

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	4855.R2
True Name	Encephalomyelitis-Rhinopneumonitis-Influenza-West Nile Virus Vaccine, Eastern & Western, Killed Virus, Killed Flavivirus Chimera, Tetanus Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Prestige V+WNV - Merck Animal Health
Date of Compilation Summary	September 17, 2019

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

Study Type	Efficacy
Pertaining to	Clostridum tetani
Study Purpose	Demonstrate efficacy against C. tetani
Product Administration	One dose administered subcutaneously.
Study Animals	Ten guinea pigs (5 females and 5 males, 450-550g)
Challenge Description	Not applicable
Interval observed after	Six weeks after vaccination, guinea pigs were bled for serological
challenge	testing.
Results	Efficacy of <i>C. tetani</i> was demonstrated in laboratory animals according to 9CFR 113.114(c). Satisfactory result is an antitoxin titer of at least 2.0 A.U. per mL for the serum pool. Pooled Guinea Pig Antitoxin titer (A.U./mL) 2.082
USDA Approval Date	June 15, 2010

Study Type	Efficacy			
Pertaining to	Eastern Equine E	Encephalomyelitis (I	EEE)	
Study Purpose	Demonstrate effi	cacy against EEE		
Product Administration	Two doses admin	nistered intramuscu	larly 3 weeks ap	art.
Study Animals	Twelve guinea p	igs, 10 vaccinates a	nd 2 controls, ea	ich 300-500g
Challenge Description	Not applicable			
Interval observed after	14 days post 2nd	vaccination, guinea	a pigs were bled	for
challenge	serological testin	ıg.		
Results	Efficacy of EEE according to 9CH Satisfactory test at least 9 out of 1 vaccinates).	was demonstrated i FR 113.207(b). result is a Virus Ner 10 vaccinates (2 nd st	n laboratory ani utralization Tite age - at least 17	mals r of≥ 1:40 in out of 20
	Treatment		Test	
	group	Results	Disposition	
	Vaccinates	$17/20 \ge 1:40$	Satisfactory	
	Controls	2/2 <1:4	Satisfactory	
USDA Approval Date	June 15, 2010			

Study Type	Efficacy			
Pertaining to	Western Equine	Encephalomyelitis	(WEE)	
Study Purpose	Demonstrate effi	cacy against WEE	· · ·	
Product Administration	Two doses admir	nistered intramuscu	larly 3 weeks ap	oart.
Study Animals	Twelve guinea pi	igs, 10 vaccinates a	and 2 controls, ea	ach 300-500g
Challenge Description	Not applicable			
Interval observed after	14 days post 2nd	vaccination, guine	a pigs were bled	
challenge	for serological te	sting.		
Results	Efficacy of WEE according to 9CF Satisfactory test at least 9 of the v	was demonstrated R 113.207(b). result is a Virus Ne raccinates.	l in laboratory an	imals $r \text{ of } \ge 1:40 \text{ in}$
	Treatment		Test	
	group	Results	Disposition	
	Vaccinates	$9/10 \ge 1:40$	Satisfactory	
	Controls	2/2 <1:4	Sutistactory	
USDA Approval Date	June 15, 2010			

Study Type	Efficacy					
Pertaining to	Equine Herpesvirus-S	ubtype 1 (l	EHV-1), DA3	35 strain		
Study Purpose	Efficacy against respire	ratory disea	ase caused by	EHV-1		
Product	Two doses, administer	red intramu	scularly, 21	days apar	t.	
Administration						
Study Animals	16 vaccinates and 16 p	placebo-va	ccinated cont	rols, sero	negativ	e to EHV-1.
	Horses were 11 month	is of age, n	nixed sex.			
Challenge	Horses were challenge	ed with EH	V-1, 23 days	post seco	ond vac	cination.
Description					<u> </u>	
Interval	Observed for 14 days	post challe	nge for clinic	al signs o	of respin	ratory disease.
observed after						
Challenge					66 4	
Results	Animals displaying cl	inical signs	s were consid	ered to b	e arrect	ed by the
	chanenge. Result sun	imaries del	low.			
	Body Temperatures >	102 5°E w	ara considera	d to be a	lavatad	
	Body remperatures ≥	102.3 I' w			icvatcu.	
	Treatment Gro	un	Vaccin	atas		Controls
	Humorthormio Aff	ootod	15/16 or	0.49/	16/	$\frac{16}{16} \text{ or } 100\%$
	Hypertilemita An	ecteu	13/10 01	9470	10/	10 01 10070
	Observations of nasal di	scharged w	ere scored as:			
	0 - Normal	senargea	ere secrea as.			
	1 - Very Mild					
	2 - Moderate					
	3 - Severe					Ţ]
	Treatment Group			Vaccii	nates	Controls
		Mildly	Affected	5/16 or	31%	1/16 or 6%
		Moderate	ely Affected	7/16 or	44%	2/16 or 13%
	Nasal Discharge	Severe	y Affected	4/16 or	25%	13/16 or 80%
	Observations of cough	ning were s	cored as:			
	0 - No coughing or co	ughed once	e			
	2 - Coughed twice					
	3 - Coughed three time	es or more				
	Animals were scored a	as a 2 or 3	for coughing.		Γ	
	Treatment Group		Vaccinates		Contro	ols
	Coughing Affected		0/16 or 0%		4/16 or	25%
	Treatment Gro	oup	Vaccina	ates		Controls
	Abnormal Respiration	Affected	3/16 or	19%	12	/16 or 75%

