p><u>Summary of Isolation from Tissues</u></p> <table> <tr> <td>Vaccinates</td> <td>0/20</td> </tr> <tr> <td>Controls</td> <td>10/10</td> </tr> </table> <p><b>See the attached tables for raw data for this study:</b></p> <p>Table 1. Mortality  Table 2. <i>Leptospira</i> Isolation from Tissues Collected at End of Study  Table 3. Number of Times Clinical Signs Were Observed in 21 Days Post-Challenge  Table 4. Clinical Observations Post-Challenge</p>	Vaccinates	0/20	Controls	6/10	Vaccinates	0/20	Controls	10/10
Vaccinates	0/20								
Controls	6/10								
Vaccinates	0/20								
Controls	10/10								
<b>USDA Approval Date</b>	September 18, 2008								



**Table 1. Mortality**

<b>Treatment Group</b>	<b>Dog ID</b>	<b>Mortality</b>
A	PRL-7	No
	QDL-7	No
	QTK-7	No
	REL-7	No
	RPL-7	No
	RSK-7	No
	SAL-7	No
	SWL-7	No
	TBL-7	No
	TTK-7	No
	UPK-7	No
	USL-7	No
	VBL-7	No
	VYL-7	No
	WFL-7	No
	WHL-7	No
	XDL-7	No
	XHL-7	No
	XRL-7	No
	YGL-7	No
B	AUK-7	Yes
	PTK-7	No
	QRL-7	No
	RHL-7	Yes
	RQL-7	Yes
	SUL-7	No
	TDK-7	Yes
	UIL-7	Yes
	WAK-7	No
	XBL-7	Yes

**Group A – Vaccinates; Group B - Controls**

**Table 2. Leptospira Isolation from Tissues Collected at End of Study**

Treatment Group	Dog ID	Kidney	Liver	Urine/Bladder
A	PRL-7	0	0	0
	QDL-7	0	0	0
	QTK-7	0	0	0
	REL-7	0	0	0
	RPL-7	0	0	0
	RSK-7	0	0	0
	SAL-7	0	0	0
	SWL-7	0	0	0
	TBL-7	0	0	0
	TTK-7	0	0	0
	UPK-7	0	0	0
	USL-7	0	0	0
	VBL-7	0	0	0
	VYL-7	0	0	0
	WFL-7	0	0	0
	WHL-7	0	0	0
	XDL-7	0	0	0
	XHL-7	0	0	0
	XRL-7	0	0	0
	YGL-7	0	0	0
B	AUK-7	2	2	2
	PTK-7	2	0	0
	QRL-7	2	0	0
	RHL-7	2	2	2
	RQL-7	2	2	2
	SUL-7	2	0	1
	TDK-7	2	2	2
	UIL-7	2	2	2
	WAK-7	2	0	0
	XBL-7	2	2	2

**Group A - Vaccinates**

**Group B - Controls**

**2 = Isolated from the original culture**

**1 = Isolated from subculture**

**0 = Negative culture**

**Table 3. Number of Times Clinical Signs Were Observed in 21 Days Post-Challenge**

Treatment Group	Dog ID	Low/High Rect. Temps.	Inappetance	Ocular Congestion	Depression/Lethargy	Vomiting
A	PRL-7	0	0	0	0	0
	QDL-7	1	0	1	0	0
	QTK-7	2	0	0	0	1
	REL-7	0	0	0	0	0
	RPL-7	0	0	6	0	0
	RSK-7	0	0	2	0	0
	SAL-7	2	0	1	0	0
	SWL-7	0	0	0	0	0
	TBL-7	0	0	0	0	0
	TTK-7	0	0	4	0	1
	UPK-7	0	0	0	0	0
	USL-7	0	0	0	0	1
	VBL-7	0	0	6	0	1
	VYL-7	0	0	3	0	0
	WFL-7	0	0	0	0	0
	WHL-7	0	0	4	0	0
	XDL-7	1	0	8	0	0
XHL-7	0	0	0	0	0	
XRL-7	0	0	5	0	1	
YGL-7	0	0	4	0	2	
<b>Total</b>		<b>6</b>	<b>0</b>	<b>44</b>	<b>0</b>	<b>7</b>
B	AUK-7	1	1	1	2	1
	PTK-7	1	1	10	2	1
	QRL-7	4	1	4	1	3
	RHL-7	3	3	2	5	3
	RQL-7	2	2	2	4	2
	SUL-7	4	1	8	1	1
	TDK-7	2	2	2	2	2
	UIL-7	1	2	1	3	2
	WAK-7	2	1	8	0	0
	XBL-7	2	2	2	3	2
<b>Total</b>		<b>22</b>	<b>16</b>	<b>40</b>	<b>23</b>	<b>17</b>

Group A - Vaccinates; Group B – Controls  
 Table 3 continued on next page

**Table 3 continued. Summary of Clinical Signs Post-Challenge**

Treatment Group	Dog ID	Jaundice	Dehydration	Hematuria	Melena	Petechiae	Total Score
A	PRL-7	0	0	0	1	0	1
	QDL-7	0	0	0	0	0	2
	QTK-7	0	0	0	1	0	4
	REL-7	0	0	0	0	0	0
	RPL-7	0	0	0	0	0	6
	RSK-7	0	0	0	0	0	2
	SAL-7	0	0	0	0	0	3
	SWL-7	0	0	0	0	0	0
	TBL-7	0	0	0	0	0	0
	TTK-7	0	0	0	2	0	7
	UPK-7	0	0	0	0	0	0
	USL-7	0	0	0	0	0	1
	VBL-7	0	0	0	0	0	7
	VYL-7	0	0	0	0	0	3
	WFL-7	0	0	0	0	0	0
	WHL-7	0	0	0	0	0	4
	XDL-7	0	0	0	0	0	9
	XHL-7	0	0	0	0	1	1
XRL-7	0	0	0	2	0	8	
YGL-7	0	0	0	0	0	0	6
<b>Total</b>		<b>0</b>	<b>0</b>	<b>0</b>	<b>7</b>	<b>0</b>	
B	AUK-7	1	1	1	2	0	11
	PTK-7	0	0	0	1	0	16
	QRL-7	0	0	0	5	0	18
	RHL-7	1	2	1	3	0	23
	RQL-7	1	1	2	2	0	18
	SUL-7	0	0	0	2	0	17
	TDK-7	0	0	1	2	0	13
	UIL-7	1	0	1	1	0	12
	WAK-7	0	0	0	1	0	12
	XBL-7	0	0	1	2	0	14
<b>Total</b>		<b>4</b>	<b>4</b>	<b>7</b>	<b>21</b>	<b>0</b>	

**Group A - Vaccinates; Group B - Controls**

**Table 4. Clinical Observations Post-Challenge.**

Treatment Group	Dog ID	SD# 47	SD 48	SD 49*	SD 50*	SD 51	SD 52
A	PRL-7	-	-	-	-	-	-
	QDL-7	-	-	-	-	-	-
	QTK-7	-	-	-	-	-	-
	REL-7	-	-	-	-	-	-
	RPL-7	-	-	-	-	-	C
	RSK-7	-	-	-	-	-	-
	SAL-7	-	-	-	-	-	-
	SWL-7	-	-	-	-	-	-
	TBL-7	-	-	-	-	-	-
	TTK-7	-	-	-	-	-	V
	UPK-7	-	-	-	-	-	-
	USL-7	-	-	-	-	-	-
	VBL-7	-	-	-	-	-	-
	VYL-7	-	-	-	-	-	-
	WFL-7	-	-	-	-	-	-
	WHL-7	-	-	-	-	-	C
	XDL-7	-	-	-	-	-	-
XHL-7	-	-	-	-	-	-	
XRL-7	-	-	-	-	-	-	
YGL-7	-	-	-	-	-	-	
B	AUK-7	-	-	-	-	-	I,C,M
	PTK-7	-	-	-	-	L1	I,C,L1,V,M
	QRL-7	-	-	-	-	L1,M	I,C,M
	RHL-7	-	-	-	-	L1	I,L1,V,H,M
	RQL-7	-	-	-	-	-	I,C,L2,V,H,M
	SUL-7	-	-	-	-	-	-
	TDK-7	-	-	-	-	-	I,C,L1,V,H,M
	UIL-7	-	-	-	-	-	I,L1,V,H
	WAK-7	-	-	-	-	-	I
	XBL-7	-	-	-	-	-	I,C,L2,V,H,M

**Group A = Vaccinates; Group B = Controls**

**# SD = Study Day**

**\* = Challenge administration days**

**(-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice; D = Dehydration; H = Hematuria; M = Melena; I = Inappetence**

**Table 4 continued next page**

**Table 4 continued. Clinical Observations Post-Challenge.**

Treatment Group	Dog ID	SD 53	SD 54	SD 55	SD 56	SD 57	SD 58
A	PRL-7	-	-	-	-	-	-
	QDL-7	C	-	-	-	-	-
	QTK-7	-	-	-	-	-	-
	REL-7	-	-	-	-	-	-
	RPL-7	C	-	-	-	-	-
	RSK-7	C	C	-	-	-	-
	SAL-7	-	C	-	-	-	-
	SWL-7	-	-	-	-	-	-
	TBL-7	-	-	-	-	-	-
	TTK-7	C	C	-	-	-	-
	UPK-7	-	-	-	-	-	-
	USL-7	-	-	-	V	-	-
	VBL-7	-	-	C,V	C	-	-
	VYL-7	-	-	-	-	C	-
	WFL-7	-	-	-	-	-	-
	WHL-7	-	C	-	-	-	-
	XDL-7	-	C	C	C	C	C
XHL-7	-	-	-	M	-	-	
XRL-7	-	C,M	C	-	M	-	
YGL-7	C	C	-	-	-	V	
B	AUK-7	-	L2,V,J,D,H,M	Dead	Dead	Dead	Dead
	PTK-7	C	-	C	C	C	C
	QRL-7	C	C	VM	-	V,M	V
	RHL-7	I,C,L1,V,D,M	I,C,L2,V,J,D,M	Dead	Dead	Dead	Dead
	RQL-7	I,C,L2,V,J,D,H,M	Dead	Dead	Dead	Dead	Dead
	SUL-7	C,L1,V,M	C	C	I,C,M	C	-
	TDK-7	I,C,L1,V,M	Dead	Dead	Dead	Dead	Dead
	UIL-7	I,C,L2,V,J,M	Dead	Dead	Dead	Dead	Dead
	WAK-7	-	C	C	C	C	C
XBL-7	I,C,L1,V,M	Dead	Dead	Dead	Dead	Dead	

**Group A = Vaccinates; Group B = Controls**

**# SD = Study Day**

**(-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice; D = Dehydration; H = Hematuria; M = Melena; I = Inappetence**

**Table 4 continued on next page**

**Table 4 continued. Clinical Observations Post-Challenge**

Treatment Group	Dog ID	SD# 59	SD 60	SD 61	SD 62	SD 63	SD 64
A	PRL-7	-	-	-	-	-	M
	QDL-7	-	-	-	-	-	-
	QTK-7	-	-	V,M	-	-	-
	REL-7	-	-	-	-	-	-
	RPL-7	-	-	-	C	-	C
	RSK-7	-	-	-	-	-	-
	SAL-7	-	-	-	-	-	-
	SWL-7	-	-	-	-	-	-
	TBL-7	-	-	-	-	-	-
	TTK-7	-	-	-	-	M	C,M
	UPK-7	-	-	-	-	-	-
	USL-7	-	-	-	-	-	-
	VBL-7	-	-	-	C	-	C
	VYL-7	-	-	-	C	-	C
	WFL-7	-	-	-	-	-	-
	WHL-7	C	C	-	-	-	-
XDL-7	-	-	-	-	-	C	
XHL-7	-	-	-	-	-	-	
XRL-7	-	-	-	-	-	C	
YGL-7	-	-	-	-	-	C	
B	AUK-7	Dead	Dead	Dead	Dead	Dead	Dead
	PTK-7	C	C	-	C	-	C
	QRL-7	-	-	-	-	-	C,M
	RHL-7	Dead	Dead	Dead	Dead	Dead	Dead
	RQL-7	Dead	Dead	Dead	Dead	Dead	Dead
	SUL-7	C	-	-	C	-	C
	TDK-7	Dead	Dead	Dead	Dead	Dead	Dead
	UIL-7	Dead	Dead	Dead	Dead	Dead	Dead
	WAK-7	C	C	-	C	-	M
	XBL-7	Dead	Dead	Dead	Dead	Dead	Dead

