



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	2126.01
True Name	Borrelia Burgdorferi Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Nobivac Lyme - Merck Animal Health Nobivac Lyme - No distributor specified
Date of Compilation Summary	April 10, 2019

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

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Borrelia burgdorferi</i>
<b>Study Purpose</b>	To demonstrate efficacy against <i>B. burgdorferi</i> . (subclinical arthritis)
<b>Product Administration</b>	
<b>Study Animals</b>	Canine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	March 19, 2007

Study Type	Efficacy																		
Pertaining to	<i>Borrelia burgdorferi</i>																		
Study Purpose	To demonstrate efficacy against <i>B. burgdorferi</i> one year after vaccination.																		
Product Administration	Two doses administered subcutaneously, 3 weeks apart																		
Study Animals	39 dogs; 8 weeks of age at the time of first vaccination; 20 controls and 19 vaccinates																		
Challenge Description	All dogs were challenged 1 year after the second vaccination with <i>B. burgdorferi</i> -infected ticks.																		
Interval observed after challenge	Dogs were observed daily for 21 weeks (5 months) post-challenge for clinical signs of limb/joint disorder. Skin tissues were examined weekly. Joint tissues were examined at the end of the study.																		
Results	<p><b>Primary Variable:</b> Limb/joint disorder, defined as at least one of:</p> <ul style="list-style-type: none"><li>• Stiffness, limping, and/or lameness for 3 consecutive days or multiple episodes of these clinical signs;</li><li>• Joint inflammation as demonstrated by erosive changes in joint tissues evident on histopathology); or</li><li>• Recovery of <i>B. burgdorferi</i> from joint tissues</li></ul> <table><tr><th>Treatment Group</th><th>Total # of Dogs</th><th># of Dogs Affected</th></tr><tr><td>Controls</td><td>20</td><td>15</td></tr><tr><td>Vaccinates</td><td>19</td><td>7</td></tr></table> <p><b>Secondary Variable:</b> Persistent skin infection defined as 2 consecutive skin biopsy positive cultures or at least 3 separate skin positive cultures during the 5-month post challenge observation period.</p> <table><tr><th>Treatment Group</th><th>Total # of Dogs</th><th># of Dogs Affected</th></tr><tr><td>Controls</td><td>20</td><td>17</td></tr><tr><td>Vaccinates</td><td>19</td><td>7</td></tr></table> <p>Raw data shown on attached pages. Days are post challenge (PC).</p>	Treatment Group	Total # of Dogs	# of Dogs Affected	Controls	20	15	Vaccinates	19	7	Treatment Group	Total # of Dogs	# of Dogs Affected	Controls	20	17	Vaccinates	19	7
Treatment Group	Total # of Dogs	# of Dogs Affected																	
Controls	20	15																	
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Treatment Group	Total # of Dogs	# of Dogs Affected																	
Controls	20	17																	
Vaccinates	19	7																	
USDA Approval Date	February 13, 2013																		

Dog ID	Treatment Group	<i>B. burgdorferi</i> infection in the skin	Limb/Joint Disorder			
			<i>B. burgdorferi</i> -Associated Stiffness/ Limping/ Lameness	<i>B. burgdorferi</i> Isolation from Joint Tissues*	Inflammatory Changes in Joint Tissues	Affected
AAC-0	Vaccinates	-	-	-	-	
ACC-0		+	+	-	+	+
AQD-0		+	-	-	-	
AVC-0		-	-	-	+	+
AWF-0		+	+	+	+	+
AXE-0		+	-	-	-	
BOC-0		+	-	+	+	+
BVF-0		-	-	-	-	
CZF-0		+	+	+	-	+
DTE-0		-	-	-	-	
YAD-0		-	-	-	-	
YBC-0		-	-	-	-	
YID-0		-	-	-	-	
YKD-0		-	-	-	-	+
YQD-0		-	-	-	-	
YZC-0		-	-	-	-	
ZBC-0		-	-	-	-	
ZVC-0		+	-	+	+	+
ZXC-0		-	-	-	-	
ASD-0	Controls	+	-	+	+	+
BID-0		+	-	-	+	+
BLC-0		+	-	-	-	
BXE-0		+	-	+	+	+
BZE-0		+	-	+	-	+
CFE-0		+	-	+	-	+
DCF-0		-	-	-	-	
DEF-0		-	-	-	-	
DJE-0		+	-	+	-	+
DPF-0		+	+	-	-	+
DYD-0		+	-	-	-	
YCC-0		+	-	+	+	+
YFD-0		+	-	+	+	+
YJD-0		+	-	+	+	+
YLC-0		+	+	-	-	+
YOD-0		+	-	+	+	+
YPD-0		+	-	+	-	+
YVC-0		+	-	+	-	+
YXD-0		-	-	-	-	
ZWC-0		+	-	+	+	+