	Animals were considered and the second secon	dered postiv sal swab.	e for Virus Isolation	(VI) with recovery of at
	Treatment Group		Vaccinates	Controls
	Virus Isolation Recove	ery	6/16 or 37%	12/16 or 75%
	Treatment Group	0 Days	Vaccinates 10/16 or 63%	Controls 4/16 or 25%
	Virus Isolation,	1 Day	5/16 or 31%	6/16 or 38%
	Duration	\geq 2 Days	1/16 or 6%	6/16 or 38%
	Raw data shown on	attached pag	ges.	
USDA Approval Date	September 26, 2006			

e with virulent EHV-1	hallenge with EHV-1:	8 9 10 11 12 13 14	101.0 100.2 100.2 100.2 100.6 100.8 101.1	103.3 100.0 99.4 99.0 100.2 100.2 99.8	101.2 100.0 99.5 98.9 100.5 99.9 99.7	100.7 99.9 99.3 99.9 100.2 98.9 99.8	101.6 100.1 99.9 99.5 100.8 100.1 99.3	100.1 100.0 99.1 99.0 100.2 100.1 100.1	100.9 100.5 99.9 98.9 100.2 100.0 100.0	101.0 100.7 99.3 98.1 101.1 100.1 99.4	100.7 100.5 100.2 99.9 100.1 100.8 100.2	100.2 100.5 99.2 100.9 101 100.2 99.5	105.4 100.3 100.0 99.5 100.7 100.0 99.7	100.2 100.5 99.9 99.5 100.8 100.0 100.0	101.3 101.2 100.4 101.0 101.7 100.2 100.8	100.3 100.2 99.1 99.7 101.6 100.3 100.0	101.0 100.0 100.1 100.0 100.5 100.1 100.3	102.5 101.1 99.7 98.6 99.7 99.5 99.8	100.0 100.9 100.2 99.7 99.9 100.8 100.1	100.7 100.0 100.0 99.2 101.2 100.1 101.1	Died Died Died Died Died Died	100.7 99.9 99.8 100.2 100.2 99.0 100.0	101.5 100.3 100.2 99.3 100.2 100.9 100.1	103.0 100.5 99.9 99.4 100.3 100.0 99.9	101.4 100.2 99.9 99.2 100.6 100.0 100.0	100.2 99.9 99.8 99.2 99.7 99.4 99.9	103.8 100.8 101.1 98.5 100.1 99.8 99.8	101.3 99.5 100.0 98.4 100.4 99.0 98.8	101.5 101.1 100.9 100.2 100.2 100.2 100.0	101.6 99.7 99.4 98.8 100.2 99.4 99.3	102.7 101.3 100.1 99.7 100.1 99.7 100.0	101.0 101.7 100.7 101.8 100.4 100.1 100.0	102.7 100.4 99.0 98.7 99.7 99.2 99.5	
t EHV-1	-1:	11 0	0.2 100.2	.4 99.0	.5 98.9	.3 99.9	99.5	0.1 99.0	98.9	.3 98.1	0.2 99.9	100.9	0.0 99.5	99.5	0.4 101.0	9.1 99.7	0.1 100.0	98.6	0.2 99.7	0.0 99.2	ed Died	9.8 100.2	0.2 99.3	9.9 99.4	99.2	99.2	1.1 98.5	0.0 98.4	0.9 100.2	9.4 98.8	0.1 99.7	0.7 101.8	9.0 98.7	
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challen	ays post-	7	102.5	102.1	101.4	100.8	102.3	99.9	101.1	101.9	101.5	103.1	103.5	105.8	101.4	102.4	102.9	102.7	100.1	100.3	Died	101.4	103.0	100.1	104.0	103.9	103.8	100.1	102.5	102.0	102.8	102.3	102.2	
post-	res on di	9	104.0	102.4	102.1	102.3	102.4	101.1	102.1	102.4	102.6	102.1	104.3	105.0	102.3	101.4	104.0	104.0	100.6	101.7	Died	102.6	102.8	99.7	100.9	103.5	102.7	101.6	102.6	103.6	103.2	103.8	104.5	
1 to 14	emperatu	2	103.0	102.1	101.4	102.7	102.0	102.5	102.1	102.9	100.9	102.8	101.0	102.9	103.4	102.9	103.1	101.7	101.4	100.2	Died	102.9	102.7	100.2	103.5	102.9	103.3	100.2	103.9	102.7	103.8	102.3	104.1	
days -:	I body t	4	102.5	103.2	101.9	102.2	103.6	101.9	102.0	101.9	100.3	102.1	104.0	101.9	102.6	102.2	102.4	104.3	102.5	103.4	Died	104.9	104.1	102.7	104.3	104.9	103.4	102.4	103.6	103.9	103.7	104.1	104.5	
es on	Recta	m	102.1	103.2	103.8	102.2	103.7	101.4	101.6	102.4	101.0	103.6	102.0	101.6	101.9	102.1	102.2	103.3	103.5	104.1	102.6	102.4	103.7	103.5	102.6	102.1	104.5	103.1	103.3	103.5	104.8	103.7	104.2	
f hors		2	102.4	103.1	102.8	102.4	103.5	102.4	102.9	103.1	101.9	105.5	102.4	103.1	102.4	101.9	104.0	104.0	105.1	106.8	106.9	105.3	106.3	106.1	105.1	104.2	105.0	106.2	104.5	106.2	106.1	105.2	107.0	
cures o			102.3	100.6	100.0	99.2	102.0	100.2	100.8	100.0	100.8	102.4	101.5	100.2	102.5	101.7	101.8	100.6	102.3	101.1	101.0	101.3	99.3	100.1	101.8	100.6	100.2	101.6	103.4	101.8	100.9	100.7	100.8	,
mperat		•	101.3	101.9	101.3	101.2	101.2	101.6	101.1	102.4	102.1	103.6	101.8	102.7	103.0	101.2	103.2	102.1	101.0	101.0	101.0	102.3	101.7	101.1	102.8	101.5	103.5	102.7	103.2	101.1	101.8	102.9	101.8	
ody te		-	102.3	101.6	101.5	101.5	100.7	100.8	101.3	102.0	101.8	101.0	102.5	100.9	102.5	101.5	102.0	103.0	101.4	101.4	101.5	101.2	101.0	102.1	103.1	101.2	102.5	100.4	102.0	101.9	101.9	102.8	101.1	
. Rectal b		Group									VACCIDATES													_		Placebo	Controls				_			
Table 2	Horse	ON 165	280	282	284	287	10	294	295	296	297	298	299	305	307	308	313	315	285	286	288	290	293	300	302	303	304	306	309	310	311	312	314	

