



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	2668.00
True Name	Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Nobivac Lepto 4 - Merck Animal Health Nobivac Lepto 4 - No distributor specified
Date of Compilation Summary	March 19, 2019

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	<i>Leptospira canicola</i>
Study Purpose	Efficacy against leptospirosis due to <i>L.canicola</i> .
Product Administration	Two doses were administered subcutaneously (SC) 21 days apart.
Study Animals	7-8 week old dogs, sero-negative for antibodies specific to <i>Leptospira</i> ; 20 vaccinates and 10 controls
Challenge Description	All animals were challenged with <i>L. canicola</i> Day 21 and Day 22 after the last vaccination.
Interval observed after challenge	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.
Results	<p>Summary of Results:</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>See the attached tables for raw data for this study:</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>
USDA Approval Date	September 22, 2008

Table 1. Mortality

Treatment Group	Dog ID	Mortality
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 ^b	46	2	2	2
B	QSK-7	63	2	0	0
B	RFL-7 ^a	45	2	2	2
B	ROL-7 ^b	46	2	2	2
B	SYL-7	63	1	0	0
B	XUK-7 ^b	46	2	2	2
B	SPL-7	63	1	0	0
B	TEK-7 ^c	47	2	2	2
B	TVK-7 ^b	46	2	2	2
B	TWL-7 ^d	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.**

^a Dog died on study day 45 (3 days after challenge)

^b Dogs died on study day 46 (4 days after challenge)

^c Dog died on study day 47 (5 days after challenge)

^d 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
Total		0	20	0	0	15
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
Total		13	38	30	24	22

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
Total		0	0	2	0	14	
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
Total		2	21	10	11	35	

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

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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

Study Type	Efficacy				
Pertaining to	<i>Leptospira canicola</i>				
Study Purpose	To evaluate urinary shedding in vaccinated dogs following challenge with <i>L. canicola</i> .				
Product Administration	Two doses administered subcutaneously 21 days apart.				
Study Animals	36 dogs, sero-negative to all 4 Leptospira serovars, 8 weeks of age. 24 vaccinates, 12 controls.				
Challenge Description	All animals were challenged with <i>L. canicola</i> 14 days after the last vaccination.				
Interval observed after challenge	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.				
Results	<p>Summary of Results (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				
USDA Approval Date	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

Study Type	Efficacy
Pertaining to	<i>Leptospira grippotyphosa</i>
Study Purpose	Pivotal efficacy against leptospirosis due to <i>L. grippotyphosa</i>
Product Administration	Two doses were administered subcutaneously (SC) 21 days apart.
Study Animals	7- to 8-week-old dogs, sero-negative for antibodies specific to <i>Leptospira</i> ; 20 vaccinates and 10 controls
Challenge Description	All animals were challenged with <i>L. grippotyphosa</i> Day 35, Day 36, and Day 37 after the last vaccination.
Interval observed after challenge	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.
Results	<p>Summary of Results:</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>See the attached tables for raw data for this study:</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>
USDA Approval Date	September 22, 2008

Table 1. Mortality

Treatment Group	Dog ID	Mortality
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
	OAD-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	
Total		9	15	15	8	9
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	
Total		25	56	35	56	11

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
Total		0	1	1	11	0	
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
Total		14	36	19	29	7	

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

Study Type	Efficacy
Pertaining to	<i>Leptospira grippotyphosa</i>
Study Purpose	To evaluate urinary shedding in vaccinated dogs following challenge with <i>L. grippotyphosa</i> ..
Product Administration	Two doses administered subcutaneously 21 days apart.
Study Animals	35 dogs, sero-negative to all 4 Leptospira serovars, 7-8 weeks of age. 23 vaccinates, 12controls.
Challenge Description	All animals were challenged with <i>L. grippotyphosa</i> 14 days after the last vaccination.
Interval observed after challenge	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.
Results	<p>Summary of Results (See Table 1 for raw data)</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>
USDA Approval Date	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

Study Type	Efficacy								
Pertaining to	<i>Leptospira icterohaemorrhagiae</i>								
Study Purpose	Pivotal efficacy against leptospirosis due to <i>L. icterohaemorrhagiae</i>								
Product Administration	Two doses were administered subcutaneously (SC) 21 days apart.								
Study Animals	7- to 8-week-old dogs, sero-negative for antibodies specific to <i>Leptospira</i> ; 20 vaccinates and 10 controls.								
Challenge Description	All animals were challenged with <i>L. grippityphosa</i> on Day 28 and 29 after the last vaccination.								
Interval observed after challenge	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.								
Results	<p>Summary of Results:</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>See the attached tables for raw data for this study:</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								
USDA Approval Date	September 18, 2008								

Table 1. Mortality

Treatment Group	Dog ID	Mortality
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	
Total		6	0	44	0	7
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
Total		22	16	40	23	17

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	0	2	0	8
YGL-7	0	0	0	0	0	0	6
Total		0	0	0	7	0	
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
Total		4	4	7	21	0	