**Group A = Vaccinates; Group B = Controls**

**# SD = Study Day**

**(-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice; D = Dehydration; H = Hematuria; M = Melena; I = Inappetence**

**Table 4 contined on next page**

**Table 4. Clinical Observations Post-Challenge**

Treatment Group	Dog ID	SD 65	SD 66	SD 67	SD 68	SD 69	SD 70
A	PRL-7	-	-	-	-	-	-
	QDL-7	-	-	-	-	-	-
	QTK-7	-	-	-	-	-	-
	REL-7	-	-	-	-	-	-
	RPL-7	C	C	-	-	-	-
	RSK-7	-	-	-	-	-	-
	SAL-7	-	-	-	-	-	-
	SWL-7	-	-	-	-	-	-
	TBL-7	-	-	-	-	-	-
	TTK-7	-	C	-	-	-	-
	UPK-7	-	-	-	-	-	-
	USL-7	-	-	-	-	-	-
	VBL-7	C	C	-	-	-	-
	VYL-7	-	-	-	-	-	-
	WFL-7	-	-	-	-	-	-
	WHL-7	-	-	-	-	-	-
XDL-7	C	C	-	-	-	-	
XHL-7	-	-	-	-	-	-	
XRL-7	C	C	-	-	-	V	
YGL-7	C	-	-	-	-	V	
B	AUK-7	Dead	Dead	Dead	Dead	Dead	Dead
	PTK-7	-	-	-	-	-	-
	QRL-7	-	-	-	-	-	-
	RHL-7	Dead	Dead	Dead	Dead	Dead	Dead
	RQL-7	Dead	Dead	Dead	Dead	Dead	Dead
	SUL-7	-	-	-	-	-	-
	TDK-7	Dead	Dead	Dead	Dead	Dead	Dead
	UIL-7	Dead	Dead	Dead	Dead	Dead	Dead
	WAK-7	-	-	-	-	-	-
	XBL-7	Dead	Dead	Dead	Dead	Dead	Dead

**Group A = Vaccinates; Group B = Controls**

**# SD = Study Day**

**(-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice; D = Dehydration; H = Hematuria; M = Melena; I = Inappetence**



<b>Study Type</b>	Efficacy				
<b>Pertaining to</b>	<i>Leptospira icterohaemorrhagiae</i>				
<b>Study Purpose</b>	To evaluate urinary shedding in vaccinated dogs following challenge with <i>L. icterohaemorrhagiae</i> .				
<b>Product Administration</b>	Two doses administered subcutaneously 21 days apart.				
<b>Study Animals</b>	36 dogs, sero-negative to all 4 Leptospira serovars, 8 weeks of age. 24 vaccinates, 10 controls.				
<b>Challenge Description</b>	All animals were challenged with <i>L. icterohaemorrhagiae</i> 21 days after the last vaccination.				
<b>Interval observed after challenge</b>	Animals were observed daily for 14 days post-challenge for clinical signs of leptospirosis. Urine samples were collected on days 10, 14, 17, 21, 24, 28, 31, and 35 post-challenge.				
<b>Results</b>	<p><b>Summary of Results</b> (See Table 1 for raw data)</p> <p><u>Urine Culture Results</u></p> <table> <tr> <td>Vaccinates</td> <td>0/24</td> </tr> <tr> <td>Controls*</td> <td>8/10</td> </tr> </table> <p>* Two dogs in the Control group died 6 days post-challenge due to severe clinical signs after challenge and data is not available.</p>	Vaccinates	0/24	Controls*	8/10
Vaccinates	0/24				
Controls*	8/10				
<b>USDA Approval Date</b>	October 28, 2011				

**Table 1. Leptospira Isolation from Urine**

Treatment Group	Dog ID	Day Post-Challenge							
		10	14	17	21	24	28	31	35
A (Vaccinates)	AAH-0	o	o	o	o	o	o	o	o
	AEH-0	o	o	o	o	o	o	o	o
	AIH-0	o	o	o	o	o	o	o	o
	AOH-0	o	o	o	o	o	o	o	o
	APH-0	o	o	o	o	o	o	o	o
	AUH-0	o	o	o	o	o	o	o	o
	AVG-0	o	o	o	o	o	o	o	o
	BBH-0	o	o	o	o	o	o	o	o
	BCG-0	o	o	o	o	o	o	o	o
	BDH-0	o	o	o	o	o	o	o	o
	BGH-0	o	o	o	o	o	o	o	o
	BIH-0	o	o	o	o	o	o	o	o
	BSG-0	o	o	o	o	o	o	o	o
	BUH-0	o	o	o	o	o	o	o	o
	BXH-0	o	o	o	o	o	o	o	o
	CAG-0	o	o	o	o	o	o	o	o
	CFH-0	o	o	o	o	o	o	o	o
	CJG-0	o	o	o	o	o	o	o	o
	CQH-0	o	o	o	o	o	o	o	o
	YTG-0	o	o	o	o	o	o	o	o
YZG-0	o	o	o	o	o	o	o	o	
ZFH-0	o	o	o	o	o	o	o	o	
ZPH-0	o	o	o	o	o	o	o	o	
ZQC-0	o	o	o	o	o	o	o	o	
B (Controls)	ALG-0	o	o	o	o	o	o	o	o
	AXG-0	o	+	o	+	+	+	+	o
	AZH-0	+	+	o	+	o	o	o	o
	BEH-0	+	+	+	+	+	+	o	o
	BRH-0	o	o	+	+	+	o	o	o
	CGH-0	+	+	+	+	+	+	o	o
	CPH-0	+	+	+	+	+	+	o	+
	ZAG-0	o	o	o	o	o	o	o	o
	ZJH-0	+	+	+	+	+	o	+	+
	ZOH-0	+	o	o	o	o	o	+	o

**o = culture negative**  
**+ = culture positive**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira pomona</i>
<b>Study Purpose</b>	Pivotal efficacy against leptospirosis due to <i>L. pomona</i>
<b>Product Administration</b>	Two doses were administered subcutaneously (SC) 21 days apart.
<b>Study Animals</b>	7- to 8-week-old dogs, sero-negative for antibodies specific to <i>Leptospira</i> ; 21 vaccinates and 9 controls
<b>Challenge Description</b>	All animals were challenged with <i>L. pomona</i> on Day 21, 22, and 23 after the last vaccination.
<b>Interval observed after challenge</b>	Clinical signs, including fever, were monitored daily for 21 days after challenge. Tissues were examined on day 21 post challenge or on the day when the dog died if earlier than day 21.
<b>Results</b>	<p><b>Summary of Results:</b></p> <p><u>Summary of Mortality after Challenge</u></p> <p>Vaccinates            0/21  Controls                4/9</p> <p><u>Summary of Isolation from tissues</u></p> <p>Vaccinates            0/21  Controls                6/9</p> <p><b>See the attached tables for raw data for this study:</b></p> <p>Table 1. Mortality  Table 2. <i>Leptospira</i> Isolation from Tissues Collected at End of Study  Table 3. Number of Times Clinical Signs Were Observed in 21 Days Post-Challenge  Table 4. Clinical Observations Post-Challenge</p>
<b>USDA Approval Date</b>	September 18, 2008

**Table 1. Mortality**

<b>Treatment Group</b>	<b>Dog ID</b>	<b>Mortality</b>
A	KSO-7	No
A	KVP-7	No
A	LCP-7	No
A	LOP-7	No
A	LZP-7	No
A	PCP-7	No
A	PIO-7	No
A	POP-7	No
A	PTO-7	No
A	QFP-7	No
A	RBP-7	No
A	RZO-7	No
A	SCP-7	No
A	SHO-7	No
A	SKP-7	No
A	SPP-7	No
A	SVP-7	No
A	TFP-7	No
A	TLP-7	No
A	TTO-7	No
A	TXP-7	No
B	LRO-7	Yes
B	OCO-7	No
B	PEP-7	Yes
B	PRP-7	No
B	QJO-7	Yes
B	QTP-7	No
B	RKP-7	No
B	RXP-7	No
B	SZO-7	Yes

**Group A - Vaccinates; Group B – Controls;**

**Table 2. Leptospira Isolation from Tissues Collected at End of Study.**

Treatment Group	Dog ID	Tissue Collection Date* (Study Day)	Kidney	Liver	Urine/Bladder
A	KSO-7	63	0	0	0
A	KVP-7	63	0	0	0
A	LCP-7	63	0	0	0
A	LOP-7	63	0	0	0
A	LZP-7	63	0	0	0
A	PCP-7	63	0	0	0
A	PIO-7	63	0	0	0
A	POP-7	63	0	0	0
A	PTO-7	63	0	0	0
A	QFP-7	63	0	0	0
A	RBP-7	63	0	0	0
A	RZO-7	63	0	0	0
A	SCP-7	63	0	0	0
A	SHO-7	63	0	0	0
A	SKP-7	63	0	0	0
A	SPP-7	63	0	0	0
A	SVP-7	63	0	0	0
A	TFP-7	63	0	0	0
A	TLP-7	63	0	0	0
A	TTO-7	63	0	0	0
A	TXP-7	63	0	0	0
B	LRO-7 <sup>b</sup>	47	2	2	2
B	OCO-7	63	0	0	0
B	PEP-7 <sup>a</sup>	46	2	2	2
B	PRP-7	63	0	0	0
B	QJO-7 <sup>b</sup>	47	2	2	2
B	QTP-7	63	2	0	0
B	RKP-7	63	1	0	0
B	RXP-7	63	0	0	0
B	SZO-7 <sup>a</sup>	46	2	2	2

**Group A - Vaccinates**  
**Group B - Controls**

(2) = Leptospira isolated from tissue.  
(1) = Leptospira isolated from tissue only after subculture.  
(0) = Leptospira not isolated from tissue.

\* Several dogs in the control group died prior to the end of study (Study Day 63, 21 days post challenge) and the tissue collection date was earlier than Study Day 63.

<sup>a</sup> Dogs died on study day 46 (4 days after challenge)  
<sup>b</sup> Dogs died on study day 47 (5 days after challenge)

**Table 3. Number of Times Clinical Signs Were Observed in 21 Days Post-Challenge.**

Dog ID	Group	High or Low Rectal Temp.	Ocular Congestion	Inappetence	Depression	Vomiting
KSO-7	A	0	0	0	0	0
KVP-7	A	0	5	0	0	0
LCP-7	A	0	0	0	0	0
LOP-7	A	0	0	0	0	0
LZP-7	A	0	0	0	0	0
PCP-7	A	0	2	0	0	0
PIO-7	A	0	0	0	0	0
POP-7	A	0	3	0	0	0
PTO-7	A	0	0	0	0	0
QFP-7	A	0	0	0	0	0
RBP-7	A	0	2	0	0	1
RZO-7	A	0	0	0	0	0
SCP-7	A	0	0	0	0	0
SHO-7	A	0	1	0	0	1
SKP-7	A	0	0	0	0	0
SPP-7	A	0	0	0	0	0
SVP-7	A	0	0	0	0	0
TFP-7	A	0	0	0	0	1
TLP-7	A	0	4	0	0	1
TTO-7	A	0	0	0	0	0
TXP-7	A	0	0	0	0	0
<b>Total</b>		<b>0</b>	<b>17</b>	<b>0</b>	<b>0</b>	<b>4</b>
LRO-7	B	0	0	2	1	2
OCO-7	B	1	0	1	0	0
PEP-7	B	1	2	0	0	1
PRP-7	B	1	8	3	1	0
QJO-7	B	0	4	3	4	3
QTP-7	B	1	8	1	0	0
RKP-7	B	0	8	4	4	2
RXP-7	B	2	8	2	2	1
SZO-7	B	0	2	1	2	2
<b>Total</b>		<b>6</b>	<b>40</b>	<b>17</b>	<b>14</b>	<b>11</b>