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Body Temperatures $\geq 102.5^{\circ}F$ were considered to be elevated.

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Table 4.	Coughing scor	es of ho	rses on	days -1	to 14 p	ost-chal	dhing Sc	tth viru	lent BHV	-1 ost-chal	lenge wi	th BHV-					
NO	Group	1-		-	2		4	2	9	4		6	101	11	12	13	14
280		•	0	0	0	0	0	0	0	0	0	0	0		•	0	0
282		0	•	0	0		0	0	0	•	0	0	0	0	0	0	0
284		0	•	0	•	0	0	0	•	0	0	0	0	0	0	0	
287		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
291		0	0	0	0	0	0	0		0	•	0	0	•	•	0	•
294		0	°	0	0	0		0	0	0	0	0	0	0	0	0	0
295		0	0		0	0		•	•	0	0	0	0	0	0	0	0
296		0	•	•	0	0		0	0	0	0	0	0	•	0	0	0
297	Vaccinates	0	0	•	0	0	0	•	•	0	0	0	0	0	0	0	0
298	_	0	•	0	•	0	0	0	0	•		•	0	•	0	0	•
299	-	0	•	0	0	0	0	•	•	0	0	0	0	0	0	0	0
305		•	•	0	0	0	0	•	0			0	•	0	0	0	0
307		•	•	•	0	•	•	•	0	0	•	0	0		0	0	0
308	_	0	0	0	•	•	0	•	•	0	0	•	•	•	•	0	•
313		0	0	0	•	•	•	•	0	0	0	0	•	0	•	0	•
315		•	0	0	•	0	0	•	•	0	0	0	•	0	0	0	0
285		0	•	0	0	•	•	•	0	0	0	0	0	0	0	0	0
286		0	0	0	0	0	•	•	0	•	0	0	0	0	0	0	0
288		0	0	•	•	•	Died	Died	Died	Died	Died	Died	Died	Died	Died	Died	Died
290		0		•	0	0	•	•	•	0	0	0	0	0	•	0	0
293		•	•	•	0	0	0	0	•	0	•	•	0	0	0	0	0
300		•	•	0	0	•	•	•	0	0	0	•	•	0		•	•
302		0	•		0	0	•	•	0	•	•	0	0	0	0	0	0
303	Placebo	•	•	0	0	0	0	•	2	•	0	•	0	0	0	0	0
304	Controls		0	•	0	0	0	61	3	e	e	3	e	2	5	5	5
306	-	0	0	0	m	0	•	0	•	•	0	•	0	0	0	0	0
309	_	0	0	0	•	0	0	0	0	0	0	0	0	0	0	0	0
310	_	0	0	0	0	0	0	0	•	0	•	•	0	•	0	0	•
311	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
312	T-	0	0	0	0	0	0	0	0	0	•		0	•	0	0	0
314		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
316	1	0	0	0	0	0	0	0	2	0	•	•	0	•	0	•	0
0=norma	 1=coughed ox 	nce durin	ig obser	vation,	2-coughe	ad twice	during	observat	ion, 3=0	padpuot	three or	more t	imes dur	ing obse	rvation		

-1 to 14 post-challenge with virulent BHV-1 Asve ŝ 2 of ho ş ì and the second se ł , ł

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Animals were scored as a 2 or 3 for coughing