**Clinical Observations Post-Challenge**

Treatment Group	Dog ID	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15	Day 16	Day 17	Day 18	Day 19	Day 20
A (Vaccinates)	AAC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ACC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AQD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AWF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AXE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BOC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	CZF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DTE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YAD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YBC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YID-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YKD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YQD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YZC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZBC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZXC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
B (Controls)	ASD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BID-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BLC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BXE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BZE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	CFE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DCF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DEF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DJE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DPF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DYD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YCC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YFD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YJD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YLC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YOD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YPD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YXD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N	N	N	N	N	N	N	N

**N = Normal**

**Clinical Observations Post-Challenge - continued**

<b>Treatment Group</b>	<b>Dog ID</b>	<b>Day 21</b>	<b>Day 22</b>	<b>Day 23</b>	<b>Day 24</b>	<b>Day 25</b>	<b>Day 26</b>	<b>Day 27</b>	<b>Day 28</b>	<b>Day 29</b>	<b>Day 30</b>	<b>Day 31</b>	<b>Day 32</b>	<b>Day 33</b>
<b>A</b> (Vaccinates)	AAC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ACC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AQD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AWF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AXE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BOC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	CZF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DTE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YAD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YBC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YID-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YKD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YQD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YZC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZBC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZXC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
<b>B</b> (Controls)	ASD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BID-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BLC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BXE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BZE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	CFE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DCF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DEF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DJE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DPF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DYD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YCC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YFD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YJD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YLC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YOD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YPD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YXD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
<b>N = Normal</b>														

**Clinical Observations Post-Challenge - continued**

<b>Treatment Group</b>	<b>Dog ID</b>	<b>Day 34</b>	<b>Day 35</b>	<b>Day 36</b>	<b>Day 37</b>	<b>Day 38</b>	<b>Day 39</b>	<b>Day 40</b>	<b>Day 41</b>	<b>Day 42</b>	<b>Day 43</b>	<b>Day 44</b>	<b>Day 45</b>	<b>Day 46</b>
<b>A</b> (Vaccinates)	AAC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ACC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AQD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AWF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AXE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BOC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	CZF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DTE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YAD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YBC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YID-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YKD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YQD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YZC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZBC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZXC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
<b>B</b> (Controls)	ASD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BID-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BLC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BXE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BZE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	CFE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DCF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DEF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DJE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DPF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DYD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YCC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YFD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YJD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YLC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YOD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YPD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YXD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N	N	N	N	N	N	N	N

**N = Normal**

**Clinical Observations Post-Challenge - continued**

Treatment Group	Dog ID	Day 47	Day 48	Day 49	Day 50	Day 51	Day 52	Day 53	Day 54	Day 55	Day 56	Day 57	Day 58	Day 59
A (Vaccinates)	AAC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ACC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AQD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AWF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AXE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BOC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	CZF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DTE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YAD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YBC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YID-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YKD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YQD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YZC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZBC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZXC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
B (Controls)		N	N	N	N	N	N	N	N	N	N	N	N	N
	ASD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BID-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BLC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BXE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BZE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	CFE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DCF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DEF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DJE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DPF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DYD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YCC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YFD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YJD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YLC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YOD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YPD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YXD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
N = Normal														



**Clinical Observations Post-Challenge - continued**

Treatment Group	Dog ID	Day 60	Day 61	Day 62	Day 63	Day 64	Day 65	Day 66	Day 67	Day 68	Day 69	Day 70	Day 71
A (Vaccinates)	AAC-0	N	N	N	N	N	N	N	N	N	N	N	N
	ACC-0	N	N	N	N	N	N	N	N	N	N	N	N
	AQD-0	N	N	N	N	N	N	N	N	N	N	N	N
	AVC-0	N	N	N	N	N	N	N	N	N	N	N	N
	AWF-0	N	N	N	N	N	N	N	N	N	N	N	N
	AXE-0	N	N	N	N	N	N	N	N	N	N	N	N
	BOC-0	N	N	N	N	N	N	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	N	N	N	N	N	N	N
	CZF-0	N	N	N	N	N	N	N	N	N	N	N	N
	DTE-0	N	N	N	N	N	N	N	N	N	N	N	N
	YAD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YBC-0	N	N	N	N	N	N	N	N	N	N	N	N
	YID-0	N	N	N	N	N	N	N	N	N	N	N	N
	YKD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YQD-0	N	N	N	N	N	N	N	N	M <sup>4</sup> ; 103.1	N	N	N
	YZC-0	N	N	N	N	N	N	N	N	N	N	N	N
	ZBC-0	N	N	N	N	N	N	N	N	N	N	N	N
	ZVC-0	N	N	N	N	N	N	N	N	N	N	N	N
	ZXC-0	N	N	N	N	N	N	N	N	N	N	N	N
B (Controls)	ASD-0	N	N	N	N	N	N	N	N	N	N	N	N
	BID-0	N	N	N	N	N	N	N	N	N	N	N	N
	BLC-0	N	N	N	N	N	N	N	N	N	N	N	N
	BXE-0	N	N	N	N	N	N	N	N	N	N	N	N
	BZE-0	N	N	N	N	N	N	N	N	N	N	N	N
	CFE-0	N	N	N	N	N	N	N	N	N	N	N	N
	DCF-0	N	N	N	N	N	N	N	N	N	N	N	N
	DEF-0	N	N	N	N	N	N	N	N	N	N	N	N
	DJE-0	N	N	N	N	N	N	N	N	N	N	N	N
	DPF-0	N	N	N	N	N	N	N	N	N	N	N	N
	DYD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YCC-0	N	N	N	N	N	N	N	N	N	N	N	N
	YFD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YJD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YLC-0	N	N	N	N	N	N	N	N	N	N	N	N
	YOD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YPD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YVC-0	N	N	N	N	N	N	N	N	N	N	N	N
	YXD-0	N	N	N	N	N	N	N	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N	N	N	N	N	N	N

