



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	2668.03
True Name	Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Nobivac Edge Lepto4 - No distributor specified
Date of Compilation Summary	September 01, 2017

**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>	<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**

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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**

<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
	OAQ-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	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	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**

<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>	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