Respiration rate scores of horses on days 1 to 1 2 2 lagitation rate scores on days 2 post-challange 6roup -1 0
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O-normal, 1=Abnormal (>36 per minute, dyspnea, tachypnea)

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nasal		-1	'		'	'		÷	'	,	-	+	•	+			,	+	ł	÷	÷	'	1	÷	+	÷	+	÷	÷	+	'	÷	+	1
us from		0	'	'		•	1	'	'	,	1	'	'			'			,				'		,	,		'		'	,	1	1	
of vir		-1-		1	 	,	, 					'		ŀ			'	,		ŀ			'	,	'	•			'	'	4	'	'	'
Isolation	1	dnors									Vaccinates															Placebo	Controls							
Table 6.	Horse	No	280	282	284	287	291	294	295	296	297	298	299	305	307	308	313	315	285	286	288	290	293	300	302	303	304	306	309	310	311	312	314	316

	i virulent	
	with	
	challenge	
¢	post	
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	horses	
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	svabs	
	nasal	
	from	
	virus	
	of	
	Isolation	
	9	;

Study Type	Efficacy			
Pertaining to	Equine Herpes	virus-Subty	/pe 4 (EHV-4)	
Study Purpose	Efficacy again	st respirator	ry disease cause	ed by EHV-4
Product	Two doses, ad	ministered i	intramuscularly	, 3 weeks apart
Administration				
Study Animals	21 vaccinates a	and 11 cont	rols, seronegati	ve to EHV-4. Horses were 6
	months of age,	mixed sex.		
Challenge	Horses were ch	nallenged w	ith EHV-4, 21	days post second vaccination.
Description				
Interval	Observed for 1	4 days post	t challenge for c	clinical signs of respiratory disease.
observed after				
challenge				
Results	Animals displa	ying clinic	al signs were co	onsidered to be affected by the
	challenge if the	ey had sligh	nt or copious am	nounts of nasal discharge for two or
	more consecut	ive days, ar	nd exhibit cough	ning for two or more consecutive
	days.			
			-	7
	Group	# of	Presence of	
	37	Animals	clinical signs	-
	Vaccinates	21	2	-
	Controls	11	8	
	Down data ab	m on atta -1-	ad pages	
	Kaw data show	in on attach	ieu pages.	
USDA Approval	April 7, 2004			

Nasal Discharge

Horse				Nasa	l dis	charge	obse	rvatio	ons on	days	post	challe	ange w	ith EF	rv-4:		
No.	Group	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1		N	N	N	N	SM	N	N	N	SM	N	S	N	N	N	SM	N
2		N	N	N	N	SM	N	S	N	N	SM	N	N	N	N	N	N
3		N	N	N	N	N	SM	N	N	CM	N	SM	N	N	N	SM	N
4		N	N	N	N	N	N	SM	N	N	N	N	N	N	N	N	N
7		N	N	N	N	SM	N	N	N	N	N	N	N	N	SM	N	N
9		N	N	N	N	N	N	SM	N	N	N	CM	N	N	N	SM	N
12		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
14		N	N	N	N	SM	SM	SM	SM	SM	CM	N	N	N	N	SM	N
15		N	N	N	N	SM	CM	SM	CM	SM	SM	SM	N	N	N	N	N
19		N	N	N	N	SM	N	N	N	N	N	N	N	N	N	N	N
20	Vaccinates	N	N	N	N	N	SM	N	S	SM	N	N	N	SM	N	SM	N
24		N	N	N	N	N	N	N	S	N	SM	N	N	N	N	N	SM
27		N	N	N	N	N	SM	N	N	N	N	N	N	N	N	N	N
29		N	N	N	N	N	SM	N	N	SM	N	N	N	N	SM	N	N
33		N	N	N	٠N	SM	N	CM	N	N	Ň	N	N	N	N	S	SM
37		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
45		N	N	N	N	N	N	N	N	SM	N	N	N	N	SM	S	N
47		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
58		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
61		N	N	N	N	N	N	N	N	N	N	SM	N	N	N	N	SM
83		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
.5		N	N	N	N	N	CM	CM	CM	CM	CM	N	CM	N	N	N	N
25		N	N	N	N	N	CM	CM	N	CM	CM	CM	N	N	CM	N	N
39		N	N	N	N	SM	CM	N	CM	N	N ·	CM	N	N	N	N	N
40		N	N	N	N	SM	CM	CM	CM	N	N	N	N	N	N	N	N
43		N	N	N	N	SM	SM	N	CM	CM	N	N	N	SM	N	N	N
59	Controls	N	N	N	N	N	N	CM	CM	CM	N	CM	N	N	N	N	SM
63		N	N	N	N	N	N	N	N	N	CM	CM	N	N	N	SM	CM
65		N	N	N	N	N	SM	CM	CM	CM	N	SM	N	N	N	N	SM
71		N	N	N	N	N	CM	SM	CM	N	Ň	CM	N	CM	CM	N	N
79		N	N	N	N	SM	N	CM	CM	CM	SM	N	N	N	N	SM	N
91		N	N	N	N	N	CM	CM	CM	CM	N	N	N	N	N	N	N

N=normal (score of 0), S=copious serous discharge (score of 1), SM=slight mucopurulent discharge (score of 2), CM=copious mucopurulent discharge (score of 4)