Group A - Vaccinates; Group B – Controls  
 Table 3 continued on next page

**Table 3. continued: Number of Times Clinical Signs Were Observed in 21 Days Post-Challenge.**

<b>Dog ID</b>	<b>Group</b>	<b>Jaundice</b>	<b>Dehydration</b>	<b>Hematuria</b>	<b>Petechiae</b>	<b>Melena</b>
KSO-7	A	0	0	0	0	0
KVP-7	A	0	0	0	0	0
LCP-7	A	0	0	0	0	0
LOP-7	A	0	0	0	0	0
LZP-7	A	0	0	0	0	0
PCP-7	A	0	0	0	0	0
PIO-7	A	0	0	0	0	0
POP-7	A	0	0	0	0	0
PTO-7	A	0	0	0	0	0
QFP-7	A	0	0	0	0	0
RBP-7	A	0	0	0	0	0
RZO-7	A	0	0	0	0	0
SCP-7	A	0	0	0	0	0
SHO-7	A	0	0	0	0	0
SKP-7	A	0	0	0	0	0
SPP-7	A	0	0	0	0	0
SVP-7	A	0	0	0	0	0
TFP-7	A	0	0	0	0	0
TLP-7	A	0	0	0	0	0
TTO-7	A	0	0	0	0	0
TXP-7	A	0	0	0	0	0
<b>Total</b>		<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
LRO-7	B	2	1	2	1	2
OCO-7	B	0	0	0	0	1
PEP-7	B	1	0	1	0	1
PRP-7	B	9	7	0	2	2
QJO-7	B	2	2	0	1	2
QTP-7	B	0	2	0	0	3
RKP-7	B	9	6	0	3	3
RXP-7	B	6	7	0	0	2
SZO-7	B	1	1	1	0	1
<b>Total</b>		<b>30</b>	<b>26</b>	<b>4</b>	<b>7</b>	<b>17</b>

**Group A - Vaccinates; Group B – Controls**

**Table 4. Clinical Observations Post-Challenge.**

Treatment Group	Dog ID	SD# 40	SD 41	SD 42*	SD 43*	SD 44*	SD 45
A	KSO-7	-	-	-	-	-	-
A	KVP-7	-	-	-	-	C	C
A	LCP-7	-	-	-	-	-	-
A	LOP-7	-	-	-	-	-	-
A	LZP-7	-	-	-	-	-	-
A	PCP-7	-	-	-	-	-	-
A	PIO-7	-	-	-	-	-	-
A	POP-7	-	-	-	-	C	C
A	PTO-7	-	-	-	-	-	-
A	QFP-7	-	-	-	-	-	-
A	RBP-7	-	-	-	-	-	-
A	RZO-7	-	-	-	-	-	-
A	SCP-7	-	-	-	-	-	-
A	SHO-7	-	-	-	-	-	-
A	SKP-7	-	-	-	-	-	-
A	SPP-7	-	-	-	-	-	-
A	SVP-7	-	-	-	-	-	-
A	TFP-7	-	-	-	-	-	-
A	TLP-7	-	-	-	-	C	C,V
A	TTO-7	-	-	-	-	-	-
A	TXP-7	-	-	-	-	-	-
B	LRO-7	-	-	-	-	-	-
B	OCO-7	-	-	-	-	-	I,M
B	PEP-7	-	-	-	-	C	C
B	PRP-7	-	-	-	-	C,M	I,C
B	QJO-7	-	-	-	-	C	I,C,L1,V
B	QTP-7	-	-	-	-	-	C,M
B	RKP-7	-	-	-	-	C	C
B	RXP-7	-	-	-	L1	C,M	C,D
B	SZO-7	-	-	-	-	-	C,V

**Group A - Vaccinates; Group B - Controls**

**# SD = Study Day**

**\* Challenge**

**(-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice;**

**D = Dehydration; H = Hematuria; P = Petechiae; M = Melena; I = Inappetence**

**Table 4 continued on next page**



**Table 4 continued. Clinical Observations Post-Challenge**

Treatment Group	Dog ID	SD 46	SD 47	SD 48	SD 49
A	KSO-7	-	-	-	-
A	KVP-7	C	-	-	-
A	LCP-7	-	-	-	-
A	LOP-7	-	-	-	-
A	LZP-7	-	-	-	-
A	PCP-7	C	-	-	-
A	PIO-7	-	-	-	-
A	POP-7	-	-	-	C
A	PTO-7	-	-	-	-
A	QFP-7	-	-	-	-
A	RBP-7	-	-	C,V	-
A	RZO-7	-	-	-	-
A	SCP-7	-	-	-	-
A	SHO-7	C	-	-	-
A	SKP-7	-	-	-	-
A	SPP-7	-	-	-	-
A	SVP-7	-	-	-	-
A	TFP-7	-	-	V	-
A	TLP-7	-	C	-	-
A	TTO-7	-	-	-	-
A	TXP-7	-	-	-	-
B	LRO-7	I,V,J,H,M	I,L1,V,J,D,H,P,M	Dead	Dead
B	OCO-7	-	-	-	-
B	PEP-7	V,J,H,E,M (Dead)	Dead	Dead	Dead
B	PRP-7	I,C,L1,J,D,M	I,C,J,D,P	C,J,D,P	C,J,D
B	QJO-7	I,C,L1,V,J,D,M	I,C,L2,V,J,D,P,M	Dead	Dead
B	QTP-7	C,D	I,C,D,M	C	C,M
B	RKP-7	I,C,L1,V,J,D,P,M	I,C,L2,V,J,D,P,M	I,C,L1,J,D,P,M	I,C,J,D
B	RXP-7	I,C,L1,V,J,D,M	I,C,L1,J,D	C,J,D	C,J,D
B	SZO-7	I,C,L2,V,J,D,H,M	Dead	Dead	Dead

**Group A - Vaccinates; Group B - Controls**

**# SD = Study Day**

**\* Challenge**

**(-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice;**

**D = Dehydration; H = Hematuria; P = Petechiae; M = Melena; I = Inappetence**

**Table 4 continued on next page**

**Table 4 continued. Clinical Observations Post-Challenge**

Treatment Group	Dog ID	SD# 50	SD 51	SD 52	SD 53	SD 54	SD 55	SD 56
A	KSO-7	-	-	-	-	-	-	-
A	KVP-7	C	C	-	-	-	-	-
A	LCP-7	-	-	-	-	-	-	-
A	LOP-7	-	-	-	-	-	-	-
A	LZP-7	-	-	-	-	-	-	-
A	PCP-7	-	-	C	-	-	-	-
A	PIO-7	-	-	-	-	-	-	-
A	POP-7	-	-	-	-	-	-	-
A	PTO-7	-	-	-	-	-	-	-
A	QFP-7	-	-	-	-	-	-	-
A	RBP-7	-	-	C	-	-	-	-
A	RZO-7	-	-	-	-	-	-	-
A	SCP-7	-	-	-	-	-	-	-
A	SHO-7	V	-	-	-	-	-	-
A	SKP-7	-	-	-	-	-	-	-
A	SPP-7	-	-	-	-	-	-	-
A	SVP-7	-	-	-	-	-	-	-
A	TFP-7	-	-	-	-	-	-	-
A	TLP-7	-	C	-	-	-	-	-
A	TTO-7	-	-	-	-	-	-	-
A	TXP-7	-	-	-	-	-	-	-
B	LRO-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	OCO-7	-	-	-	-	-	-	-
B	PEP-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	PRP-7	C,J,D	C,J,D	J,D	J	J	-	-
B	QJO-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	QTP-7	-	C	C	C	-	-	-
B	RKP-7	C,J,D	C,J,D	J	J	J	-	-
B	RXP-7	C,J,D	C,J,D	-	-	-	-	-
B	SZO-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead

**Group A - Vaccinates; Group B - Controls**

**# SD = Study Day**

**(-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice;**

**D = Dehydration; H = Hematuria; P = Petechiae; M = Melena; I = Inappetence**

**Table 4 continued on next page**

**Table 4 continued. Clinical Observations Post-Challenge**

Treatment Group	Dog ID	SD 57	SD 58	SD 59	SD 60	SD 61	SD 62	SD 63
A	KSO-7	-	-	-	-	-	-	-
A	KVP-7	-	-	-	-	-	-	-
A	LCP-7	-	-	-	-	-	-	-
A	LOP-7	-	-	-	-	-	-	-
A	LZP-7	-	-	-	-	-	-	-
A	PCP-7	-	-	-	-	-	-	-
A	PIO-7	-	-	-	-	-	-	-
A	POP-7	-	-	-	-	-	-	-
A	PTO-7	-	-	-	-	-	-	-
A	QFP-7	-	-	-	-	-	-	-
A	RBP-7	-	-	-	-	-	-	-
A	RZO-7	-	-	-	-	-	-	-
A	SCP-7	-	-	-	-	-	-	-
A	SHO-7	-	-	-	-	-	-	-
A	SKP-7	-	-	-	-	-	-	-
A	SPP-7	-	-	-	-	-	-	-
A	SVP-7	-	-	-	-	-	-	-
A	TFP-7	-	-	-	-	-	-	-
A	TLP-7	-	-	-	-	-	-	-
A	TTO-7	-	-	-	-	-	-	-
A	TXP-7	-	-	-	-	-	-	-
B	LRO-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	OCO-7	-	-	-	-	-	-	-
B	PEP-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	PRP-7	-	-	-	-	-	-	-
B	QJO-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead
B	QTP-7	-	-	-	-	-	-	-
B	RKP-7	-	-	-	-	-	-	-
B	RXP-7	-	-	-	-	-	-	-
B	SZO-7	Dead	Dead	Dead	Dead	Dead	Dead	Dead

**Group A - Vaccinates; Group B - Controls**

**# SD = Study Day**

**(-) = Normal; C = Congestion/Mattering of the Sclera/Eye; L1 = Moderately Depressed; L2 = Severely Depressed; V = Vomiting; J = Jaundice;  
D = Dehydration; H = Hematuria; P = Petechiae; M = Melena; I = Inappetence**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira pomona</i>
<b>Study Purpose</b>	To evaluate urinary shedding in vaccinated dogs following challenge with <i>L. pomona</i>
<b>Product Administration</b>	Two doses administered subcutaneously 21 days apart.
<b>Study Animals</b>	36 dogs, sero-negative to all 4 Leptospira serovars, 8 weeks of age. 24 vaccinates, 12 controls.
<b>Challenge Description</b>	All animals were challenged with <i>L. Pomona</i> 14 days after the last vaccination.
<b>Interval observed after challenge</b>	Animals were observed daily for 14 days post-challenge for clinical signs of leptospirosis. Urine samples were collected on days 10, 14, 17, 21, 24, 28, 31 and 35 postchallenge.
<b>Results</b>	<p><b>Summary of Results</b> (See Table 1 for raw data)</p> <p><u>Urine Culture Results</u></p> <p>Vaccinates     0/24  Controls*       3/11</p> <p>* One dog in the Control group died 11 days post-challenge.</p>
<b>USDA Approval Date</b>	October 28, 2011

**Table 1. Leptospira Isolation from Urine**

Treatment Group	Dog ID	Day Post-Challenge								
		10	14	17	21	24	28	31	35	
A (Vaccinates)	EPE-0	o	o	o	o	o	o	o	o	
	HTF-0	o	o	o	o	o	o	o	o	
	HVE-0	o	o	o	o	o	o	o	o	
	IBE-0	o	o	o	o	o	o	o	o	
	IIF-0	o	o	o	o	o	o	o	o	
	IOF-0	o	o	o	o	o	o	o	o	
	IRE-0	o	o	o	o	o	o	o	o	
	ITF-0	o	o	o	o	o	o	o	o	
	IWE-0	o	o	o	o	o	o	o	o	
	JEF-0	o	o	o	o	o	o	o	o	
	JGE-0	o	o	o	o	o	o	o	o	
	JJF-0	o	o	o	o	o	o	o	o	
	JLF-0	o	o	o	o	o	o	o	o	
	JRE-0	o	o	o	o	o	o	o	o	
	JUF-0	o	o	o	o	o	o	o	o	
	JXE-0	o	o	o	o	o	o	o	o	
	KAF-0	o	o	o	o	o	o	o	o	
	KBF-0	o	o	o	o	o	o	o	o	
	KEE-0	o	o	o	o	o	o	o	o	
	KLE-0	o	o	o	o	o	o	o	o	
	KWE-0	o	o	o	o	o	o	o	o	
	KXF-0	o	o	o	o	o	o	o	o	
KZE-0	o	o	o	o	o	o	o	o		
LAF-0	o	o	o	o	o	o	o	o		
B (Controls)	EKF-0	o	o	o	o	o	o	o	o	
	ICE-0	o	o	o	o	+	o	o	o	
	ILF-0	o	Dead							
	ISF-0	o	o	o	o	o	o	o	o	
	IUE-0	o	o	o	o	o	o	o	o	
	JPE-0	o	o	o	o	o	o	o	o	
	JSF-0	+	o	o	o	+	o	o	o	
	JYE-0	o	o	+	+	o	o	o	o	
	KDE-0	+	o	o	o	o	o	o	o	
	KKF-0	o	o	o	o	o	o	o	o	
	KQF-0	o	+	o	+	+	+	o	o	
LDE-0	+	o	o	o	o	o	o	o		