N = Normal; M = Lamé; <sup>1</sup> left front limb; <sup>2</sup> right front limb; <sup>3</sup> left rear limb; <sup>4</sup> right rear limb

**Clinical Observations Post-Challenge - continued**

<b>Treatment Group</b>	<b>Dog ID</b>	<b>Day 72</b>	<b>Day 73</b>	<b>Day 74</b>	<b>Day 75</b>	<b>Day 76</b>	<b>Day 77</b>	<b>Day 78</b>	<b>Day 79</b>	<b>Day 80</b>	<b>Day 81</b>	<b>Day 82</b>	<b>Day 83</b>	<b>Day 84</b>
<b>A</b> (Vaccinates)	AAC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ACC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AQD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AWF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AXE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BOC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	CZF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DTE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YAD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YBC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YID-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YKD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YQD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YZC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZBC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZXC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
<b>B</b> (Controls)	ASD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BID-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BLC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BXE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	BZE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	CFE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DCF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DEF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DJE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DPF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	DYD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YCC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YFD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YJD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YLC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YOD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YPD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YVC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	YXD-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N	N	N	N	N	N	N	N

**N = Normal**

**Clinical Observations Post-Challenge - continued**

Treatment Group	Dog ID	Day 85	Day 86	Day 87	Day 88	Day 89	Day 90	Day 91	Day 92	Day 93	Day 94	Day 95	Day 96
A (Vaccinates)	AAC-0	N	N	N	N	N	N	N	N	N	N	N	N
	ACC-0	N	N	N	N	N	N	N	N	N	N	N	N
	AQD-0	N	N	N	N	N	N	N	N	N	N	N	N
	AVC-0	N	N	N	N	N	N	N	N	N	N	N	N
	AWF-0	N	N	N	N	N	N	L <sup>1</sup> ; 103.1	N	N	N	N	N
	AXE-0	N	N	N	N	N	N	N	N	N	N	N	N
	BOC-0	N	N	N	N	N	N	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	N	N	N	N	N	N	N
	CZF-0	N	N	N	N	N	N	N	N	N	N	N	N
	DTE-0	N	N	N	N	N	N	N	N	N	N	N	N
	YAD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YBC-0	N	N	N	N	N	N	N	N	N	N	N	N
	YID-0	N	N	N	N	N	N	N	N	N	N	N	N
	YKD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YQD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YZC-0	N	N	N	N	N	N	N	N	N	N	N	N
	ZBC-0	N	N	N	N	N	N	N	N	N	N	N	N
	ZVC-0	N	N	N	N	N	N	N	N	N	N	N	N
	ZXC-0	N	N	N	N	N	N	N	N	N	N	N	N
B (Controls)	ASD-0	N	N	N	N	N	N	N	N	N	N	N	N
	BID-0	N	N	N	N	N	N	N	N	N	N	N	N
	BLC-0	N	N	N	N	N	N	N	N	N	N	N	N
	BXE-0	N	N	N	N	N	N	N	N	N	N	N	N
	BZE-0	N	N	N	N	N	N	N	N	N	N	N	N
	CFE-0	N	N	N	N	N	N	N	N	N	N	N	N
	DCF-0	N	N	N	N	N	N	N	N	N	N	N	N
	DEF-0	N	N	N	N	N	N	N	N	N	N	N	N
	DJE-0	N	N	N	N	N	N	N	N	N	N	N	N
	DPF-0	N	N	N	N	N	N	N	N	N	N	N	N
	DYD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YCC-0	N	N	N	N	N	N	N	N	N	N	N	N
	YFD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YJD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YLC-0	N	N	N	N	N	N	N	N	N	N	N	N
	YOD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YPD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YVC-0	N	N	N	N	N	N	N	N	N	N	N	N
	YXD-0	N	N	N	N	N	N	N	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N	N	N	N	N	N	N

N = Normal; L = Limping; <sup>1</sup> left front limb; <sup>2</sup> right front limb; <sup>3</sup> left rear limb; <sup>4</sup> right rear limb