Coughing

Horse	G				Coughi	ng ob	servat	ions	on day	s pos	t chal	llenge	with	EHV-4	:		
No	Group	-1	0	1	. 2	3	4	5	6	7	8	9	10	11	12	13	14
1		N	N	N	N	N	C	N	N	N	N	N	N	N	N	N	N
2		N	N	N	'N	N	N	N	C	N	N	N	N	N	N	N	- C
3		N	N	N	N	N	N	N	N	N	N	N	N	N	N	C	N
4		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
7		Ň	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
9		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
12		Ň	Ň	N	N	Ň	N	N	N	N	N		N	N	N	N	N
14		N	N	N	N	C	C C	C	N	N	C	N	N	N	N	C	N
15		N	N	N	N	~ C	C	CHI	C .	rida <mark>C</mark> } →	C	C	N	C i	N	, C	N
19		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
20	Vaccinates	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
24		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
27		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
29		N	N	N	N	N	C.	N	N	Ň	N	N	N	N	N	N	N
33		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
37	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
45		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
47		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
58		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
61	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
83	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
5		N	N	N	N	N	N	C	C.	N	N	N	N	N	N	N	N
25	1	N	N	N	N	N	C	C	N	N	N	N	N	N	N	N	N
39	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
40	1	N	N	N	N	N	C	C	N	N	N	N	N	N	N	N	N
43	1	N	N	N	N	N	N	C	C. T	N	N	N	N	N	N	N	N
59	Controls	N	N	N	N	N	С	N	K.C.	N	N	N	N	N	N	N	N
63	1	N	N	N	N	N	C	N	N	N	N	N	N	N	N	N	N
65	1	N	N	N	N	N	N	C C	- C	N	N	N	N	N	N	N	N
71	1	N	N	N	N	N	C	C.	C C	N	N	N	N	N	N	N	N
79	1	N	N	N	N	N	C	N	°C	C	N	N	N	N	N	N	N
91	1	N	N	N	N	N	C	C	N	N	N	N	N	N	N	N	N

N=no coughing , C=coughing

Study Type	Efficacy						
Pertaining to	Equine Herpe	svirus-Subtype	e 4 (El	HV-4)			
Study Purpose	Efficacy agair	st respiratory	diseas	e and shedd	ling ca	used by EHV-	-4
Product	Two doses, ad	lministered int	ramus	cularly, 21	days aj	part	
Administration							
Study Animals	16 vaccinates	and 15 contro	ls, sero	onegative to	EHV-	-4. Horses we	re 6
	months of age	, mixed sex.					
Challenge	Horses were c	hallenged with	h EHV	'-4, 21 days	post s	econd vaccina	tion.
Description							
Interval	Horses were o	bserved daily	for 21	days post-o	challen	ge for clinical	signs.
observed after	Nasal swabs v	vere collected	daily f	for virus isc	lation.		
challenge							
Results	Virus Sheddir	<u>ig</u> – The numb	er of p	ost-challen	ige day	s between the	last and
	first, inclusive	e, with a positi	ve tite	r.			
							-
		Duration	of Vi	rus Sheddi	ng	1	
	Group	Minimum	Q1	Median	Q3	Maximum	
	Vaccinates	3	5	6	8	14	
	Controls	4	7	11	15	19	
	Nasal Dischar	ge					
	Group	Unaffected	Af	fected			
	Vaccinates	4 (25%)	12	(75%)			
	Controls	0 (0%)	15 (100%)			
				<u> </u>			
	Coughing was	s not observed	in vac	cinates or c	ontrol	s.	
	Raw data show	wn on attached	l page	5.			
USDA Approval	July 2, 2007						
Date							

<u>Nasal Discharge – Vaccinates</u>

					Na	asal di	scharg	je scor	es ^a on	post-cha	alleng	e days.											
Horse No	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
648	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0
649	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
653	0	0	0	0	0	1	2	0	2	1	1	0	3	0	1	0	0	0	0	0	0	0	0
654	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
657	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
661	0	0	0	0	0	1	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
663	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
666	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
667	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
669	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
671	0	0	0	0	0	2	1	0	1	0	3	0	0	0	0	0	0	0	0	0	0	0	0
672	0	0	0	0	0	0	1	0	1	0	1	3	0	1	0	0	1	0	0	0	0	0	0
673	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
676	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
677	0	0	0	0	0	1	1	1	1	2	1	0	1	0	0	0	0	0	0	0	0	0	0
678	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Avg	0	0	0	0	0	0.5	0.5	0.13	0.44	0.19	0.5	0.19	0.31	0.06	0.06	0	0.06	0	0	0	0	0	0

a (0=normal, 1=abnormal serous, 2=slight mucopurulent, 3=copius mucopurulent)