**o = culture negative**  
**+ = culture positive**

<b>Study Type</b>	Efficacy								
<b>Pertaining to</b>	Canine Parainfluenza (CPI)								
<b>Study Purpose</b>	To demonstrate the effectiveness against canine parainfluenza								
<b>Product Administration</b>	Two doses administered subcutaneously, 21 days apart								
<b>Study Animals</b>	8-week-old dogs, seronegative to CPI; 20 vaccinates and 10 controls								
<b>Challenge Description</b>	All dogs were challenged with CPI 27 days after second vaccination								
<b>Interval observed after challenge</b>	Dogs were observed daily for clinical signs, and rectal temperatures were recorded for 14 days post challenge. Nasal swabs for CPI isolation were collected daily for 10 days post challenge.								
<b>Results</b>	<p style="text-align: center;"><b>Summary of serology after vaccination</b> (See raw data in attached Table 1)</p> <p style="text-align: center;"><u>Neutralizing Antibodies to CPI (positive if titer <math>\geq</math> 1:4)</u></p> <table style="margin-left: auto; margin-right: auto;"> <tr> <td style="padding-right: 20px;">Vaccinates</td> <td>19/20</td> </tr> <tr> <td>Controls</td> <td>0/10</td> </tr> </table> <p>Table 2 is Body temperature. Fever is considered rectal temperature <math>\geq</math>103.4°F.</p> <p style="text-align: center;"><b>Summary of clinical signs following challenge</b> (See raw data in attached Table 3)</p> <p style="text-align: center;"><u>Clinical signs</u></p> <table style="margin-left: auto; margin-right: auto;"> <tr> <td style="padding-right: 20px;">Vaccinates</td> <td>1/20</td> </tr> <tr> <td>Controls</td> <td>0/10</td> </tr> </table> <p style="text-align: center;"><b>Virus shedding from nasal secretions following challenge</b> (See raw data in attached Table 4)</p> <p>Requirements per 9 CFR 113.316 were met.</p> <p>Study Date (SD) SD0 is the date of the first vaccination. SD21 is the date of the second vaccination. SD49 is the date of the challenge corresponding to 27 days after the second vaccination.</p>	Vaccinates	19/20	Controls	0/10	Vaccinates	1/20	Controls	0/10
Vaccinates	19/20								
Controls	0/10								
Vaccinates	1/20								
Controls	0/10								
<b>USDA Approval Date</b>	January 14, 2010								

**Table 1. CPI Serum Neutralization Titers.**

Dog ID	Treatment Group	Study Day 0	Study Day 21	Study Day 35	Study Day 49*	Study Day 63
0817903		<2	<2	19	45	>4096
0817904		<2	<2	<2	<2	1024
0817905		<2	<2	10	54	>4096
0817906		<2	<2	54	>256	>4096
0818002		<2	<2	128	>256	>4096
0818003		<2	<2	215	>256	>4096
0818004		<2	<2	38	NA**	NA**
0818005		<2	5	76	128	>4096
0818006		<2	13	76	152	>4096
0818101		<2	<2	128	>256	>4096
0818102	A	<2	<2	181	256	>4096
0818105	Vaccinates	<2	<2	>256	>256	>4096
0818201		<2	<2	27	76	>4096
0818202		<2	<2	64	152	>4096
0818203		<2	<2	27	54	>4096
0818204		<2	<2	181	>256	>4096
0818303		<2	<2	152	152	>4096
0884702		<2	<2	128	152	>4096
0884703		<2	<2	91	256	>4096
0884704		<2	<2	45	215	>4096
0884705		<2	<2	38	91	>4096
<hr/>						
0817901		<2	<2	<2	<2	215
0817902		<2	<2	<2	<2	152
0818001		<2	<2	<2	<2	304
0818007		<2	<2	<2	<2	362
0818103		<2	<2	<2	<2	152
0818104	B	<2	<2	<2	<2	362
0818205	Controls	<2	<2	<2	<2	431
0818206		<2	<2	<2	<2	152
0818301		<2	<2	<2	<2	256
0884701		<2	<2	<2	<2	45

GMT = Geometric Mean Titer

\* Prior to challenge

\*\* Dog 0818004 no longer in study since only 20 out the 21 dogs were needed for challenge

# CPI serum neutralizing titer  $\geq 4$  is considered as positive. All controls were negative prior to challenge.

**Table 2. Post-Challenge Body Temperatures (°F)**

Dog ID	Treatment Group	SD 47	SD 48	SD 49*	SD 50	SD 51	SD 52	SD 53	SD 54	SD 55	SD 56
0817903		100.4	100.9	100.6	100.2	100.7	100.3	101.0	100.2	100.5	100.4
0817904		100.3	100.7	100.7	100.8	100.5	100.8	101.7	100.8	100.6	100.6
0817905		100.4	100.8	100.9	100.3	100.5	100.6	100.8	100.2	100.1	100.3
0817906		100.0	100.4	100.2	101.1	100.4	100.4	100.8	100.4	100.5	100.3
0818002		100.3	100.5	100.7	100.5	100.9	100.6	100.9	100.3	100.3	100.5
0818003		100.8	100.8	100.8	101.3	100.4	100.7	100.8	100.2	100.5	100.7
0818005		100.5	100.4	101.7	101.4	100.4	100.6	101.6	100.7	100.6	100.3
0818006		101.1	100.7	101.3	101.2	100.4	101.3	101.2	100.3	100.9	101.0
0818101	A	100.6	100.4	100.4	101.1	100.9	100.4	100.6	100.4	100.9	100.8
0818102	Vaccinates	100.4	100.5	100.4	100.9	100.7	100.6	101.7	100.6	100.4	100.8
0818105		100.6	100.3	100.9	100.4	100.3	100.5	101.8	101.0	100.8	101.2
0818201		100.5	100.8	100.5	100.8	100.8	101.0	101.5	100.8	101.2	100.9
0818202		100.2	100.8	100.7	100.7	101.0	100.9	101.0	100.6	100.4	100.7
0818203		100.6	100.4	100.4	100.1	100.8	10.4	101.3	100.2	100.3	100.3
0818204		101.0	101.4	101.3	101.6	101.4	101.2	101.2	100.4	101.2	101.6
0818303		100.7	100.7	100.6	101.3	100.2	100.3	100.9	100.3	100.6	100.8
0884702		101.2	101.2	101.2	100.1	101.3	100.8	101.5	100.9	100.7	100.4
0884703		100.9	100.6	100.7	100.6	100.8	100.8	101.6	100.8	100.6	101.1
0884704		100.8	101.0	100.7	101.7	101.0	101.3	100.8	100.4	101.4	100.9
0884705		100.5	101.0	101.6	100.7	101.5	101.3	102.1	101.0	100.6	100.4
0817901		100.2	101.5	101.3	101.2	102.5	100.5	101.4	101.7	101.7	101.3
0817902		100.1	100.3	101.2	100.4	100.5	100.9	100.5	100.4	100.7	100.5
0818001		100.5	100.8	101.1	100.8	100.3	101.0	101.0	100.4	100.8	101.1
0818007		100.7	101.6	100.5	101.0	101.0	101.0	101.8	100.8	100.5	100.9
0818103	B	100.7	100.8	100.8	100.7	100.5	100.7	101.6	100.4	101.2	101.1
0818104	Controls	100.4	101.0	100.5	100.3	101.4	100.4	101.1	101.4	100.5	100.7
0818205		101.4	101.3	100.5	100.9	101.5	100.7	101.6	100.1	100.7	100.5
0818206		100.8	101.0	102.1	101.4	101.1	100.7	102.1	101.2	100.8	101.5
0818301		101.2	101.7	101.3	100.7	100.8	102.0	101.5	100.8	101.2	101.0
0884701		100.6	101.3	100.8	101.0	101.2	100.6	101.4	101.3	100.5	101.5

SD = study day  
\* Challenge



**Table 2. Post-Challenge Body Temperatures (°F) - continued**

Dog ID	Treatment Group	SD 57	SD 58	SD 59	SD 60	SD 61	SD 62	SD 63
0817903		100.5	101.3	101.2	100.8	100.4	100.1	101.5
0817904		100.8	100.7	100.1	100.7	100.7	100.5	100.4
0817905		100.5	100.6	100.9	100.6	100.1	100.8	101.3
0817906		100.5	100.4	100.2	100.1	100.5	100.5	100.4
0818002		101.1	101.0	100.7	100.3	100.6	100.9	100.8
0818003		100.8	101.0	100.9	100.9	100.5	100.5	102.4
0818005		100.7	100.7	101.0	100.5	100.5	101.0	101.3
0818006		100.6	100.8	101.1	100.8	100.6	100.8	100.9
0818101		100.7	100.5	100.2	100.6	100.8	100.5	100.5
0818102	A	100.8	100.3	100.4	100.9	100.2	100.6	101.2
0818105	Vaccinates	100.8	101.7	100.1	100.7	100.2	100.2	100.6
0818201		101.0	100.9	100.9	101.1	100.4	100.3	101.0
0818202		100.4	101.0	100.6	100.7	101.2	100.6	100.9
0818203		100.8	100.6	100.4	101.3	101.0	100.4	100.2
0818204		101.8	101.6	100.4	101.0	101.6	101.0	100.7
0818303		100.9	100.6	100.7	100.7	100.4	100.5	100.7
0884702		101.3	101.3	100.9	100.5	101.2	100.7	101.2
0884703		100.7	100.3	100.9	100.6	100.3	100.7	101.5
0884704		101.2	100.7	100.8	100.4	100.3	100.8	101.6
0884705		100.5	100.9	100.2	101.1	100.3	100.2	100.7
0817901		101.7	101.1	100.9	101.2	102.2	101.8	100.9
0817902		100.3	100.9	100.3	100.4	100.8	100.3	100.3
0818001		101.2	101.4	100.7	101.4	101.0	100.7	100.5
0818007		101.3	101.4	100.6	100.9	100.7	100.9	100.8
0818103	B	101.2	100.5	100.9	100.8	100.5	100.4	100.5
0818104	Controls	100.4	100.5	100.5	100.4	100.4	100.6	100.1
0818205		100.2	100.6	100.7	100.6	100.5	100.4	100.6
0818206		100.7	101.0	101.2	100.7	100.8	100.7	101.5
0818301		101.0	100.8	101.5	100.9	100.8	101.1	100.9
0884701		100.9	101.3	101.0	100.6	100.8	100.1	101.1

SD = study day

**Table 3. Post-Challenge Clinical Observations**

Dog ID	Treatment Group	SD 47	SD 48	SD 49*	SD 50	SD 51	SD 52	SD 53	SD 54	SD 55	SD 56
0817903		-	-	-	-	-	-	-	-	-	-
0817904		-	-	-	-	-	-	-	-	-	-
0817905		-	-	-	-	-	-	-	-	-	-
0817906		-	-	-	-	-	-	-	-	-	-
0818002		-	-	-	-	-	-	-	-	-	-
0818003		-	-	-	-	-	-	-	-	-	-
0818005		-	-	-	-	-	-	-	-	-	-
0818006		-	-	-	-	-	-	-	-	-	-
0818101		-	-	-	-	-	-	-	R	-	-
0818102	A	-	-	-	-	-	-	-	-	-	-
0818105	Vaccinates	-	-	-	-	-	-	-	-	-	-
0818201		-	-	-	-	-	-	-	-	-	-
0818202		-	-	-	-	-	-	-	-	-	-
0818203		-	-	-	-	-	-	-	-	-	-
0818204		-	-	-	-	-	-	-	-	-	-
0818303		-	-	-	-	-	-	-	-	-	-
0884702		-	-	-	-	-	-	-	-	-	-
0884703		-	-	-	-	-	-	-	-	-	-
0884704		-	-	-	-	-	-	-	-	-	-
0884705		-	-	-	-	-	-	-	-	-	-
0817901		-	-	-	-	-	-	-	-	-	-
0817902		-	-	-	-	-	-	-	-	-	-
0818001		-	-	-	-	-	-	-	-	-	-
0818007		-	-	-	-	-	-	-	-	-	-
0818103	B	-	-	-	-	-	-	-	-	-	-
0818104	Controls	-	-	-	-	-	-	-	-	-	-
0818205		-	-	-	-	-	-	-	-	-	-
0818206		-	-	-	-	-	-	-	-	-	-
0818301		-	-	-	-	-	-	-	-	-	-
0884701		-	-	-	-	-	-	-	-	-	-

