

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.

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Study Type	Efficacy
Pertaining to	Borrelia burgdorferi
Study Purpose	To demonstrate efficacy against B. burgdorferi. (subclinical
	arthritis)
Product Administration	
Study Animals	Canine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	March 19, 2007

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Study Type	Efficacy									
Pertaining to	Borrelia burgdorferi									
Study Purpose	To demonstrate effic vaccination.	acy against B. bur	gdorferi one year	after						
Product Administration	Two doses administe	ered subcutaneous	ly, 3 weeks apart							
Study Animals	39 dogs; 8 weeks of			20 controls						
	and 19 vaccinates									
Challenge Description	All dogs were challed B. burgdorferi-infect		he second vaccina	ation with						
Interval observed after	Dogs were observed daily for 21 weeks (5 months) post-challenge									
challenge	for clinical signs of limb/joint disorder. Skin tissues were									
	examined weekly. Joint tissues were examined at the end of the									
	study.									
Results	 Primary Variable: Limb/joint disorder, defined as at least one of: Stiffness, limping, and/or lameness for 3 consecutive days or multiple episodes of these clinical signs; Joint inflammation as demonstrated by erosive changes in joint tissues evident on histopathology); or Recovery of <i>B. burgdorferi</i> from joint tissues 									
	Treatment	Total # of	# of Dogs							
	Group Dogs Affected									
	Controls	20	15							
	Vaccinates	19	7							
	Secondary Variable: 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.									
	Treatment Group	# of Dogs Affected								
	Controls	Dogs 20	17							
	Vaccinates	19	7							
USDA Approval Date	Raw data shown on attached pages. Days are post challenge (PC).									
OSDA Approvar Date	February 13, 2013									

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

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Clinical Observations Post-Challenge

	AAC-0 ACC-0 AQD-0 AVC-0	N N	N	N										
	AQD-0 AVC-0			14	Ν	N	N	N	N	N	N	N	N	N
	AVC-0	M	N	Ν	N	N	N	N	N	N	N	N	N	N
		14	N	Ν	Ν	N	N	N	N	N	N	N	N	N
		N	N	N	N	N	N	N	N	N	N	N	N	N
	AWF-0	N	N	N	N	N	N	N	Ν	N	N	N	N	Ν
	AXE-0	N	N	Ν	N	N	N	N	N	N	N	N	N	N
	BOC-0	N	N	Ν	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	Ν	N	N	N	N	N	N	N	N	N	N	N	N
Α	DTE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
(Vaccinates)	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
	ASD-0	N	N	Ν	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	
	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
	YOD-0	N	N	N	N	N		N		N	N	N	N	N
	YPD-0	N	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	N	N	N	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N	N	N	N	N	N	N	N

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Clinical Observations Post-Challenge - continued

Treatment Group	Dog ID	Day 21	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28	Day 29	Day 30	Day 31	Day 32	Day 33
	AAC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ACC-0	N	Ν	Ν	N	N	N	N	N	N	N	N	N	N
	AQD-0	N	Ν	Ν	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	Ν	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
Α	DTE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
(Vaccinates)	YAD-0	N	N	N	Ν	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	Ν	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
	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	Ν	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	Ν	N
В	DPF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
(Controls)	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

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Clinical Observations Post-Challenge - continued

Treatment Group	Dog ID	Day 34	Day 35	Day 36	Day 37	Day 38	Day 39	Day 40	Day 41	Day 42	Day 43	Day 44	Day 45	Day 46
	AAC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ACC-0	N	Ν	Ν	N	N	N	N	N	N	N	N	N	N
	AQD-0	N	Ν	Ν	N	N	N	N	N	N	N	N	N	N
	AVC-0	N	Ν	N	N	N	N	Ν	N	N	N	N	N	N
	AWF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	AXE-0	N	Ν	Ν	N	Ν	N	N	N	N	N	N	N	N
	BOC-0	N	Ν	Ν	N	N	N	N	N	N	N	N	N	N
	BVF-0	N	Ν	N	N	Ν	N	N	N	N	N	N	Ν	Ν
	CZF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
Α	DTE-0	Ν	Ν	Ν	N	N	N	N	N	N	N	N	N	N
(Vaccinates)	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	Ν	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	Ν	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	Ν	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	Ν	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
В	DPF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
(Controls)	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
				N	N	N	N	N	N	N	N	N	N	N
	YXD-0	N	N	130	1/4	1/1	IN.	1/4	IN	N.		D.I	INI.	