<u>Nasal Discharge – Controls</u>

					1	Vasal d	lischa	arge sc	ores ^a (Day P	ost-Cha	alleng	e)										
Horse No	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
650	0	0	0	0	0	0	1	1	2	2	0	1	1	1	1	1	1	1	1	0	0	0	0
651	0	0	0	0	0	1	0	1	1	1	1	1	0	1	1	1	0	1	0	0	0	0	0
652	0	0	0	0	0	0	2	1	2	2	3	3	1	2	1	1	1	0	0	0	0	0	0
655	0	0	0	0	0	2	2	1	2	2	3	2_	1	0	2	1	0	0	0	0	0	0	0
656	0	0	0	0	0	1	1	1	1	2	3	1	1	1	3	1	1	1	1	1	0	0	0
658	0	0	0	0	0	2	0	1	1	0	0	1	1	0	0	1	0	0	0	1	0	0	0
659	0	0	0	0	0	. 1	1	2	2	1	0	3	0	1	1	1	1	1	0	0	0	0	0
660	0	0	0	0	0	1	1	1	0	1	1	1	1	1	1	1	1	0	0	0	0	0	0
662	0	0	0	0	0	1	1	1	0	3	1	2	1	1	1	0	0	0	0	0	0	0	0
664	0	0	0	0	0	0	1	1	1	0	0	1	0	1	1	1	0	0	1	0	0	0	0
665	0	0	0	0	0	1	1	3	1	3	3	3	1	1	2	1	0	0	1	0	0	0	0
668	0	0	0	0	0	0	1	1	2	1	1	3	3	1	1	2	1	1	0	1	1	0	0
670	0	0	0	0	0	1	1	1	2	2	1	2	1	1	0	1	1	1	1	0	0	0	0
674	0	0	0	0	0	1	1	2	2	3	1	0	0	1	0	1	0	0	0	0	0	0	0
675	0	0	0	0	0	1	1	1	0	1	1	0	1	1	1	1	1	1	1	0	0	0	0
Avg	0	0	0	0	0	0.87	1	1.27	1.27	1.6	1.27	1.6	0.87	0.93	1.07	1	1.36	1.35	1.35	1.24	1.18	1.18	1.24

a (0=normal, 1=abnormal serous, 2=slight mucopurulent, 3=copius mucopurulent)

Virus Isolation – Vaccinates

							_	Day	Post-	Challe	nge V	iral Ti	iters (l	_ og 10	CID	₅₀ /m	L)							
Horse No	Group	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
648	Vaccinate	0	0	0	0	3.53	<1	3.19	4.53	2.53	0	<1	0	0	0	0	0	0	0	0	0	0	0	0
649	Vaccinate	0	0	0	0	2.53	2.86	3.53	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
653	Vaccinate	0	0	0	<1	3.53	3.53	3.32	4.07	0	0	0	0	0	0	0	1.86	<1	0	0	0	0	0	0
654	Vaccinate	0	0	0	0	2.07	4.07	3.32	3.19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
657	Vaccinate	0	0	<1	3.19	3.07	3.92	3.19	3.53	2.19	2.07	0	0	0	0	0	0	0	0	0	0	0	0	0
661	Vaccinate	0	0	0	0	2.86	4.19	4.19	3.86	2.19	<1	0	0	0	0	0	0	0	0	0	0	0	0	0
663	Vaccinate	0	0	0	2.19	2.19	2.19	2.53	2.53	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
666	Vaccinate	0	0	0	0	3.19	3.07	4.07	2.19	1.86	0	0	0	0	0	0	0	0	0	0	0	0	0	0
667	Vaccinate	0	0	0	0	2.86	2.53	4.53	4.86	1.86	0	0	0	0	0	0	0	0	0	0	0	0	0	0
669	Vaccinate	0	0	0	0	2.52	1.86	3.19	3.53	2.32	0	0	0	0	0	0	0	0	0	0	0	0	0	0
671	Vaccinate	0	0	0	0	3.38	1.86	4.19	3.53	2.53	1.86	2.86	<1	<1	0	0	0	0	0	0	0	0	0	0
672	Vaccinate	0	0	0	0	<1	2.01	2.32	2.19	1.86	<1	0	0	0	0	0	0	0	0	0	0	0	0	0
673	Vaccinate	0	0	0	2.32	<1	3.07	3.19	2.86	0	0	1.86	1.86	2.19	0	0	0	0	0	0	0	0	0	0
676	Vaccinate	0	0	0	0	0	0	0	2.32	<1	2.86	2.32	<1	0	0	0	0	0	0	0	0	0	0	0
677	Vaccinate	0	0	0	<1	4.53	3.53	2.86	3.19	2.86	<1	<1	0	0	0	0	0	0	0	0	0	0	0	0
678	Vaccinate	0	0	0	1.86	<1	<1	0	1.86	2.32	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Avg	0	0	0.03	0.66	2.36	2.48	2.98	3.02	1.44	0.52	0.51	0.18	0.17	0	0	0.12	0.03	0	0	0	0	0	0