SD = study day  
 \* Challenge  
 R = retching

**Table 3. Post-Challenge Clinical Observations - continued**

Dog ID	Treatment Group	SD 57	SD 58	SD 59	SD 60	SD 61	SD 62	SD 63
0817903		-	-	-	-	-	-	-
0817904		-	-	-	-	-	-	-
0817905		-	-	-	-	-	-	-
0817906		-	-	-	-	-	-	-
0818002		-	-	-	-	-	-	-
0818003		-	-	-	-	-	-	-
0818005		-	-	-	-	-	-	-
0818006		-	-	-	-	-	-	-
0818101		-	-	-	-	-	-	-
0818102	A	-	-	-	-	-	-	-
0818105	Vaccinates	-	-	-	-	-	-	-
0818201		-	-	-	-	-	-	-
0818202		-	-	-	-	-	-	-
0818203		-	-	-	-	-	-	-
0818204		-	-	-	-	-	-	-
0818303		-	-	-	-	-	-	-
0884702		-	-	-	-	-	-	-
0884703		-	-	-	-	-	-	-
0884704		-	-	-	-	-	-	-
0884705		-	-	-	-	-	-	-
0817901		-	-	-	-	-	-	-
0817902		-	-	-	-	-	-	-
0818001		-	-	-	-	-	-	-
0818007		-	-	-	-	-	-	-
0818103	B	-	-	-	-	-	-	-
0818104	Controls	-	-	-	-	-	-	-
0818205		-	-	-	-	-	-	-
0818206		-	-	-	-	-	-	-
0818301		-	-	-	-	-	-	-
0884701		-	-	-	-	-	-	-

SD = study day

\* Challenge

R = retching

**Table 4. CPI Virus Isolation Titers (log<sub>10</sub> TCID<sub>50</sub>/mL)**

Dog ID	Treatment Group	SD 49*	SD 50**	SD 51	SD 52	SD 53	SD 54	SD 55	SD 56	SD 57	SD 58	SD 59
0817903	A Vaccinates	0	0.75	5.25	4.5	3.5	3.25	1.5	0	0	0	0
0817904		0	1.25	4.0	4.25	3.5	2.75	1.5	0	0	0	0
0817905		0	0.75	4.25	5.0	3.75	3.5	0	0	0	0	0
0817906		0	0	4.25	4.5	4.25	3.0	1.75	0	0	0	0
0818002		0	0	2.25	1.25	0	0	0	0	0	0	0
0818003		0	0	0	0.75	0	3.75	0.75	0	0	0	0
0818005		0	0	3.25	4.0	4.25	5.0	3.0	0	0	0	0
0818006		0	0.75	3.25	4.5	3.25	2.75	0	0	0	0	0
0818101		0	0.75	3.0	4.0	3.0	2.5	0	0	0	0	0
0818102		0	0	3.25	3.25	2.75	2.75	3.0	0	0	0	0
0818105		0	0	3.5	3.25	3.5	3.75	3.0	0	0	0	0
0818201		0	1.0	4.75	3.75	3.25	3.0	3.5	0	0	0	0
0818202		0	0.75	4.5	4.25	3.75	3.25	0	0	0	0	0
0818203		0	1.25	4.25	4.0	3.75	3.0	1.0	0	0	0	0
0818204		0	0	0	3.0	3.0	2.0	1.75	0	0	0	0
0818303		0	0	3.25	3.5	2.5	2.25	0	0	0	0	0
0884702		0	0	3.25	4.0	4.25	3.0	0	0	0	0	0
0884703		0	0.75	2.75	3.75	4.0	4.0	0	0	0	0	0
0884704		0	0	3.5	1.5	2.25	3.0	0	0	0	0	0
0884705		0	1.0	4.75	4.0	3.25	3.75	0	0	0	0	0
0817901	B Controls	0	0.75	4.25	5.25	≥5.5	4.75	4.25	3.75	0.75	0	0
0817902		0	0.75	5.0	5.0	5.25	4.25	3.0	1.5	0	0	0
0818001		0	0	3.25	4.25	4.5	4.5	3.25	2.0	0	0	0
0818007		0	0.75	4.25	5.0	4.75	4.25	3.25	3.75	0	0	0
0818103		0	1.0	4.5	≥5.5	5.0	3.5	3.0	1.0	0	0	0
0818104		0	0.75	3.25	5.0	4.0	4.25	3.0	2.75	0.75	0	0
0818205		0	0	4.75	5.0	5.0	3.75	0	2.5	0.75	0	0
0818206		0	0.75	4.0	4.5	4.75	4.5	2.75	2.25	0	0	0
0818301		0	1.5	5.0	5.25	4.75	4.0	2.75	1.0	0	0	0
0884701		0	1.0	4.5	4.25	4.75	3.75	2.5	0.75	0	0	0

SD = study day  
 \* Pre-challenge  
 \*\* Day 1 post-challenge  
 0 = no virus detected

<b>Study Type</b>	Efficacy																																	
<b>Pertaining to</b>	Canine Distemper Virus (CDV)																																	
<b>Study Purpose</b>	To demonstrate effectiveness against canine distemper virus																																	
<b>Product Administration</b>	Two doses administered subcutaneously, 21 days apart																																	
<b>Study Animals</b>	Twenty five dogs, seronegative to CDV, 8 weeks of age, 20 vaccinates and 5 controls																																	
<b>Challenge Description</b>	All dogs were challenged with CDV 6 weeks after the second vaccination																																	
<b>Interval observed after challenge</b>	Dogs were observed daily for clinical signs for 21 days post challenge.																																	
<b>Results</b>	<p>Summary of the mortality, rectal temperatures, and clinical signs after challenge are listed below; see attached Table 1 and 2 for raw data.</p> <p style="text-align: center;"><b>Mortality after Challenge:</b> Vaccinates 0/20      Controls 5/5</p> <p style="text-align: center;"><b>Rectal Temperatures and Clinical Signs following Challenge:</b></p> <table style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th style="text-align: center;">Vaccinate</th> <th style="text-align: center;">Control</th> </tr> </thead> <tbody> <tr> <td>Neuromuscular ties</td> <td style="text-align: center;">0/20</td> <td style="text-align: center;">2/5</td> </tr> <tr> <td>Seizures/convulsions</td> <td style="text-align: center;">0/20</td> <td style="text-align: center;">4/5</td> </tr> <tr> <td>Inappetence</td> <td style="text-align: center;">1/20</td> <td style="text-align: center;">5/5</td> </tr> <tr> <td>Diarrhea</td> <td style="text-align: center;">4/20</td> <td style="text-align: center;">4/5</td> </tr> <tr> <td>Diarrhea with blood</td> <td style="text-align: center;">0/20</td> <td style="text-align: center;">1/5</td> </tr> <tr> <td>Dehydration</td> <td style="text-align: center;">0/20</td> <td style="text-align: center;">4/5</td> </tr> <tr> <td>Vomiting</td> <td style="text-align: center;">2/20</td> <td style="text-align: center;">3/5</td> </tr> <tr> <td>Moderate depression</td> <td style="text-align: center;">0/20</td> <td style="text-align: center;">4/5</td> </tr> <tr> <td>Severe depression</td> <td style="text-align: center;">0/20</td> <td style="text-align: center;">2/5</td> </tr> <tr> <td>Fever (<math>\geq 103.4^{\circ}\text{F}</math>)</td> <td style="text-align: center;">0/20</td> <td style="text-align: center;">4/5</td> </tr> </tbody> </table> <p>Requirements per 9 CFR 113.306 were met.</p> <p>Study Date (SD) SD0 is the date of the first vaccination. SD21 is the date of the second vaccination. SD63 is the date of the challenge corresponding to six weeks after the second vaccination.</p>		Vaccinate	Control	Neuromuscular ties	0/20	2/5	Seizures/convulsions	0/20	4/5	Inappetence	1/20	5/5	Diarrhea	4/20	4/5	Diarrhea with blood	0/20	1/5	Dehydration	0/20	4/5	Vomiting	2/20	3/5	Moderate depression	0/20	4/5	Severe depression	0/20	2/5	Fever ( $\geq 103.4^{\circ}\text{F}$ )	0/20	4/5
	Vaccinate	Control																																
Neuromuscular ties	0/20	2/5																																
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Fever ( $\geq 103.4^{\circ}\text{F}$ )	0/20	4/5																																
<b>USDA Approval Date</b>	December 15, 2009																																	

**Table 1. CDV Serum Neutralization Titers.**

Dog ID	Treatment Group	Study Day 0	Study Day 21	Study Day 29	Study Day 63
0815102	A Vaccinates	<2	2435	1722	2896
0815104		<2	2048	1448	1024
0815106		<2	152	431	76
0815107		<2	1448	2048	1218
0815205		<2	>4096	2896	2048
0815206		<2	304	1218	512
0815208		<2	431	1024	861
0815209		<2	609	861	1024
0815402		<2	724	1218	512
0815403		<2	2435	2435	512
0815404		<2	304	512	431
0815501		<2	304	724	362
0815502		<2	1024	4871	1448
0815505		<2	304	609	152
0815506		<2	4096	2896	1722
0815601		<2	2435	2048	1218
0883301		<2	<2	Dead	Dead
0883302		<2	1024	2048	512
0883303		<2	<2	6	861
0883305		<2	431	861	431
0883401	<2	609	2435	362	
0815103	B Controls	<2	<2	<2	<2
0815105		<2	<2	<2	NA
0815204		<2	<2	<2	<2
0815207		<2	<2	<2	NA
0815401		<2	<2	<2	NA
0815503		<2	<2	<2	NA
0815504		<2	<2	<2	<2
0815602		<2	<2	<2	<2
0883304		<2	<2	<2	<2
0883402		<2	<2	<2	NA

GMT = Geometric Mean Titer  
 NA = dog no longer in study  
 Seronegative is GMT <2

**Table 2. CDV Post-Challenge Clinical Observations**

Dog ID	Treatment Group	SD 61	SD 62	SD 63*	SD 64	SD 65	SD 66
0815102		-	-	-	-	V	-
0815104		-	-	-	-	-	-
0815106		-	-	-	-	-	-
0815107		-	-	-	-	-	-
0815205		-	-	-	-	-	-
0815206		-	-	-	-	-	-
0815208		-	-	-	-	-	-
0815209		-	-	-	-	-	-
0815402		-	-	-	-	-	-
0815403	A	-	-	-	-	-	-
0815404	Vaccinates	-	-	-	-	-	-
0815501		-	-	-	-	-	-
0815502		-	-	-	-	-	-
0815505		-	-	-	-	-	-
0815506		-	-	-	-	-	-
0815601		-	-	-	-	-	-
0883302		-	-	-	-	-	-
0883303		-	-	-	-	-	-
0883305		-	-	-	-	-	-
0883401		-	-	-	-	-	-
0815103		-	-	-	-	V	-
0815204	B	-	-	-	-	-	-
0815504	Controls	-	-	-	-	-	-
0815602		-	-	-	-	-	-
0883304		-	-	-	-	-	-

SD = study day; \* Challenge

**T** = neuromuscular tics; **S** = seizures / convulsions; **L1** = moderate depression; **L2** = severe depression; **I** = Inappetence; **H** = Dehydration; **D** = diarrhea; **B** = diarrhea with blood; **V** = vomiting

\* In the raw data package, the clinical observations recorded for dog 0815602 were mistakenly attributed to dog 0815601.