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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
	AAC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ACC-0	N	Ν	N	N	N	N	N	N	N	N	N	N	N
	AQD-0	N	Ν	Ν	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	Ν	N	Ν	Ν	N	N	N	N	N	N	N	N	N
	BOC-0	N	N	Ν	N	N	N	N	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	N	N	N	N	N	N	N	Ν
	CZF-0	N	N	N	N	N	N	N	N	N	N	N	Ν	N
A	DTE-0	N	N	N	N	N	N	N	N	N	N	N	N	N
(Vaccinates)	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	Ν
	YID-0	N	N	N	N	N	N	N	N	N	N	N	N	Ν
	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	Ν	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
		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	Ν
	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
В	DPF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
(Controls)	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
				N			1.4	1.5	14	1.4	1.4	1.4	1.4	14

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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
	AAC-0	N	N	N	N	N	N	N	N	N	N	N	N
	ACC-0	Ν	N	N	N	N	N	N	N	N	N	N	N
	AQD-0	Ν	N	Ν	N	N	N	N	N	N	N	N	N
	AVC-0	Ν	Ν	Ν	N	N	N	N	N	N	N	N	N
	AWF-0	Ν	N	Ν	N	N	N	Ν	N	N	N	N	N
	AXE-0	Ν	N	Ν	Ν	N	N	N	N	N	N	N	N
	BOC-0	Ν	N	Ν	N	N	Ν	N	N	N	N	N	N
	BVF-0	Ν	N	Ν	Ν	N	N	N	N	N	N	N	N
	CZF-0	Ν	N	N	N	N	N	Ν	N	N	N	N	N
A	DTE-0	N	N	N	N	N	N	N	N	N	N	N	N
(Vaccinates)	YAD-0	Ν	N	Ν	N	N	N	N	Ν	N	N	N	N
	YBC-0	N	N	N	N	N	N	Ν	Ν	N	N	N	N
	YID-0	N	N	N	N	N	N	Ν	N	N	N	N	N
	YKD-0	N	N	N	N	N	N	Ν	Ν	N	N	N	N
	YQD-0	N	N	N	N	N	N	N	N	M⁴; 103.1	N	N	N
	YZC-0	N	N	N	N	N	N	N	N	N	Ν	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	Ν	N	N	N	N
	ZXC-0	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
	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	Ν
	DEF-0	N	N	N	N	N	N	N	N	N	N	N	N
	DJE-0	Ν	N	N	N	N	N	N	N	N	N	N	N
В	DPF-0	N	N	N	Ν	N	N	N	N	N	N	N	Ν
(Controls)	DYD-0	N	N	N	N	N	N	N	N	N	N	N	Ν
	YCC-0	Ν	N	N	N	N	N	N	N	N	N	N	N
	YFD-0	Ν	N	N	N	N	N	N	N	N	N	N	N
	YJD-0	Ν	N	N	N	N	N	N	N	N	N	N	N
	YLC-0	Ν	N	N	N	N	N	N	N	N	N	N	N
	YOD-0	N	N	N	Ν	N	N	N	N	N	N	N	N
	YPD-0	N	N	N	Ν	N	N	N	N	N	N	N	N
	YVC-0	N	N	N	Ν	N	N	N	N	N	N	N	N
	YXD-0	N	N	N	N	Ν	N	N	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N	N	N	N	N	N	N