**Clinical Observations Post-Challenge - continued**

<b>Treatment Group</b>	<b>Dog ID</b>	<b>Day 97</b>	<b>Day 98</b>	<b>Day 99</b>	<b>Day 100</b>	<b>Day 101</b>	<b>Day 102</b>	<b>Day 103</b>	<b>Day 104</b>
<b>A</b> (Vaccinates)	AAC-0	N	N	N	N	N	N	N	N
	ACC-0	N	N	N	N	N	N	N	N
	AQD-0	N	N	N	N	N	N	N	N
	AVC-0	N	N	N	N	N	N	N	N
	AWF-0	N	N	N	N	N	N	N	N
	AXE-0	N	N	N	N	N	N	N	N
	BOC-0	N	N	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	N	N	N
	CZF-0	N	N	N	N	N	N	N	N
	DTE-0	N	N	N	N	N	N	N	N
	YAD-0	N	N	N	N	N	N	N	N
	YBC-0	N	N	N	N	N	N	N	N
	YID-0	N	N	N	N	N	N	N	N
	YKD-0	N	N	N	N	N	N	N	L <sup>1,2</sup> ; 104.3
	YQD-0	N	N	N	N	N	N	N	N
	YZC-0	N	N	N	N	N	N	N	N
	ZBC-0	N	N	N	N	N	N	N	N
	ZVC-0	N	N	N	N	N	N	N	N
	ZXC-0	N	N	N	N	N	N	N	N
<b>B</b> (Controls)	ASD-0	N	N	N	N	N	N	N	N
	BID-0	N	N	N	N	N	N	N	N
	BLC-0	N	N	N	N	N	N	N	N
	BXE-0	N	N	N	N	N	N	N	N
	BZE-0	N	N	N	N	N	N	N	N
	CFE-0	N	N	N	N	N	N	N	N
	DCF-0	N	N	N	N	N	N	N	N
	DEF-0	N	N	N	N	N	N	N	N
	DJE-0	N	N	N	N	N	N	N	N
	DPF-0	N	N	N	N	N	N	N	N
	DYD-0	N	N	N	N	N	N	N	N
	YCC-0	N	N	N	N	N	N	N	N
	YFD-0	N	N	N	N	N	N	N	N
	YJD-0	N	N	N	N	N	N	N	N
	YLC-0	N	S <sup>2,3,4</sup> ; 103.1	S <sup>3,4</sup> ; 103.7	S, L <sup>3,4</sup> ; 101.1	S, L <sup>3,4</sup>	S, L <sup>3,4</sup>		
	YOD-0	N	N	N	N	N	N	N	N
	YPD-0	N	N	N	N	N	N	N	N
	YVC-0	N	N	N	N	N	N	N	N
	YXD-0	N	N	N	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N	N	N

N = Normal; S = Stiff; L = Limping; <sup>1</sup> left front limb; <sup>2</sup> right front limb; <sup>3</sup> left rear limb; <sup>4</sup> right rear limb

Clinical Observations Post-Challenge - continued									
Treatment Group	Dog ID	Day 105	Day 106	Day 107	Day 108	Day 109	Day 110	Day 111	Day 112
A (Vaccinates)	AAC-0	N	N	N	N	N	N	N	N
	ACC-0	N	N	N	N	N	N	N	N
	AQD-0	N	N	N	N	N	N	N	N
	AVC-0	N	N	N	N	N	N	N	N
	AWF-0	N	N	N	N	N	N	N	D1; L <sup>1,2,4</sup> ; 104.2
	AXE-0	N	N	N	N	N	N	N	N
	BOC-0	N	N	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	N	N	L <sup>4</sup> ; 103.6
	CZF-0	N	N	N	N	N	L <sup>1,3</sup> ; 103.7	L <sup>1,2,3,4</sup> ; 102.4	L <sup>2,3,4</sup> ; 103.1
	DTE-0	N	N	N	N	N	N	N	S <sup>3</sup> ; 102.6
	YAD-0	N	N	N	N	N	N	N	N
	YBC-0	N	N	N	N	N	N	N	N
	YID-0	N	N	N	N	N	N	N	N
	YKD-0	L <sup>1,2</sup> ; 102.9	L <sup>1</sup> ; 102.8	N	N	N	N	N	S <sup>3</sup> ; 104.6
	YQD-0	N	N	N	N	N	N	N	N
	YZC-0	N	N	N	N	N	N	N	N
	ZBC-0	N	N	N	N	N	N	N	N
	ZVC-0	N	N	N	N	N	N	N	N
	ZXC-0	N	N	N	N	N	N	N	N
B (Controls)	ASD-0	N	N	N	N	N	N	N	N
	BID-0	N	N	N	N	N	N	N	N
	BLC-0	N	N	N	N	N	N	N	L <sup>1,3,4</sup> ; 102.0
	BXE-0	N	N	N	N	N	N	N	N
	BZE-0	N	N	N	N	N	N	N	N
	CFE-0	N	N	N	N	N	N	N	N
	DCF-0	N	N	N	N	N	N	N	N
	DEF-0	N	N	N	N	N	N	N	N
	DJE-0	N	N	N	N	N	N	N	N
	DPF-0	N	N	N	N	N	N	N	N
	DYD-0	N	N	N	N	N	N	N	N
	YCC-0	N	N	N	N	N	N	N	N
	YFD-0	N	N	N	N	N	N	N	N
	YJD-0	N	N	N	N	N	N	N	L <sup>4</sup> ; 103.7
	YLC-0								
	YOD-0	N	N	N	N	N	N	N	N
	YPD-0	N	N	N	N	N	N	N	N
	YVC-0	N	N	N	N	N	N	N	N
	YXD-0	N	N	N	N	N	N	N	L <sup>1,2,3,4</sup> ; 102.7
	ZWC-0	N	N	N	N	N	N	N	N