**Table 2. CDV Post-Challenge Clinical Observations-continued.**

Dog ID	Treatment Group	SD 67	SD 68	SD 69	SD 70	SD 71
0815102		-	-	-	-	-
0815104		-	-	-	-	-
0815106		-	-	-	D	D
0815107		-	-	-	-	-
0815205		-	-	-	-	-
0815206		-	-	-	-	-
0815208		-	-	-	-	-
0815209		-	-	-	-	-
0815402		-	-	-	-	-
0815403	A	-	-	-	-	D
0815404	Vaccinates	-	-	-	-	-
0815501		-	-	-	-	-
0815502		-	-	-	-	-
0815505		-	-	-	-	-
0815506		-	-	-	-	-
0815601		-	-	-	-	-
0883302		-	-	-	-	-
0883303		-	-	-	-	-
0883305		-	-	-	-	-
0883401		-	-	-	-	-
0815103		L1, I, D, V	L1, I, H, D, V	L1, I, H	T, L2, I, H, D	Dead
0815204	B	I	D	-	S	Dead
0815504	Controls	L1, I, V	-	H	S	Dead
0815602		I	L1, I, H, B	T, L1, I, H, D*	S, L1, I, H	Dead
0883304		I	I, H, D	H	H	L1, I, H, V

SD = study day

**T** = neuromuscular tics; **S** = seizures / convulsions; **L1** = moderate depression; **L2** = severe depression; **I** = Inappetence; **H** = Dehydration; **D** = diarrhea; **B** = diarrhea with blood; **V** = vomiting

\* In the raw data package, the clinical observations recorded for dog 0815602 were mistakenly attributed to dog 0815601.



**Table 2. CDV Post-Challenge Clinical Observations - continued**

Dog ID	Treatment Group	SD 72	SD 73	SD 74	SD 75	SD 76	SD 77	SD 78	SD 79	SD 80	SD 81	SD 82	SD 83	SD 84
0815102		-	-	-	-	-	-	-	-	-	-	-	-	-
0815104		-	-	-	-	-	-	-	-	-	-	-	-	-
0815106		-	-	-	-	-	-	-	-	-	-	-	-	-
0815107		-	-	-	-	-	-	-	-	-	-	V	-	-
0815205		-	-	-	-	-	-	-	-	-	-	-	-	-
0815206		-	-	-	-	-	-	-	-	-	-	D	-	-
0815208		-	-	-	-	-	-	-	-	-	-	-	-	-
0815209		-	-	-	-	-	-	-	-	-	-	-	-	-
0815402		-	-	-	-	-	-	-	-	-	-	-	-	-
0815403	A	V	-	-	-	-	-	-	-	-	-	-	-	-
0815404	Vaccinates	-	-	-	-	-	-	-	-	-	-	-	-	-
0815501		-	-	-	-	D	D	-	-	-	-	-	-	-
0815502		-	-	-	-	-	-	-	-	-	-	-	-	-
0815505		-	-	-	-	-	-	-	-	-	-	-	-	-
0815506		-	-	-	-	-	-	-	-	-	-	-	-	-
0815601		I	-	-	-	-	-	-	-	-	-	-	-	-
0883302		-	-	-	-	-	-	-	-	-	-	-	-	-
0883303		-	-	-	-	-	-	-	-	-	-	-	-	-
0883305		-	-	-	-	-	-	-	-	-	-	-	-	-
0883401		-	-	-	-	-	-	-	-	-	-	-	-	-
0815103		Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead
0815204	B	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead
0815504	Controls	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead
0815602		Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead
0883304		S, L2, I, H, D, V	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead

SD = study day

**S** = seizures / convulsions; **L2** = severe depression; **I** = Inappetence; **H** = Dehydration;

**D** = diarrhea; **V** = vomiting

**Table 3. CDV Post-Challenge Rectal Temperatures (°F)**

Dog ID	Treatment Group	SD 61	SD 62	SD 63*	SD 64	SD 65	SD 66	SD 67	SD 68	SD 69	SD 70	SD 71	SD 72	SD 73
0815102		100.2	100.6	100.7	100.4	100.5	100.6	101.1	100.9	100.9	101.5	101.4	102.3	101.3
0815104		100.3	101.9	100.8	100.9	100.8	101.3	100.8	101.4	100.7	101.1	101.2	101.7	100.5
0815106		101.5	100.6	101.4	101.6	102.0	102.0	102.3	101.4	102.6	101.4	101.9	102.3	102.6
0815107		101.1	101.9	100.8	102.0	101.5	102.3	101.7	101.0	101.6	100.9	101.2	102.1	100.9
0815205		101.3	102.4	100.6	101.2	101.4	101.8	101.6	101.6	100.4	102.0	101.2	102.3	101.2
0815206		101.2	102.1	101.4	101.8	101.6	102.4	101.5	101.8	100.8	101.2	101.0	101.7	101.2
0815208		101.9	101.6	100.4	101.2	100.6	101.2	101.4	101.4	100.7	101.2	101.2	101.2	102.7
0815209		100.8	102.2	100.6	100.9	101.1	101.4	101.6	101.4	101.0	100.1	101.1	101.4	102.7
0815402		100.9	101.0	101.6	101.9	100.4	100.5	101.3	101.2	100.8	101.0	101.1	100.9	102.9
0815403	A	100.8	101.3	101.1	101.5	101.3	101.8	102.1	101.5	101.8	100.4	100.8	101.9	101.9
0815404	Vaccinates	102.1	102.1	101.0	101.2	101.7	101.2	101.6	101.3	101.4	101.6	101.4	102.3	100.6
0815501		101.8	101.7	101.3	100.9	101.2	101.8	102.7	101.7	101.3	101.5	100.8	101.7	102.6
0815502		101.0	101.6	100.2	100.7	100.4	101.5	101.1	101.4	101.5	101.3	101.3	102.2	100.9
0815505		100.5	102.2	101.8	102.0	101.9	101.6	102.3	101.4	102.0	101.4	101.8	101.5	103.4
0815506		101.0	101.6	100.8	101.7	101.0	101.6	100.6	101.4	101.0	101.6	101.4	102.0	101.3
0815601		100.3	101.5	100.6	100.3	100.4	100.7	100.6	100.5	100.8	100.6	100.7	100.6	101.6
0883302		102.0	101.1	100.3	101.8	102.0	101.9	102.1	101.4	102.0	100.9	101.6	102.1	102.9
0883303		102.2	101.0	101.8	101.1	101.7	102.0	101.4	101.5	102.2	101.5	102.2	102.3	103.4
0883305		101.1	101.8	101.3	100.8	101.5	101.1	101.3	101.2	101.6	100.6	101.6	102.6	101.3
0883401		100.9	102.2	100.9	101.0	101.5	102.2	102.0	101.3	101.3	101.2	102.2	102.7	102.0
0815103		101.2	101.5	101.2	101.1	100.5	103.5	104.3	103.1	103.0	102.4	Dead	Dead	Dead
0815204	B	100.4	102.0	100.4	101.2	101.8	103.0	102.5	102.5	102.6	Dead	Dead	Dead	Dead
0815504	Controls	100.2	100.9	100.5	100.6	100.6	102.7	104.1	102.2	101.6	Dead	Dead	Dead	Dead
0815602		100.7	102.2	100.5	100.7	101.1	103.4	104.7	103.4	102.4	101.0	Dead	Dead	Dead
0883304		102.1	102.0	101.6	101.1	101.5	103.8	103.3	102.2	102.3	100.7	100.9	Dead	Dead

SD = study day  
 \* Challenge

**Table 2. CDV Post-Challenge Rectal Temperatures (°F) - continued**

Dog ID	Treatment Group	SD 74	SD 75	SD 76	SD 77	SD 78	SD 79	SD 80	SD 81	SD 82	SD 83	SD 84
0815102		100.7	101.6	101.0	100.3	100.4	100.9	100.5	100.9	100.8	100.6	101.0
0815104		100.9	101.5	101.3	100.6	100.6	101.3	100.8	101.3	100.5	100.6	100.9
0815106		101.4	102.2	102.9	102.2	101.4	102.6	101.6	101.1	101.7	101.1	102.0
0815107		101.5	101.6	101.3	101.0	101.4	102.0	100.5	101.1	101.5	100.5	100.5
0815205		101.0	101.9	101.3	101.2	101.2	101.7	100.9	101.2	100.9	101.1	100.9
0815206		101.3	102.2	101.8	100.9	101.4	101.2	101.0	101.2	100.9	100.5	100.3
0815208		100.6	101.5	101.5	100.7	101.1	101.5	101.2	101.9	101.4	101.3	101.7
0815209		100.8	101.6	100.8	101.0	101.4	101.5	101.1	100.8	100.7	100.9	101.3
0815402		100.4	101.3	101.1	100.6	101.3	100.7	100.7	101.0	100.4	101.1	100.7
0815403	A	100.8	101.7	102.1	100.9	101.2	101.9	101.2	101.0	101.2	101.5	102.0
0815404	Vaccinates	101.7	101.9	102.2	101.2	101.4	101.4	101.6	101.3	100.9	101.0	101.7
0815501		101.8	101.9	101.9	100.8	102.3	101.6	101.1	101.3	101.4	101.2	101.5
0815502		101.1	101.6	101.2	100.8	101.2	100.7	101.5	100.8	101.1	100.5	101.6
0815505		102.2	101.6	102.4	101.8	101.7	102.1	102.0	101.5	101.8	102.7	101.8
0815506		100.5	101.5	102.1	101.1	100.5	101.0	101.8	100.9	100.8	100.9	100.4
0815601		100.7	100.4	100.7	100.3	100.7	100.6	100.5	100.4	100.3	100.3	100.5
0883302		101.5	102.4	103.1	102.0	102.1	102.4	101.7	102.2	101.9	101.5	101.9
0883303		101.9	101.5	102.5	101.4	102.1	102.2	102.0	101.6	101.1	101.7	101.9
0883305		101.5	102.0	102.1	101.4	101.2	101.7	101.4	101.6	101.2	100.6	100.8
0883401		101.4	101.7	102.5	101.7	102.1	101.0	102.0	101.0	101.2	101.1	101.2
0815103		Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead
0815204	B	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead
0815504	Controls	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead
0815602		Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead
0883304		Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead

SD = study day  
\* Challenge

<b>Study Type</b>	Efficacy															
<b>Pertaining to</b>	Canine Parvovirus (CPV)															
<b>Study Purpose</b>	Efficacy against CPV															
<b>Product Administration</b>	Two doses administered subcutaneously, 21 days apart															
<b>Study Animals</b>	8-week-old dogs, seronegative to CPV; 20 vaccinates and 5 controls															
<b>Challenge Description</b>	All dogs were challenged with CPV 2b 75 days after second vaccination															
<b>Interval observed after challenge</b>	Dogs were observed daily for clinical signs, and rectal temperatures were recorded for 14 days post challenge. Blood and fecal swabs were collected from the dogs 10 days post challenge.															
<b>Results</b>	<p><b><u>Summary of CPV Efficacy Results:</u></b></p> <table border="1"> <thead> <tr> <th></th> <th>Fever</th> <th>Lymphopenia</th> <th>Clinical Signs of Disease</th> <th>Fecal Virus Shedding</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>1/20</td> <td>0/20</td> <td>0/20</td> <td>0/20</td> </tr> <tr> <td>Controls</td> <td>3/5</td> <td>5/5</td> <td>5/5</td> <td>2/5</td> </tr> </tbody> </table> <p>Requirements per 9 CFR 113.317 were met.</p> <p>Detailed summary of Criteria of Infection after challenge is listed in Table 1; see Table 2, 3, 4 and 5 for raw data of rectal temperatures, mortality and clinical signs, virus shedding, and lymphopenia, respectively, after challenge.</p> <p>Study Date (SD) SD0 is the date of the first vaccination. SD21 is the date of the second vaccination. SD96 is the date of the challenge corresponding to 75 days after the second vaccination.</p>		Fever	Lymphopenia	Clinical Signs of Disease	Fecal Virus Shedding	Vaccinates	1/20	0/20	0/20	0/20	Controls	3/5	5/5	5/5	2/5
	Fever	Lymphopenia	Clinical Signs of Disease	Fecal Virus Shedding												
Vaccinates	1/20	0/20	0/20	0/20												
Controls	3/5	5/5	5/5	2/5												
<b>USDA Approval Date</b>	December 16, 2009															