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

Study Type	Efficacy				
Pertaining to	<i>Leptospira icterohaemorrhagiae</i>				
Study Purpose	To evaluate urinary shedding in vaccinated dogs following challenge with <i>L. icterohaemorrhagiae</i> .				
Product Administration	Two doses administered subcutaneously 21 days apart.				
Study Animals	36 dogs, sero-negative to all 4 Leptospira serovars, 8 weeks of age. 24 vaccinates, 10 controls.				
Challenge Description	All animals were challenged with <i>L. icterohaemorrhagiae</i> 21 days after the last vaccination.				
Interval observed after challenge	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.				
Results	<p>Summary of Results (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				
USDA Approval Date	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	0	0	0	0	0	0	0	0
	AEH-0	0	0	0	0	0	0	0	0
	AIH-0	0	0	0	0	0	0	0	0
	AOH-0	0	0	0	0	0	0	0	0
	APH-0	0	0	0	0	0	0	0	0
	AUH-0	0	0	0	0	0	0	0	0
	AVG-0	0	0	0	0	0	0	0	0
	BBH-0	0	0	0	0	0	0	0	0
	BCG-0	0	0	0	0	0	0	0	0
	BDH-0	0	0	0	0	0	0	0	0
	BGH-0	0	0	0	0	0	0	0	0
	BIH-0	0	0	0	0	0	0	0	0
	BSG-0	0	0	0	0	0	0	0	0
	BUH-0	0	0	0	0	0	0	0	0
	BXH-0	0	0	0	0	0	0	0	0
	CAG-0	0	0	0	0	0	0	0	0
	CFH-0	0	0	0	0	0	0	0	0
	CJG-0	0	0	0	0	0	0	0	0
	CQH-0	0	0	0	0	0	0	0	0
	YTG-0	0	0	0	0	0	0	0	0
YZG-0	0	0	0	0	0	0	0	0	
ZFH-0	0	0	0	0	0	0	0	0	
ZPH-0	0	0	0	0	0	0	0	0	
ZQC-0	0	0	0	0	0	0	0	0	
B (Controls)	ALG-0	0	0	0	0	0	0	0	0
	AXG-0	0	+	0	+	+	+	+	0
	AZH-0	+	+	0	+	0	0	0	0
	BEH-0	+	+	+	+	+	+	0	0
	BRH-0	0	0	+	+	+	0	0	0
	CGH-0	+	+	+	+	+	+	0	0
	CPH-0	+	+	+	+	+	+	0	+
	ZAG-0	0	0	0	0	0	0	0	0
	ZJH-0	+	+	+	+	+	0	+	+
ZOH-0	+	0	0	0	0	0	+	0	

0 = culture negative
+ = culture positive

Study Type	Efficacy
Pertaining to	<i>Leptospira pomona</i>
Study Purpose	Pivotal efficacy against leptospirosis due to <i>L. pomona</i>
Product Administration	Two doses were administered subcutaneously (SC) 21 days apart.
Study Animals	7- to 8-week-old dogs, sero-negative for antibodies specific to <i>Leptospira</i> ; 21 vaccinates and 9 controls
Challenge Description	All animals were challenged with <i>L. pomona</i> on Day 21, 22, and 23 after the last vaccination.
Interval observed after challenge	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.
Results	<p>Summary of Results:</p> <p><u>Summary of Mortality after Challenge</u> Vaccinates 0/21 Controls 4/9</p> <p><u>Summary of Isolation from tissues</u> Vaccinates 0/21 Controls 6/9</p> <p>See the attached tables for raw data for this study:</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>
USDA Approval Date	September 18, 2008

Table 1. Mortality

Treatment Group	Dog ID	Mortality
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 ^b	47	2	2	2
B	OCO-7	63	0	0	0
B	PEP-7 ^a	46	2	2	2
B	PRP-7	63	0	0	0
B	QJO-7 ^b	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 ^a	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.

^a Dogs died on study day 46 (4 days after challenge)
^b 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
Total		0	17	0	0	4
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
Total		6	40	17	14	11

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
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
Total		0	0	0	0	0
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
Total		30	26	4	7	17

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**

Study Type	Efficacy
Pertaining to	<i>Leptospira pomona</i>
Study Purpose	To evaluate urinary shedding in vaccinated dogs following challenge with <i>L. pomona</i>
Product Administration	Two doses administered subcutaneously 21 days apart.
Study Animals	36 dogs, sero-negative to all 4 Leptospira serovars, 8 weeks of age. 24 vaccinates, 12 controls.
Challenge Description	All animals were challenged with <i>L. Pomona</i> 14 days after the last vaccination.
Interval observed after challenge	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.
Results	<p>Summary of Results (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>
USDA Approval Date	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

Study Type	Safety								
Pertaining to	ALL								
Study Purpose	To demonstrate safety under field conditions								
Product Administration	Two doses, given 19 - 28 days apart, administered by the subcutaneous route								
Study Animals	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.								
Challenge Description	Not applicable								
Interval observed after challenge	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.								
Results	<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%)
# 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%)						
USDA Approval Date	March 15, 2010								

Summary of Adverse Events (AE)

Description of AE	# of AE*
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 (≤ 4 days) without treatment.