N = Normal; M = Lame; 1 left front limb; 2 right front limb; 3 left rear limb; 4 right rear limb

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Clinical Observations Post-Challenge - continued

Treatment Group	Dog ID	Day 72	Day 73	Day 74	Day 75	Day 76	Day 77	Day 78	Day 79	Day 80	Day 81	Day 82	Day 83	Day 84
	AAC-0	N	N	N	N	N	N	N	N	N	N	N	N	N
	ACC-0	N	N	Ν	N	N	N	N	N	N	N	N	N	N
	AQD-0	Ν	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	Ν	N	N	N	N	N	N	N	N	N	N	N
	BOC-0	N	Ν	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
A	DTE-0	Ν	N	N	N	N	N	N	N	N	N	N	N	N
(Vaccinates)	YAD-0	Ν	N	Ν	N	N	N	N	N	N	N	N	N	N
	YBC-0	Ν	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	Ν	N	N	N	N	N	N	N	N	N
	YQD-0	N	N	N	N	N	N	N	N	Ν	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
	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
В	DPF-0	N	N	N	N	N	N	N	N	N	N	N	N	N
(Controls)	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

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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
	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	Ν
	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	Ν	N	N	N	N	N	L1; 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	Ν
A	DTE-0	N	N	N	N	Ν	N	N	N	N	N	N	Ν
(Vaccinates)	YAD-0	N	N	N	N	Ν	N	N	N	N	N	N	Ν
	YBC-0	N	N	N	N	N	N	N	N	N	N	N	Ν
	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
	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
В	DPF-0	N	N	N	N	N	N	N	N	N	N	N	N
(Controls)	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
	V X 1 - 1 1												

N = Normal; L = Limping; 1 left front limb; 2 right front limb; 3 left rear limb; 4 right rear limb

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Clinical Observations Post-Challenge - continued

Treatment Group	Dog ID	Day 97	Day 98	Day 99	Day 100	Day 101	Day 102	Day 103	Day 104
	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
Α	DTE-0	N	N	N	N	N	N	N	N
(Vaccinates)	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	Ν	N
	YKD-0	N	N	N	N	N	N	N	L1,2; 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
	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
В	DPF-0	N	N	N	N	N	N	N	N
(Controls)	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	S2,3,4; 103.1	S3,4; 103,7	S, L ^{3,4} ; 101.1	S. L3,4	S, L3,4	Marie San	
	YOD-0	N	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; 1 left front limb; 2 right front limb; 3 left rear limb; 4 right rear limb

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Treatment Group	Dog ID	Day 105	Day 106	Day 107	Day 108	Day 109	Day 110	Day 111	Day 112
	AAC-0	N	N	N	N	N	N	N	N
	ACC-0	Ν	N	Ν	N	N	N	N	N
	AQD-0	N	N	Ν	N	Ν	N	N	N
	AVC-0	N	N	Ν	Ν	N	N	N	N
	AWF-0	N	N	N	N	N	N	N	D1; L ^{1,2,4} ; 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	L4; 103.6
	CZF-0	N	N	N	N	N	L ^{1,3} ; 103.7	L ^{1,2,3,4} ; 102.4	L ^{2,3,4} ; 103.1
A	DTE-0	N	N	Ν	N	N	N	N	S³; 102.6
(Vaccinates)	YAD-0	N	N	N	N	Ν	N	N	N
	YBC-0	N	Ν	Ν	N	N	N	N	N
	YID-0	N	N	Ν	N	N	N	N	N
	YKD-0	L1,2; 102.9	L ¹ ; 102.8	N	N	N	N	N	S³; 104.6
	YQD-0	N	N	N	N	N	N	N	N
	YZC-0	N	N	Ν	N	N	N	N	N
	ZBC-0	N	N	Ν	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
	ASD-0	N	N	N	Ν	Ν	N	N	N
	BID-0	N	N	N	N	N	N	N	N N
	BLC-0	N	N	Ν	Ν	N	N	N	L ^{1,3,4} ; 102.0
	BXE-0	N	N	N	Ν	N	N	N	N
	BZE-0	N	N	Ν	N	N	N	N	N
	CFE-0	N	N	Ν	Ν	N	N	N	N
	DCF-0	N	N	Ν	N	N	N	N	N
	DEF-0	Ν	N	Ν	N	N	N	N	N
	DJE-0	N	N	Ν	N	N	N	N	N
В	DPF-0	N	N	N	N	N	N	N	N
(Controls)	DYD-0	N	N	N	N	N	Ν	N	N
	YCC-0	N	N	Ν	N	N	N	N	N
	YFD-0	Ν	N	Ν	N	N	Ν	N	N
	YJD-0	N	N	N	N	N	N	N	L⁴; 103.7
	YLC-0			130					
	YOD-0	N	N	N	Ν	N	N	N	N
	YPD-0	N	N	N	Ν	N	N	N	N
	YVC-0	N	N	N	Ν	N	N	N	N
	YXD-0	N	N	N	Ν	Ν	N	N	L ^{1,2,3,4} ; 102.7
	ZWC-0	N	N	N	Ν	N	N	N	N