**Table 1. Criteria of Infection.**

Dog ID	Treatment Group	Fever	Lymphopenia	Clinical Signs of Disease	Fecal Virus Shedding	Total No. of Criterion Displayed
0814702		o	o	o	o	0
0814704		o	o	o	o	0
0814705		o	o	o	o	0
0814801		o	o	o	o	0
0814802		o	o	o	o	0
0814804		o	o	o	o	0
0814902		o	o	o	o	0
0814904		o	o	o	o	0
0814905		o	o	o	o	0
0815001	Vaccinates	o	o	o	o	0
0815003		o	o	o	o	0
0815004		o	o	o	o	0
0815006		o	o	o	o	0
0882802		o	o	o	o	0
0882803		+	o	o	o	1
0882901		o	o	o	o	0
0882904		o	o	o	o	0
0882905		o	o	o	o	0
0883001		o	o	o	o	0
0883003		o	o	o	o	0
<hr/>						
0814701		+	+	+	+	4
0814903		o	+	+	+	3
0815007	Controls	o	+	+	o	2
0882903		+	+	+	o	3
0883002		+	+	+	o	3

o = absent  
+ = present

**Table 2. CPV Post-Challenge Rectal Temperatures (°F)**

Dog ID	Treatment Group	SD# 94	SD 95	SD 96*	SD 97	SD 98	SD 99	SD 100	SD 101	SD 102	SD 103
0814702		100.4	101.1	100.1	100.4	100.7	100.4	100.4	101.1	100.8	101.0
0814704		100.5	101.5	100.8	101.2	100.7	100.4	100.8	100.8	100.8	100.6
0814705		100.8	101.6	101.4	101.2	101.0	101.2	101.4	101.3	101.7	101.5
0814801		101.0	101.1	101.2	100.8	101.3	100.9	100.8	101.2	101.4	101.1
0814802		101.0	101.1	101.4	100.8	100.7	100.6	100.5	101.5	100.5	100.3
0814804		101.8	101.1	100.7	101.5	101.2	101.8	100.1	100.9	101.3	100.7
0814902		101.1	101.4	102.1	101.6	101.3	101.8	102.1	101.5	102.1	101.4
0814904		100.6	101.2	101.0	100.8	101.1	100.4	100.5	100.9	101.2	100.7
0814905		101.8	101.6	101.7	102.1	101.4	102.3	101.0	101.7	102.1	101.1
0815001		100.9	100.8	101.1	100.7	100.4	100.7	100.3	100.6	100.5	100.8
0815003	Vaccinates	100.6	101.2	101.2	100.4	101.1	101.0	100.4	101.2	100.8	101.0
0815004		100.4	100.3	100.6	100.6	100.5	100.3	100.3	100.6	100.6	100.7
0815006		100.8	101.0	101.5	101.0	100.7	100.4	100.6	101.9	101.0	101.5
0882802		101.9	100.9	100.5	101.1	100.3	101.5	100.9	100.8	101.4	101.2
0882803		102.6	102.5	102.5	101.5	102.6	102.3	102.4	102.1	101.4	101.8
0882901		102.2	101.1	101.3	101.2	100.9	100.3	101.1	101.5	102.0	101.6
0882904		101.4	100.5	101.0	101.0	101.1	100.6	100.9	101.5	101.6	100.9
0882905		102.1	102.1	101.3	101.3	101.7	101.3	102.1	101.5	101.2	101.4
0883001		101.1	102.4	102.2	102.1	102.5	102.5	101.9	102.4	102.1	101.1
0883003		100.9	101.6	101.2	101.7	101.3	101.3	101.3	100.5	101.5	101.3
0814701		100.2	100.8	100.6	100.5	100.9	100.8	101.1	103.6	101.7	100.7
0814903		101.0	101.2	100.7	100.6	100.9	100.7	102.2	102.3	102.7	Dead
0815007	Controls	100.3	100.2	100.4	100.5	100.2	100.1	101.9	101.5	101.2	Dead
0882903		101.5	101.7	102.2	101.3	101.2	102.3	102.4	103.5	101.7	Dead
0883002		101.9	101.6	101.7	101.2	101.5	102.2	102.0	103.6	100.5	Dead

# SD = Study Day Pre- / Post-Challenge  
 \* Challenge date is on Study Day (SD) 96  
 Rectal temperatures  $\geq 103.4^{\circ}\text{F}$  indicate fever

**Table 2. CPV Post-Challenge Rectal Temperatures (°F) - continued**

Dog ID	Treatment Group	SD# 104	SD 105	SD 106	SD 107	SD 108	SD 109	SD 110
0814702		100.4	100.5	100.4	101.3	101.0	100.7	101.0
0814704		101.0	100.8	100.5	101.4	100.5	100.6	101.0
0814705		100.9	100.3	100.7	101.6	101.2	100.6	102.2
0814801		100.9	101.3	100.3	102.0	101.8	101.4	101.1
0814802		100.8	100.9	101.0	101.7	101.5	101.6	101.3
0814804		100.4	101.2	100.7	101.9	100.9	100.5	101.4
0814902		101.4	101.3	101.1	101.7	101.0	101.4	101.4
0814904		100.5	100.3	101.2	101.1	101.0	100.8	100.4
0814905		102.2	101.0	101.5	102.6	101.3	101.3	101.6
0815001		100.4	100.8	100.4	101.2	100.8	101.0	100.8
0815003	Vaccinates	100.7	100.3	100.6	101.5	101.3	101.2	100.4
0815004		100.1	100.2	100.4	101.0	100.5	101.0	101.1
0815006		100.5	100.6	100.9	101.7	101.6	101.1	101.4
0882802		101.3	100.8	100.9	102.0	102.7	101.0	102.1
0882803		102.4	102.8	102.1	103.3	103.5	102.0	102.4
0882901		101.2	101.0	101.1	102.2	101.0	101.4	101.1
0882904		101.4	100.6	100.0	101.9	101.5	100.8	100.9
0882905		101.5	101.1	101.2	102.0	101.8	101.6	100.9
0883001		101.8	101.8	100.9	102.3	100.9	101.7	102.1
0883003		100.8	100.6	100.7	102.1	102.8	102.1	102.7
0814701		101.1	100.8	100.4	100.8	100.8	101.0	100.7
0814903		Dead	Dead	Dead	Dead	Dead	Dead	Dead
0815007	Controls	Dead	Dead	Dead	Dead	Dead	Dead	Dead
0882903		Dead	Dead	Dead	Dead	Dead	Dead	Dead
0883002		Dead	Dead	Dead	Dead	Dead	Dead	Dead

# SD = Study Day Pre- / Post-Challenge; Challenge date is on SD 96  
 Rectal temperatures  $\geq 103.4^{\circ}\text{F}$  indicate fever

**Table 3. CPV Post-Challenge Clinical Observations**

Dog ID	Treatment Group	SD# 94	SD 95	SD 96*	SD 97	SD 98
0814702		-	-	-	-	-
0814704		-	-	-	-	-
0814705		-	-	-	-	-
0814801		-	-	-	-	-
0814802		-	-	-	-	-
0814804		-	-	-	-	-
0814902		-	-	-	-	-
0814904		-	-	-	-	-
0814905		-	-	-	-	-
0815001		-	-	-	-	-
0815003	Vaccinates	-	-	-	-	-
0815004		-	-	-	-	-
0815006		-	-	V	-	-
0882802		-	-	-	-	-
0882803		-	-	-	-	D
0882901		-	-	-	-	-
0882904		-	-	-	-	-
0882905		-	-	-	-	D
0883001		-	-	-	-	-
0883003		-	-	-	-	-
<hr/>						
0814701		-	-	-	-	-
0814903		-	-	-	-	-
0815007	Controls	-	-	-	-	-
0882903		-	-	-	-	-
0883002		-	-	-	-	-

# SD = Study Day Pre- / Post-Challenge; \* Challenge date is on SD 96

**V** = Vomiting; **M** = Feces with blood or mucous; **D** = Diarrhea; **B** = Diarrhea with blood; **H** = Dehydration; **L1** = Moderate depression; **L2** = Severe depression; **I** = Inappetence



**Table 3. CPV Post-Challenge Clinical Observations – continued.**

Dog ID	Treatment Group	SD 99	SD 100	SD 101	SD 102	SD 103
0814702		-	-	-	-	-
0814704		V	-	-	-	-
0814705		-	V	-	-	-
0814801		V	-	-	-	-
0814802		-	-	-	-	-
0814804		-	-	-	-	-
0814902		-	-	-	-	-
0814904		-	-	-	-	-
0814905		-	-	-	-	-
0815001		-	-	-	-	-
0815003	Vaccinates	-	-	-	-	-
0815004		-	-	-	-	-
0815006		-	V	-	-	-
0882802		-	-	-	-	-
0882803		-	-	-	-	-
0882901		-	-	-	-	-
0882904		-	-	-	-	-
0882905		V	-	-	-	-
0883001		-	-	-	-	-
0883003		-	-	-	-	-
0814701		-	-	M	V, I	V, M, H, L1, I
0814903		-	-	B, I	V, B, H, L2, I	Dead
0815007	Controls	-	V	B, H	V, D, H, L1, I	Dead
0882903		-	-	V, M	V, B	Dead
0883002		-	V	V	V, B, H, L2, I	Dead

#SD = Study Day Pre- / Post-Challenge; \* Challenge date is on SD 96

**V** = Vomiting; **M** = Feces with blood or mucous; **D** = Diarrhea; **B** = Diarrhea with blood; **H** = Dehydration; **L1** = Moderate depression; **L2** = Severe depression; **I** = Inappetence

**Table 3. CPV Post-Challenge Clinical Observations - continued**

Dog ID	Treatment Group	SD# 104	SD 105	SD 106	SD 107	SD 108	SD 109	SD 110
0814702		-	-	-	-	-	-	-
0814704		-	-	-	-	-	-	-
0814705		-	-	-	-	-	-	-
0814801		V	-	-	-	-	-	-
0814802		-	-	-	-	V	-	-
0814804		-	-	-	-	-	-	-
0814902		-	-	-	-	-	-	-
0814904		-	-	-	-	-	-	-
0814905		-	-	-	-	-	-	-
0815001		-	-	-	-	-	-	-
0815003	Vaccinates	-	-	-	-	-	-	-
0815004		-	-	-	-	V	-	-
0815006		-	-	-	-	-	-	-
0882802		-	-	-	-	-	-	-
0882803		-	-	-	-	-	-	-
0882901		-	-	-	-	-	-	-
0882904		-	-	-	-	V	-	-
0882905		-	-	-	V	-	-	-
0883001		-	-	-	-	-	-	-
0883003		-	-	-	-	-	NA	NA
0814701		B, I	D	-	-	V	-	-
0814903		Dead	Dead	Dead	Dead	Dead	Dead	Dead
0815007	Controls	Dead	Dead	Dead	Dead	Dead	Dead	Dead
0882903		Dead	Dead	Dead	Dead	Dead	Dead	Dead
0883002		Dead	Dead	Dead	Dead	Dead	Dead	Dead

# SD = Study Day Pre- / Post-Challenge; Challenge date is on SD 96  
**V** = Vomiting; **D** = Diarrhea; **B** = Diarrhea with blood; **I** = Inappetence  
 NA = No observations recorded.