N = Normal; L = Limping; D1 = moderate depression; S = Stiff  
<sup>1</sup> left front limb; <sup>2</sup> right front limb; <sup>3</sup> left rear limb; <sup>4</sup> right rear limb

Grey bar: humane endpoint reached



**Clinical Observations Post-Challenge - continued**

Treatment Group	Dog ID	Day 113	Day 114	Day 115	Day 116	Day 117	Day 118	Day 119	Day 120
A (Vaccinates)	AAC-0	N	N	N	N	N	N	N	N
	ACC-0	N	D2; M <sup>1,3,4</sup> ; 102.7*						
	AQD-0	N	N	N	N	N	N	N	N
	AVC-0	N	L <sup>1</sup> ; 102.2	M <sup>1</sup> ; 103.5	N	N	N	N	N
	AWF-0	L <sup>1,2,4</sup> ; 105.4	N	N	N	N	N	N	N
	AXE-0	N	N	N	N	N	N	N	N
	BOC-0	N	N	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	N	N	N
	CZF-0								
	DTE-0	N	N	N	N	N	N	N	N
	YAD-0	N	N	N	N	N	N	N	N
	YBC-0	N	N	N	N	N	N	N	N
	YID-0	N	N	N	N	N	N	N	N
	YKD-0								
	YQD-0	N	N	N	N	N	N	N	N
	YZC-0	N	N	N	N	N	N	N	N
	ZBC-0	N	N	N	N	S <sup>1</sup> ; 102.7	N	N	N
	ZVC-0	N	N	N	N	N	N	N	N
	ZXC-0	N	N	N	N	N	N	N	N
B (Controls)	ASD-0	L <sup>1,3</sup> ; 104.3	N	N	N	N	N	N	N
	BID-0	N	N	N	N	N	N	N	N
	BLC-0	L <sup>1,3,4</sup> ; 103.3	N	N	N	N	N	N	N
	BXE-0	N	N	N	N	N	N	N	N
	BZE-0	N	N	N	N	N	N	N	N
	CFE-0	N	N	N	N	N	N	N	N
	DCF-0	N	N	N	N	N	N	N	N
	DEF-0	N	N	N	N	N	N	N	N
	DJE-0	N	N	N	N	N	N	N	N
	DPF-0	N	M <sup>1</sup> ; 104.3	M <sup>1</sup> ; 103.9	M <sup>1</sup> ; 102.9				
	DYD-0	N	N	N	N	N	N	N	N
	YCC-0	N	N	N	N	N	N	N	N
	YFD-0	N	N	N	N	N	N	N	N
	YJD-0	L <sup>4</sup> ; 105.0	N	N	N	N	N	N	N
	YLC-0								
	YOD-0	N	N	N	N	N	N	N	N
	YPD-0	N	N	N	N	N	N	N	N
	YVC-0	N	N	N	N	N	N	N	N
	YXD-0	L <sup>1-4</sup> ; 102.9	N	N	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N	N	N

N = Normal; L = Limping; S = Stiff; M = Lameness; D2 = severe depression

<sup>1</sup> left front limb; <sup>2</sup> right front limb; <sup>3</sup> left rear limb; <sup>4</sup> right rear limb

Grey bar: humane endpoint reached

Clinical Observations Post-Challenge - continued													
Treatment Group	Dog ID	Day 121	Day 122	Day 123	Day 124	Day 125	Day 126	Day 127	Day 128	Day 129	Day 130	Day 131	Day 132
A (Vaccinates)	AAC-0	N	N	N	N	N	N	N	N	N	N	N	N
	ACC-0												
	AQD-0	N	N	N	N	N	N	N	N	N	N	N	N
	AVC-0	N	N	N	N	N	N	N	N	N	N	N	N
	AWF-0	N	N	N	N	N	N	N	N	N	N	N	N
	AXE-0	N	N	N	N	N	N	N	N	N	N	N	N
	BOC-0	N	N	N	N	N	N	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	N	N	N	N	N	N	N
	CZF-0												
	DTE-0	N	N	N	N	N	N	N	N	N	N	N	N
	YAD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YBC-0	N	N	N	N	N	N	N	N	N	N	N	N
	YID-0	N	N	N	N	N	N	N	N	N	N	N	N
	YKD-0												
	YQD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YZC-0	N	N	N	N	N	N	N	N	N	N	N	N
	ZBC-0	N	N	N	N	N	N	N	N	N	N	N	N
	ZVC-0	N	N	N	N	N	N	N	N	N	N	N	N
	ZXC-0	N	N	N	N	N	N	N	N	N	N	N	N
B (Controls)	ASD-0	N	N	N	N	N	N	N	N	N	N	N	N
	BID-0	N	N	N	N	N	N	N	N	N	N	N	N
	BLC-0	N	N	N	N	N	N	N	N	N	N	N	N
	BXE-0	N	N	N	N	N	N	N	N	N	N	N	N
	BZE-0	N	N	N	N	N	N	N	N	N	N	N	N
	CFE-0	N	N	N	N	N	N	N	N	N	N	N	N
	DCF-0	N	N	N	N	N	N	N	N	N	N	N	N
	DEF-0	N	N	N	N	N	N	N	N	N	N	N	N
	DJE-0	N	N	N	N	N	N	N	N	N	N	N	N
	DPF-0												
	DYD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YCC-0	N	N	N	N	N	N	N	N	N	N	N	N
	YFD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YJD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YLC-0												
	YOD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YPD-0	N	N	N	N	N	N	N	N	N	N	N	N
	YVC-0	N	N	N	N	N	N	N	N	N	N	N	N
	YXD-0	N	N	N	N	N	N	N	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N	N	N	N	N	N	N
N = Normal													