ZWC-0 N N N N N

N = Normal; L = Limping; D1 = moderate depression; S = Stiff

1 left front limb; 2 right front limb; 3 left rear limb; 4 right rear limb

Grey bar: humane endpoint reached

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Treatment Group	Dog ID	Day 113	Day 114	Day 115	Day 116	Day 117	Day 118	Day 119	Day 120
	AAC-0	N	N	N	N	N	N	N	N
	ACC-0	N	D2; M ^{1,3,4} ; 102.7*						
	AQD-0	N	N	N	N	N	N	N	N
	AVC-0	N	L ¹ ; 102.2	M ¹ ; 103.5	N	N	N	N	N
	AWF-0	L1,2,4; 105.4	N	N	N	N	N	Ν	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								
Α	DTE-0	N	N	N	N	N	N	N	N
(Vaccinates)	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 ¹ ; 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
	ASD-0	L1,3; 104.3	N	N	N	N	N	N	N
	BID-0	N	N	N	N	N	N	N	N
	BLC-0	L1,3,4; 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
В	DPF-0	N	M ¹ ; 104.3	M ¹ ; 103.9	M ¹ ; 102.9				
(Controls)	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	L4; 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	L1-4; 102.9	N	N	N	N	N	N	N
	ZWC-0	N	N	N	N	N	N	N	N

ZWC-0 N N

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

left front limb; right front limb; left rear limb; right rear limb

Grey bar: humane endpoint reached

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Treatment Group	Clinical O 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
	AAC-0	N	N	N	N	N	N	N	N	N	N	N	N
	ACC-0												
	AQD-0	N	N	N	Ν	N	N	Ν	Ν	Ν	Ν	Ν	Ν
	AVC-0	N	N	N	Ν	N	N	N	N	Ν	Ν	Ν	Ν
	AWF-0	N	N	Ν	Ν	N	N	N	Ν	Ν	Ν	Ν	Ν
	AXE-0	N	N	N	Ν	N	N	N	Ν	Ν	Ν	Ν	Ν
	BOC-0	N	N	Ν	Ν	N	N	N	N	Ν	Ν	Ν	Ν
	BVF-0	N	N	N	N	N	N	N	N	Ν	N	N	N
	CZF-0												
Α	DTE-0	N	N	N	N	N	N	N	N	N	Ν	Ν	Ν
(Vaccinates)	YAD-0	N	N	N	N	N	N	N	N	N	Ν	Ν	Ν
	YBC-0	N	N	N	N	N	N	Ν	Ν	N	N	Ν	N
	YID-0	N	N	N	Ν	N	N	N	N	N	Ν	N	N
	YKD-0	PETER I											
	YQD-0	N	N	N	Ν	N	N	N	N	Ν	Ν	Ν	N
	YZC-0	N	N	N	Ν	N	N	N	N	N	Ν	Ν	Ν
	ZBC-0	N	N	N	N	N	N	N	N	N	Ν	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	Ν	N	N
	ASD-0	N	N	N	N	N	N	N	N	Ν	Ν	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	Ν	N	N
	BXE-0	N	N	N	N	N	N	N	N	Ν	Ν	Ν	Ν
	BZE-0	N	N	N	N	N	N	N	N	N	N	N	Ν
	CFE-0	N	N	N	N	N	Ν	N	N	N	Ν	Ν	Ν
	DCF-0	N	N	N	N	N	N	N	N	N	N	Ν	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
В	DPF-0										THE STATE OF		
(Controls)	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	Ν	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				3753				NE SE	1	1000		18 4 18
	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
	= Normal		.,	.,		- 13	.,	. •					14