**Table 4. CPV Virus Isolation Titers (HAU/1.0 mL)**

Dog ID	Treatment Group	SD# 96*	SD 97	SD 98	SD 99	SD 100	SD 101
0814702		< 40	< 40	< 40	< 40	< 40	< 40
0814704		< 40	< 40	< 40	< 40	< 40	< 40
0814705		< 40	< 40	< 40	< 40	< 40	< 40
0814801		< 40	< 40	< 40	< 40	< 40	< 40
0814802		< 40	< 40	< 40	< 40	< 40	< 40
0814804		< 40	< 40	< 40	< 40	< 40	< 40
0814902		< 40	< 40	< 40	< 40	< 40	< 40
0814904		< 40	< 40	< 40	< 40	< 40	< 40
0814905		< 40	< 40	< 40	< 40	< 40	< 40
0815001		< 40	< 40	< 40	< 40	< 40	< 40
0815003	Vaccinates	< 40	< 40	< 40	< 40	< 40	< 40
0815004		< 40	< 40	< 40	< 40	< 40	< 40
0815006		< 40	< 40	< 40	< 40	< 40	< 40
0882802		< 40	< 40	< 40	< 40	< 40	< 40
0882803		< 40	< 40	< 40	< 40	< 40	< 40
0882901		< 40	< 40	< 40	< 40	< 40	< 40
0882904		< 40	< 40	< 40	< 40	< 40	< 40
0882905		< 40	< 40	< 40	< 40	< 40	< 40
0883001		< 40	< 40	< 40	< 40	< 40	< 40
0883003		< 40	< 40	< 40	< 40	< 40	< 40
0814701		< 40	< 40	< 40	< 40	< 40	< 40
0814903		< 40	< 40	< 40	< 40	< 40	> 81920
0815007	Controls	< 40	< 40	< 40	< 40	< 40	< 40
0882903		< 40	< 40	< 40	< 40	< 40	< 40
0883002		< 40	< 40	< 40	< 40	< 40	< 40

# SD = Study Day;

\* Challenge date is on SD 96

Samples with titer < 40 will be considered as virus negative and samples with titer of 40 or higher will be considered virus positive

**Table 4. CPV Virus Isolation Titers (HAU/1.0 mL) – continued.**

Dog ID	Treatment Group	SD 102	SD 103	SD 104	SD 105	SD 106
0814702		< 40	< 40	< 40	< 40	< 40
0814704		< 40	< 40	< 40	< 40	< 40
0814705		< 40	< 40	< 40	< 40	< 40
0814801		< 40	< 40	< 40	< 40	< 40
0814802		< 40	< 40	< 40	< 40	< 40
0814804		< 40	< 40	< 40	< 40	< 40
0814902		< 40	< 40	< 40	< 40	< 40
0814904		< 40	< 40	< 40	< 40	< 40
0814905		< 40	< 40	< 40	< 40	< 40
0815001		< 40	< 40	< 40	< 40	< 40
0815003	Vaccinates	< 40	< 40	< 40	< 40	< 40
0815004		< 40	< 40	< 40	< 40	< 40
0815006		< 40	< 40	< 40	< 40	< 40
0882802		< 40	< 40	< 40	< 40	< 40
0882803		< 40	< 40	< 40	< 40	< 40
0882901		< 40	< 40	< 40	< 40	< 40
0882904		< 40	< 40	< 40	< 40	< 40
0882905		< 40	< 40	< 40	< 40	< 40
0883001		< 40	< 40	< 40	< 40	< 40
0883003		< 40	< 40	< 40	< 40	< 40
0814701		10240	2560	640	< 40	< 40
0814903		10240	Dead	Dead	Dead	Dead
0815007	Controls	< 40	Dead	Dead	Dead	Dead
0882903		< 40	Dead	Dead	Dead	Dead
0883002		< 40	Dead	Dead	Dead	Dead

# SD = Study Day;

\* Challenge date is on SD 96

Samples with titer < 40 will be considered as virus negative and samples with titer of 40 or higher will be considered virus positive

**Table 5. Post-Challenge Lymphocyte Counts (x 10<sup>3</sup> / μL)**

Dog ID	Treatment Group	SD <sup>#</sup> 94	SD 95	SD 96*	Baseline	SD 97	SD 98	SD 99
0814702		4.6	5.5	4.3	4.8	4.9	5.1	4.6
0814704		6.4	6.1	5.8	6.1	6.9	6.3	5.8
0814705		4.9	5.5	4.3	4.9	4.6	5.0	5.2
0814801		5.6	5.1	4.7	5.1	5.7	5.5	5.1
0814802		6.7	7.5	5.3	6.5	6.4	6.4	6.4
0814804		4.5	5.2	5.1	4.9	5.2	5.4	4.8
0814902		6.3	7.0	6.9	6.7	7.6	6.6	7.4
0814904		5.1	4.8	4.3	4.7	5.3	5.0	5.0
0814905		6.7	6.8	6.4	6.6	7.9	7.7	8.6
0815001		7.2	7.6	6.2	7.0	8.7	6.7	7.3
0815003	Vaccinates	6.8	7.5	5.1	6.5	7.3	6.1	6.7
0815004		5.8	6.8	5.5	6.0	7.0	6.2	6.0
0815006		5.1	4.9	3.9	4.6	5.0	4.9	5.5
0882802		7.9	9.9	9.1	9.0	10.1	8.6	9.6
0882803		5.5	5.2	5.5	5.4	6.4	6.7	5.4
0882901		5.2	5.9	5.4	5.5	5.7	7.0	5.7
0882904		5.7	6.1	4.7	5.5	6.9	6.1	5.8
0882905		4.0	4.4	3.8	4.1	5.4	4.5	4.8
0883001		4.9	5.2	4.1	4.7	4.9	4.7	4.5
0883003		4.9	4.8	3.9	4.5	5.5	4.3	4.2
0814701		5.1	5.8	5.8	5.6	6.4	6.0	6.2
0814903		6.3	6.8	5.2	6.1	5.3	5.8	5.5
0815007	Controls	5.4	6.7	5.5	5.9	7.0	5.8	4.2
0882903		4.0	4.2	4.1	4.1	4.4	4.4	3.5
0883002		7.8	8.6	7.3	7.9	8.1	1.3	7.7

# SD = Study Day Pre- / Post-Challenge

\* Challenge date is on SD 96

Normal Range: 1.3 - 4.1

Lymphopenia = ≥ 50% reduction from baseline

**Table 5. Post-Challenge Lymphocyte Counts (x 10<sup>3</sup> / μL) – continued.**

Dog ID	Treatment Group	SD 100	SD 101	SD 102	SD 103	SD 104	SD 105	SD 106
0814702		5.2	6.1	6.4	5.0	6.5	5.9	5.7
0814704		6.1	6.0	7.1	6.4	7.0	6.8	6.6
0814705		5.7	4.5	4.2	4.0	5.1	4.4	4.3
0814801		5.2	5.8	5.5	5.2	5.4	5.2	5.3
0814802		6.7	7.2	5.8	6.2	6.4	6.5	6.8
0814804		5.4	4.8	4.7	5.4	6.1	5.3	5.0
0814902		6.9	5.7	6.7	7.0	6.5	7.4	7.6
0814904		6.1	5.3	4.4	4.4	5.4	5.4	4.9
0814905		8.3	8.6	10.0	9.0	10.9	9.9	9.3
0815001		7.4	7.1	7.4	7.9	6.7	7.9	7.3
0815003	Vaccinates	6.4	6.9	7.2	7.2	8.3	7.6	7.9
0815004		4.7	5.9	6.4	5.6	6.4	6.6	6.3
0815006		5.3	5.4	4.5	5.5	5.7	5.4	5.5
0882802		9.5	10.6	10.1	9.4	9.5	9.7	9.1
0882803		6.3	5.5	5.7	5.5	4.9	5.0	6.2
0882901		5.3	5.3	5.8	6.4	6.3	6.2	6.4
0882904		6.5	6.4	7.1	6.5	6.9	6.6	6.8
0882905		4.4	5.2	4.3	4.5	4.4	4.7	5.3
0883001		4.5	3.9	3.9	4.4	3.7	4.8	3.7
0883003		4.7	4.5	4.9	5.1	3.9	4.2	4.3
0814701		3.6	1.4	2.5	2.3	5.0	5.6	5.3
0814903		1.7	1.7	1.0	Dead	Dead	Dead	Dead
0815007	Controls	1.6	2.1	2.0	Dead	Dead	Dead	Dead
0882903		2.4	1.5	1.8	Dead	Dead	Dead	Dead
0883002		6.1	3.5	2.7	Dead	Dead	Dead	Dead

# SD = Study Day Pre- / Post-Challenge

\* Challenge date is on SD 96

Normal Range: 1.3 - 4.1

Lymphopenia = ≥ 50% reduction from baseline

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	To demonstrate safety of product under typical field conditions.
<b>Product Administration</b>	2 doses administered subcutaneously 3 weeks apart
<b>Study Animals</b>	346 dogs from 4 states; 116 dogs were 8 weeks of age, which is the recommended minimum age, and 230 dogs were 9 weeks of age or older.
<b>Challenge Description</b>	NA
<b>Interval observed after vaccination</b>	Client-owned dog owners were contacted 14 days following each vaccination to confirm health status, and a physical examination was performed at the clinic site just prior to receiving the second vaccination. Purpose-bred dogs were observed daily for adverse events and injection site reactions for 14 days following each vaccination.
<b>Results</b>	Please see the attached Table 1 for summary of Adverse Events
<b>USDA Approval Date</b>	June 14, 2017

**Table 1: Frequency of Adverse Events**

<b>Adverse Events*</b>	<b>Min Age (8 weeks)</b>	<b>Others (9 weeks or older)</b>	<b>Total</b>
<b>Injection Site Swelling (Transient, &lt;2.5 inch diameter)<sup>#</sup></b>	0	8	8
< 1.0 in	0	4	4
1.0 - 1.5 in	0	1	1
1.5 - 2.5 in	0	3	3
<b>Injection site pain</b>	0	7	7
<b>Anorexia</b>	0	1	1
<b>Anxiety disorder</b>	0	1	1
<b>Bacterial skin infection</b>	0	1	1
<b>Behavioural disorder NOS**</b>	0	1	1
<b>Blepharitis</b>	1	0	1
<b>Cardiac insufficiency</b>	0	1	1
<b>Dermatitis and eczema</b>	0	1	1
<b>Diarrhoea</b>	0	3	3
<b>Ear infection NOS**</b>	0	4	4
<b>Emesis</b>	0	3	3
<b>Epistaxis</b>	0	1	1
<b>General pain</b>	1	0	1
<b>Hypersensitivity reaction</b>	0	1	1
<b>Lethargy</b>	1	6	7
<b>Musculoskeletal disorder NOS**</b>	0	2	2
<b>Palpable mass NOS**, not at injection site</b>	0	1	1
<b>Pruritus</b>	0	2	2
<b>Skin disorders NOS**</b>	0	2	2
<b>Sneezing</b>	0	2	2
<b>Systemic disorder NOS**</b>	0	2	2
<b>No adverse events</b>	<b>114</b>	<b>192</b>	<b>306</b>

\* Include adverse events that were documented by investigator as related to the test vaccine or were unknown as to whether they were related or not

# All injection site swellings resolved within 6 days without further treatment

\*\* NOS = Not Otherwise Specified



<b>Study Type</b>	Safety								
<b>Pertaining to</b>	ALL								
<b>Study Purpose</b>	To demonstrate safety under field conditions								
<b>Product Administration</b>	Two doses, given 19 - 28 days apart, administered by the subcutaneous route								
<b>Study Animals</b>	609 dogs of various ages (range: 7 weeks to 14 years), breeds, and sex in 4 different states. 231 dogs were ≤ 8 weeks of age and 378 dogs were > 8 weeks of age at the time of vaccination.								
<b>Challenge Description</b>	Not applicable								
<b>Interval observed after challenge</b>	Dogs were observed immediately after vaccination for adverse events. Client owned dogs were monitored by the owners for 19 ± 8 days after each vaccination. Purpose-bred dogs were observed 2 - 6 hours post-vaccination and then daily for 14 days post-vaccination.								
<b>Results</b>	<p><u>Adverse Event (AE) Frequency Summary</u></p> <table border="1"> <thead> <tr> <th># of Animals Enrolled</th> <th># of Doses Administered*</th> <th># of Doses Administered with No AE</th> <th># of AE Attributed to the Vaccine</th> </tr> </thead> <tbody> <tr> <td>609</td> <td>1,217**</td> <td>1,184</td> <td>37 (3%)</td> </tr> </tbody> </table> <p>*2 doses per dog; **One dog did not receive a 2nd vaccination.</p> <p>Adverse event data on the following page.</p>	# of Animals Enrolled	# of Doses Administered*	# of Doses Administered with No AE	# of AE Attributed to the Vaccine	609	1,217**	1,184	37 (3%)
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609	1,217**	1,184	37 (3%)						
<b>USDA Approval Date</b>	March 15, 2010								

### **Summary of Adverse Events (AE)**

<b>Description of AE</b>	<b># of AE*</b>
Scratching at injection site	8
Lethargic & panting	1
Small lump at injection site	5
Lethargic	9
Lump found at injection site, day after vaccination	3
Lethargic and salivating	1
Soreness at injection site	2
Sore and uncomfortable	1
Lethargic, trembling, and small lump at injection site	1
Lethargic & tenderness of injection site immediately after vaccination	1
Scratching at injection site & crying following vaccination	2
Lethargic, fever, & vomiting on day of vaccination	1
Lethargic & fever on day of vaccination	1
Moderate angioedema	1

\*Some dogs had multiple adverse events per vaccination

All AEs noted resolved shortly after vaccination ( $\leq 4$  days) without treatment.