Grey bar: humane endpoint reached

Clinical Observations Post-Challenge - continued											
Treatment Group	Dog ID	Day 133	Day 134	Day 135	Day 136	Day 137	Day 138	Day 139	Day 140	Day 141	Day 142
A (Vaccinates)	AAC-0	N	N	N	N	N	N	N	N	N	N
	ACC-0										
	AQD-0	N	N	N	N	N	N	N	N	N	N
	AVC-0	N	N	N	N	N	N	N	N	N	N
	AWF-0	N	N	N	N	D1; L <sup>3,4</sup> ; 104.0					
	AXE-0	N	N	N	N	N	N	N	N	N	N
	BOC-0	N	N	N	N	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	N	N	N	N	N
	CZF-0										
	DTE-0	N	N	N	N	N	N	N	S <sup>3</sup> ; 100.6	N	N
	YAD-0	N	N	N	N	N	N	N	N	N	N
	YBC-0	N	N	N	N	N	N	N	N	N	N
	YID-0	N	N	N	N	N	N	N	N	N	N
	YKD-0										
	YQD-0	N	N	N	N	N	N	N	N	N	N
	YZC-0	N	N	N	N	S <sup>1-4</sup> ; 101.1	N	N	N	N	N
	ZBC-0	N	N	N	N	S <sup>1,2,3</sup> ; 101.0	N	N	N	N	N
	ZVC-0	N	N	N	N	N	N	N	N	N	N
	ZXC-0	N	N	N	N	N	N	N	N	N	N
B (Controls)	ASD-0	N	N	N	N	N	N	N	N	N	N
	BID-0	N	N	N	N	N	N	N	N	N	N
	BLC-0	N	N	N	N	N	N	N	N	N	N
	BXE-0	N	N	N	N	N	N	N	N	N	N
	BZE-0	N	N	N	N	N	N	N	N	N	N
	CFE-0	N	N	N	N	N	N	N	N	N	N
	DCF-0	N	N	N	N	N	N	N	N	N	N
	DEF-0	N	N	N	N	N	N	N	N	N	N
	DJE-0	N	N	N	N	L <sup>1-4</sup> ; 101.2	N	N	N	N	N
	DPF-0										
	DYD-0	N	N	N	N	N	N	N	N	N	N
	YCC-0	N	N	N	N	N	N	N	N	N	N
	YFD-0	N	N	N	N	N	N	N	N	N	N
	YJD-0	N	N	N	N	N	N	N	N	N	N
	YLC-0										
	YOD-0	N	N	N	N	N	N	N	N	N	N
	YPD-0	N	N	N	N	N	N	N	N	N	N
	YVC-0	N	N	N	N	N	N	N	N	N	N
	YXD-0	N	N	N	N	S <sup>1-4</sup> ; 100.8	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N	N	N	N	N

N = Normal; L = Limping; S = Stiff; D1 = moderate depression  
<sup>1</sup> left front limb; <sup>2</sup> right front limb; <sup>3</sup> left rear limb; <sup>4</sup> right rear limb