Grey bar: humane endpoint reached

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Treatment Group	Clinical Ol Dog ID	Day 133	Day 134	Day 135	Day 136	Day 137	Day 138	Day 139	Day 140	Day 141	Day 142
	AAC-0	N	N	N	N	N	N	NI.	N	NI.	N
	ACC-0	14	IN IN	IN	N N	N	N	N	N	N	1/4
	AQD-0	N	N	N.	MI N	N.	N. N.	SUMBER			-
	AVC-0	N	N	N	N	N	N	N	N	N	N
	AWF-0	N	N		N N	N D1; L ^{3,4} ; 104.0	N	N	N	N	N
		N		N			1000000	OLD SECTION .			
	AXE-0	N	N	N	N	N	N	N	N	N	N
	BOC-0 BVF-0	N	N	N	N	N	N	N	N	N	N
	CZF-0	N	N	N	N	N	N	N	N	N	N
			ALCOHOLD !	NOTE BY	STATE OF THE PARTY.			CHEST	03.400.0		
A O(assinates)	DTE-0	N	N	N	N	N	N	N	S³; 100.6	N	N
(Vaccinates)	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				STATE OF THE PARTY.				ATHER BUSINESS		9330
	YQD-0	N	N	N	N	N 01:4 +04 +	N	N	N	N	N
	YZC-0	N	N	N	N	S ¹⁻⁴ ; 101.1	N	N	N	N	N
	ZBC-0	N	N	N	N	S ^{1,2,3} ; 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
	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	L1-4; 101.2	N	N	N	N	N
В	DPF-0	437136	SEC.	15,0150	12.45					13100	Z.E.E.
(Controls)	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 ¹⁻⁴ ; 100.8	N	N	N	N	N
	ZWC-0	N	N	N	N	N N	N	N	N	N	N

N = Normal; L = Limping; S = Stiff; D1 = moderate depression

1 left front limb; 2 right front limb; 3 left rear limb; 4 right rear limb

Grey bar: humane endpoint reached

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Treatment	Clinical	Observa					
Group	Dog ID	Day 143	Day 144	Day 145 9/20	Day 146	Day 147	Day 148
	AAC-0	N	N	N	N	N	N
	ACC-0					HEADER .	5925
	AQD-0	N	N	N	N	N	N
	AVC-0	N	N	N	N	N	N
	AWF-0		166				
	AXE-0	N	N	N	N	N	
	BOC-0	N	N	N	N	N	N
	BVF-0	N	N	N	N	N	STORY.
	CZF-0						
Α	DTE-0	N	N	N	N	N	
(Vaccinates)	YAD-0	N	N	N	N	N	N
	YBC-0	N	N	N	N	N	Ν
	YID-0	N	N	N	N	N	X2.0
	YKD-0				1200		
	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	Ν
	ASD-0	N	N	N	N	N	Ν
	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	Ν
	DJE-0	N	N	N	N	N	N
В	DPF-0		E SALVE				1000
(Controls)	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 = Nor	mal						