Virus Isolation – Controls

									Day	Post-	Challe	enge \	/iral T	iters (L	.og ₁₀	TCID₅	/mL)							
Horse No	Group	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
650	Control	0	0	0	0	<1	2.19	4.5	4.07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
651	Control	0	0	0	2.32	2.07	3.32	4.19	4.86	4.32	3.19	2.01	2.19	0	0	<1	0	0	0	0	0	0	0	0
652	Control	0	0	0	1.86	2.53	4.19	3.53	4.32	3.86	4.32	4.32	3.19	2.19	0	<1	1.86	<1	2.19	2.07	<1	0	0	0
655	Control	0	0	0	0	<1	3.53	5.07	4.86	3.07	2.53	0	0	0	0	0	<1	0	1.86	2.07	<1	0	0	0
656	Control	0	0	0	0	3.53	3.07	4.32	4.53	3.07	2.69	<1	0	0	0	<1	0	0	0	0	0	0	0	< 1
658	Control	0	0	0	1.86	3.19	4.19	5.52	4.32	3.19	<1	0	0	0	0	0	0	0	0	0	0	0	0	0
659	Control	0	0	0	0	<1	3.07	3.07	2.07	1.86	<1	0	0	<1	0	0	<1	0	0	0	0	0	0	0
660	Control	0	0	0	<1	3.07	3.86	4.19	3.86	2.86	2.86	2.19	0	0	0	0	0	<1	0	0	0	0	0	0
662	Control	0	0	0	2.19	4.53	3.53	4.19	4.07	3.53	2.32	0	0	0	0	0	0	0	0	0	0	0	0	0
664	Control	0	0	0	0	3.19	4.19	5.19	4.01	3.19	1.86	1.86	0	0	0	0	0	0	0	0	0	0	0	0
665	Control	0	0	<1	0	3.19	4.19	4.32	3.86	3.19	2.86	2.53	2.07	0	0	0	0	0	0	0	0	0	0	0
668	Control	0	0	0	0	3.53	4.19	4.07	4.19	4.32	2.53	<1	0	0	0	0	0	0	0	0	0	0	0	0
670	Control	0	0	0	0	3.86	3.53	3.53	3.19	2.53	2.07	1.86	<1	<1	2.07	2.32	0	0	0	0	0	0	0	0
674	Control	0	0	0	<1	3.07	3.86	3.53	2.86	2.53	2,32	0	0	3.86	3.19	1.86	2.07	0	1.86	0	0	0	0	0
675	Control	0	0	0	2.32	3.86	2.52	4.32	5.32	4.07	3.01	<1	<1	0	0	0	0	0	0	0	0	0	0	0
	Avg	0	0	0.03	0.77	2.74	3.56	4.24	4.03	3.04	2.24	1.09	0.56	<0.50	0.35	0.38	0.33	0.07	0.39	0.28	0.07	0	0	0.03

Study Type	Efficacy
Pertaining to	Equine Influenza Virus (EIV)
Study Purpose	To demonstrate efficacy of updated EIV strains FL/13 and RI/07
Product Administration	
Study Animals	
Challenge Description	
Interval observed after	
challenge	
Results	This product class allows the manufacturer to update micro- organisms in this vaccine under expedited procedures to respond to emerging needs. Abbreviated data to support influenza strain updates to the product composition were evaluated by USDA- APHIS and found to be acceptable based on regulations and policies at the time of approval. Full vaccination-challenge studies may not have been required for these updates.
USDA Approval Date	March 8, 2016

Study Type	Efficacy			
Pertaining to	Equine Influer	nza Virus (E	IV)	
Study Purpose	To demonstrat	te efficacy ag	gainst EIV six	months after
	vaccination.			
Product Administration	Two doses add	ministered ir	ntramuscularly	(IM) three weeks apart.
Study Animals	18 vaccinate a	and 7 control	horses were us	sed at 6 months of
	age.			
Challenge Description	All horses we	re challenged	d with EIV stra	in
	A/equine/Ken	tucky/99 six	months post se	econd vaccination.
Interval observed after	Horses were o	bserved dail	y for 14 days p	bost-challenge for
challenge	clinical signs.	Nasal swab	s were collecte	ed daily for virus
D	1solation.	1	/ 1	C 1' ' 1 ' /
Results	Disease Preva	lence – pres	ence/absence o	f any clinical sign at
	any occasion o	auring the ot	oservation perio	od (nasal discharge,
	cougning, resp	piration, tem	perature >102.	5°F).
		# ^f	Dragon og of	e
	Crown	# 01	Presence of	
	Group			15
	Vaccinates	18	14	
	Controls	/	/	
	Virus shaddin	a provolonce	a horse was	considered negative for
	shedding if all	g prevalence	st_challenge su	vahe were virus
	negative othe	rwise it was	nositive	vaus were virus
	negutive, othe	I WISC It Wus	positive.	
		# of	Virus	
	Group	Animals	Isolation	
	Vaccinates	18	12	
	Controls	7	7	
		I		l
	Raw data show	wn on attach	ed pages.	
USDA Approval Date	August 8, 200	5	10	

Table 1. Rectal body temperatures of horses vaccinated with vaccine 111103 on days post-challenge with virulent EIV KY99.