Grey bar: humane endpoint reached



Clinical Observations Post-Challenge - continued							
Treatment Group	Dog ID	Day 143	Day 144	Day 145 9/20	Day 146	Day 147	Day 148
A (Vaccinates)	AAC-0	N	N	N	N	N	N
	ACC-0						
	AQD-0	N	N	N	N	N	N
	AVC-0	N	N	N	N	N	N
	AWF-0						
	AXE-0	N	N	N	N	N	
	BOC-0	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	
	CZF-0						
	DTE-0	N	N	N	N	N	
	YAD-0	N	N	N	N	N	N
	YBC-0	N	N	N	N	N	N
	YID-0	N	N	N	N	N	
	YKD-0						
	YQD-0	N	N	N	N	N	
	YZC-0	N	N	N	N	N	N
	ZBC-0	N	N	N	N	N	N
	ZVC-0	N	N	N	N	N	N
	ZXC-0	N	N	N	N	N	N
B (Controls)	ASD-0	N	N	N	N	N	N
	BID-0	N	N	N	N	N	N
	BLC-0	N	N	N	N	N	N
	BXE-0	N	N	N	N	N	
	BZE-0	N	N	N	N	N	N
	CFE-0	N	N	N	N	N	N
	DCF-0	N	N	N	N	N	N
	DEF-0	N	N	N	N	N	N
	DJE-0	N	N	N	N	N	N
	DPF-0						
	DYD-0	N	N	N	N	N	N
	YCC-0	N	N	N	N	N	N
	YFD-0	N	N	N	N	N	
	YJD-0	N	N	N	N	N	
	YLC-0						
	YOD-0	N	N	N	N	N	
	YPD-0	N	N	N	N	N	
	YVC-0	N	N	N	N	N	N
	YXD-0	N	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N

N = Normal

Grey bar: humane endpoint reached

***B. burgdorferi* Isolation from the Skin**

Treatment Group	Dog ID	Day 35 PC	Day 63 PC	Day 91 PC	Day 119 PC	Day 146 PC
A (Vaccinates)	AAC-0	o	o	o	o	o
	ACC-0	+	+	+		
	AQD-0	o	+	+	o	+
	AVC-0	o	o	o	o	o
	AWF-0	+	+	+	o	
	AXE-0	o	+	+	+	o
	BOC-0	+	+	+	+	o
	BVF-0	o	o	o	o	o
	CZF-0	+	+	+		
	DTE-0	o	o	o	o	o
	YAD-0	o	o	o	o	o
	YBC-0	o	o	o	o	o
	YID-0	o	o	o	o	o
	YKD-0	o	o	o		
	YQD-0	o	o	o	o	o
	YZC-0	o	o	o	o	o
	ZBC-0	o	o	o	o	o
	ZVC-0	+	+	+	+	+
	ZXC-0	o	o	o	o	o
B (Controls)	ASD-0	+	+	+	+	+
	BID-0	+	+	+	+	+
	BLC-0	+	+	+	+	+
	BXE-0	+	+	+	+	+
	BZE-0	+	+	+	+	+
	CFE-0	+	+	+	+	+
	DCF-0	o	o	o	o	o
	DEF-0	o	o	o	o	o
	DJE-0	+	+	+	+	+
	DPF-0	+	+	+		
	DYD-0	+	+	+	+	+
	YCC-0	+	+	+	+	+
	YFD-0	+	+	+	+	+
	YJD-0	+	+	+	+	+
	YLC-0	o	+	+		
	YOD-0	+	+	+	+	+
	YPD-0	+	o	+	+	+
	YVC-0	+	+	+	+	+
	YXD-0	o	o	o	o	o
	ZWC-0	+	+	+	+	+

(+) = *B. burgdorferi* isolated from tissue  
(o) = *B. burgdorferi* not isolated from tissue  
PC = post-challenge

Grey bar: humane endpoint reached

### Recovery of *B. burgdorferi* from Tissue Samples

Treatment Group	Dog ID	Elbow	Carpus	Knee	Tarsus
A (Vaccinates)	AAC-0	o	o	o	o
	ACC-0	o	o	o	o
	AQD-0	o	o	o	o
	AVC-0	o	o	o	o
	AWF-0	+	o	o	o
	AXE-0	o	o	o	o
	BOC-0	+	o	o	o
	BVF-0	o	o	o	o
	CZF-0	o	o	+	o
	DTE-0	o	o	o	o
	YAD-0	o	o	o	o
	YBC-0	o	o	o	o
	YID-0	o	o	o	o
	YKD-0	o	o	o	o
	YQD-0	o	o	o	o
	YZC-0	o	o	o	o
	ZBC-0	o	o	o	o
	ZVC-0	+	+	o	o
	ZXC-0	o	o	o	o
B (Controls)	ASD-0	+	o	o	+
	BID-0	o	o	o	o
	BLC-0	o	o	o	o
	BXE-0	+	o	o	+
	BZE-0	o	+	+	o
	CFE-0	+	o	o	o
	DCF-0	o	o	o	o
	DEF-0	o	o	o	o
	DJE-0	o	+	+	o
	DPF-0	o	o	o	o
	DYD-0	o	o	o	o
	YCC-0	+	o	o	o
	YFD-0	+	o	o	o
	YJD-0	+	+	+	+
	YLC-0	o	o	o	o
	YOD-0	+	o	o	o
	YPD-0	+	+	o	+
	YVC-0	o	+	o	o
	YXD-0	o	o	o	o
	ZWC-0	+	o	+	+