Grey bar: humane endpoint reached

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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
	AAC-0	0	0	0	0	0
	ACC-0	+	+	+		6-2
	AQD-0	0	+	+	0	+
	AVC-0	0	0	0	0	О
	AWF-0	+	+	+	0	(5
	AXE-0	0	+	+	+	0
	BOC-0	+	+	+	+	0
	BVF-0	0	0	О	0	0
	CZF-0	+	+	+	2.	1 4
Α	DTE-0	0	0	o	0	0
(Vaccinates)	YAD-0	0	0	0	0	0
	YBC-0	0	o	0	0	0
	YID-0	0	0	0	0	0
	YKD-0	0	o	0	5	1
	YQD-0	0	o	0	0	0
	YZC-0	0	o	0	0	0
	ZBC-0	0	0	o	0	0
	ZVC-0	+	+	+	+	+
	ZXC-0	00	0	0	0	0
	ASD-0	+	+	+	+	+
	BID-0	+	+	+	+	+
	BLC-0	+	+	+	+	+
	BXE-0	+	+	+	+	+
	BZE-0	+	+	+	+	+
	CFE-0	+	+	+	+	+
	DCF-0	0	0	0	0	0
	DEF-0	0	0	0	0	0
	DJE-0	+	+	+	+	+
В	DPF-0	+	+	+		
(Controls)	DYD-0	+	+	+	+	+
(00.12.010)	YCC-0	+	+	+	+	+
	YFD-0	+	+	+	+	+
	YJD-0		+	+		+
	YLC-0	0		+		
	YOD-0	+		+	+	+
	YPD-0	+	0			+
	11.0-0					
	VVC-0	+	+	+	+	+
	YVC-0 YXD-0	+	+ 0	+ 0	0	0

Grey bar: humane endpoint reached

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

Recovery of B. burgdorferi from Tissue Samples

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

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^{(+) =} B. burgdorferi isolated from tissue (o) = B. burgdorferi not isolated from tissue

Development of Inflammatory Cell Infiltrations in Joint Tissues

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

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Study Type	Safety						
Pertaining to	ALL						
Study Purpose	To demonstrate safety under field conditions						
Product Administration	Two doses administered subcutaneously, 3 weeks apart						
Study Animals	168 client-owned dogs of various breeds; 8 weeks to 5 years of						
Study Tillinuis	age; 64 males and 104 females	as, o weeks to 5 years or					
Challenge Description	Not applicable						
Interval observed after	Dogs were observed by the veterinaria	an immediately following					
challenge	vaccination and by their owners for 6						
C	injection site reactions and systemic re	eactions. Owners were					
	contacted by the veterinarian 14 days						
	vaccination and again 6 months after t						
Results	Adverse Events (AE) During Vaccin	<u>iation</u>					
		Number					
	Cried when stuck with needle, before	ore o					
	contents were injected	8					
	Cried upon injection of contents	6					
	Cried several minutes after injectio	n 0					
	No AE during vaccination* 322/336 (95.8%)						
	Adverse Events Immediately After						
		Number					
	No. of Dogs with Reported AE	8					
	Total AE observed	10					
	Injection site swellin						
	Soreness at injection sit	- i					
	Letharg						
	No AE observed*	328/336 (97%)					
	All Dogs were normal at 14 days po						
	An Dogs were normal at 14 days po	st-vaccination.					
	Adverse Events Six Months After 2 ¹	nd Vaccination					
		Number					
	No. of Dogs with Reported AE 2						
	Not attributable to product 2						
	Attributable to product 0						
	No AE observed** 166/168 (99%)						
	No persistent lameness was observed in any of the dogs						
	following vaccination.						
	* Based on the total number of vacci	ne doses administered					
	(2 doses per dog).	11 1: 4 . 4 . 6					
	** Based on the total number of dogs	•					
	dog was removed from the study f						
	vaccination as affirmed by licensee.						

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USDA Approval Date	November 24, 2009
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