(+) = *B. burgdorferi* isolated from tissue

(o) = *B. burgdorferi* not isolated from tissue

### Development of Inflammatory Cell Infiltrations in Joint Tissues

Treatment Group	Dog ID	Significant (+/o) infiltrations of neutrophils and mononuclear cells			
		Elbow	Carpus	Knee	Tarsus
A (Vaccinates)	AAC-0	o	o	o	o
	ACC-0	+	o	o	o
	AQD-0	o	o	o	o
	AVC-0	o	+	o	o
	AWF-0	o	+	+	+
	AXE-0	o	o	o	o
	BOC-0	o	o	o	+
	BVF-0	o	o	o	o
	CZF-0	o	o	o	o
	DTE-0	o	o	o	o
	YAD-0	o	o	o	o
	YBC-0	o	o	o	o
	YID-0	o	o	o	o
	YKD-0	o	o	o	o
	YQD-0	o	o	o	o
	YZC-0	o	o	o	o
	ZBC-0	o	o	o	o
	ZVG-0	+	o	o	o
	ZXC-0	o	o	o	o
B (Controls)	ASD-0	+	o	o	o
	BID-0	+	o	o	o
	BLC-0	o	o	o	o
	BXE-0	o	o	o	+
	BZE-0	o	o	o	o
	CFE-0	o	o	o	o
	DCF-0	o	o	o	o
	DEF-0	o	o	o	o
	DJE-0	o	o	o	o
	DPF-0	o	o	o	o
	DYD-0	o	o	o	o
	YCC-0	+	o	o	o
	YFD-0	+	o	o	o
	YJD-0	o	+	o	o
	YLC-0	o	o	o	o
	YOD-0	+	o	o	o
	YPD-0	o	o	o	o
	YVC-0	o	o	o	o
	YXD-0	o	o	o	o
	ZWC-0	+	o	o	+

<b>Study Type</b>	Safety																																				
<b>Pertaining to</b>	ALL																																				
<b>Study Purpose</b>	To demonstrate safety under field conditions																																				
<b>Product Administration</b>	Two doses administered subcutaneously, 3 weeks apart																																				
<b>Study Animals</b>	168 client-owned dogs of various breeds; 8 weeks to 5 years of age; 64 males and 104 females																																				
<b>Challenge Description</b>	Not applicable																																				
<b>Interval observed after challenge</b>	Dogs were observed by the veterinarian immediately following vaccination and by their owners for 6 months post-vaccination for injection site reactions and systemic reactions. Owners were contacted by the veterinarian 14 days ( $\pm$ 3 days) after each vaccination and again 6 months after the 2 <sup>nd</sup> vaccination.																																				
<b>Results</b>	<p><b><u>Adverse Events (AE) During Vaccination</u></b></p> <table> <tr> <th></th><th>Number</th></tr> <tr> <td>Cried when stuck with needle, before contents were injected</td><td>8</td></tr> <tr> <td>Cried upon injection of contents</td><td>6</td></tr> <tr> <td>Cried several minutes after injection</td><td>0</td></tr> <tr> <td><b>No AE during vaccination*</b></td><td><b>322/336 (95.8%)</b></td></tr> </table> <p><b><u>Adverse Events Immediately After Vaccination</u></b></p> <table> <tr> <th></th><th>Number</th></tr> <tr> <td>No. of Dogs with Reported AE</td><td>8</td></tr> <tr> <td>Total AE observed</td><td>10</td></tr> <tr> <td>Injection site swelling</td><td>6</td></tr> <tr> <td>Soreness at injection site</td><td>1</td></tr> <tr> <td>Lethargy</td><td>2</td></tr> <tr> <td>Not attributed to the product</td><td>1</td></tr> <tr> <td><b>No AE observed*</b></td><td><b>328/336 (97%)</b></td></tr> </table> <p>All Dogs were normal at 14 days post-vaccination.</p> <p><b><u>Adverse Events Six Months After 2<sup>nd</sup> Vaccination</u></b></p> <table> <tr> <th></th><th>Number</th></tr> <tr> <td>No. of Dogs with Reported AE</td><td>2</td></tr> <tr> <td>Not attributable to product</td><td>2</td></tr> <tr> <td>Attributable to product</td><td>0</td></tr> <tr> <td><b>No AE observed**</b></td><td><b>166/168 (99%)</b></td></tr> </table> <p>No persistent lameness was observed in any of the dogs following vaccination.</p> <p>* Based on the total number of vaccine doses administered (2 doses per dog).</p> <p>** Based on the total number of dogs enrolled in the study. One dog was removed from the study for a cause unrelated to vaccination as affirmed by licensee.</p>		Number	Cried when stuck with needle, before contents were injected	8	Cried upon injection of contents	6	Cried several minutes after injection	0	<b>No AE during vaccination*</b>	<b>322/336 (95.8%)</b>		Number	No. of Dogs with Reported AE	8	Total AE observed	10	Injection site swelling	6	Soreness at injection site	1	Lethargy	2	Not attributed to the product	1	<b>No AE observed*</b>	<b>328/336 (97%)</b>		Number	No. of Dogs with Reported AE	2	Not attributable to product	2	Attributable to product	0	<b>No AE observed**</b>	<b>166/168 (99%)</b>
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<b>USDA Approval Date</b>	November 24, 2009
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