HOTRA					-	sody tem	perature	(A) 5	on days	post chi	allenge	WITH BI	7 KY99:				
No.	Group	-	•	-	2	e	4	2	9	7	8	6	10	1	12	13	14
-		100.3	100.0	99.66	99.9	101.5	101.1	100.0	9.66	100.2	99.1	100.2	98.1	100.7	99.9	100.1	100.6
		99.2	100.0	5.96	99.0	99.5	9.66	98.9	5.99.3	100.0	99.1	99.8	99.2	100.8	99.66	100.3	100.1
-		98.86	99.1	99.99	100.1	98.6	99.8	98.9	99.3	98.9	97.8	99.2	99.2	100.5	99.9	101.7	100.0
14		99.8	100.9	100.6	101.9	99.8	9.66	6.99	100.0	99.2	99.1	100.3	99.2	100.8	99.9	100.2	7.96
16		1.66	100.1	99.3	102.8	100.5	101.5	1001	98.9	98.8	98.5	98.3	98.8	100.1	99.4	100.0	100.6
6[7.99	100.6	99.9	100.0	99.66	100.2	99.4	100.0	99.7	99.5	100.0	98.6	100.0	100.6	100.9	100.2
29		100.3	100.5	9.66	99.7	99.7	100.0	99.3	99.2	99.2	100.5	99.8	100.0	100.5	100.9	100.2	100.3
30		101.2	100.1	100.5	105.4	102.6	104.4	102.1	100.9	9.66	100.4	101.5	100.7	102.4	101.3	102.1	101.4
32		98.8	100.8	100.0	100.4	99.3	100.5	99.66	99.7	99.7	98.3	9.66	100.0	101.2	100.0	100.4	102.7
33	Vaccinates	99.2	100.0	99.4	104.6	100.0	100.0	98.7	100.0	100.8	98.6	0.66	99.3	100.6	9.66	100.9	100.6
34		99.8	100.2	99.7	103.6	100.0	101.3	102.1	102.7	102.1	101.5	102.9	102.0	100.4	100.1	9.96	99.4
35		2.99	99.7	1.99	99.5	99.5	100.6	100.4	99.7	98.86	98.5	100.1	100.1	101.6	100.2	100.3	100.5
96		69.7	9.66	9.66	100.5	100.0	100.5	99.66	99.4	100.4	98.6	99.2	99.0	100.6	100.7	9.99	100.4
000		7.66	100.4	100.0	100.5	100.3	100.5	98.86	100.0	99.4	98.7	100.8	99.66	100.5	100.1	100.9	100.0
40		99.4	100.4	99.96	102.2	6.99	101.6	100.1	100.1	99.1	99.1	99.7	99.5	100.3	99.2	99.9	100.4
10		5.99	100.0	99.4	102.6	99.7	99.7	99.4	99.66	99.7	99.3	99.66	98.8	100.2	99.0	100.1	100.2
22		7.66	100.4	99.8	99.4	99.8	100.1	98.6	99.8	98.7	99.0	99.4	99.66	99.66	99.9	99.6	99.9
27		100.2	100.2	100.1	101.6	99.2	100.1	99.96	100.5	99.66	99.3	98.8	99.5	99.3	99.7	99.5	100.6
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5	A DESCRIPTION OF A DESC	99.5	100.2	99.66	104.5	103.1	103.8	103.7	103.6	102.6	102.4	104.7	102.7	102.4	101.8	102.0	100.9
8		0.66	99.9	98.86	101.9	100.8	103.0	1.99	100.7	100.2	98.9	99.9	99.3	100.4	1001	100.3	99.6
, [100.4	100.5	100.1	101.9	99.9	99.8	100.9	100.1	99.2	100.6	101.3	99.2	101.0	99.96	100.6	100.3
13		39.5	99.7	100.3	103.6	102.4	102.8	99.5	99.3	100.4	99.5	99.2	98.8	101.0	1001	100.7	99.8
25	Controls	100.1	100.6	99.5	104.7	103.6	102.2	103.1	104.2	103.2	102.3	105.4	99.5	99.8	99.8	99.7	100.1
38		99.2	100.0	99.0	104.7	103.7	104.0	104.6	104.7	103.0	103.6	103.3	101.6	101.2	99.5	99.2	5.66
44		1.99	99.9	99.8	103.2	102.6	104.4	97.2	99.8	100.4	104.6	103.8	102.6	102.9	100.6	100.0	99.4

Coughing observations of horses vaccinated with vaccinated 111103 on days postchallenge with virulent EIV KY99. Table 2.

Dree				Couc	hing	obse	rvati	ons o	n days	s post	c-chal	lenge	with	EIV K	:661		
	Group	-1	•	-	2	m	4	5	9	2	8	6	10	11	12	13	14
T		z	z	z	z	z	υ	υ	c'c	υ	υ	N	N	z	N	N	N
		z	z	z	z	z	z	z	N	N	N	N	N	N	N	N	z
Γ		z	z	z	z	z	z	N	N	N	N		N	υ	N	N	z
		z	z	z	z	z	z	z	υ	N	N	υ	υ	N	N	N	z
		z	z	z	z	oʻo	υ	c,c	c, c	c,c	N	c, c	c,c	N	N	N	N
6		z	N	z	z	z	N	z	N	N	N	N	N	z	z	N	N
5		z	z	N	z	N	z	z	N	N	U	z	N	N	z	z	z
		z	z	N	z	c'c	υ	c'c	C, C	c, c	N	c,c	N	N	z	z	z
		z	z	z	z	z	z	z	N	z	N	N	N	N	N	z	z
0	Vaccinates	N	z	z	z	0'0	0	υ	N	N	N	c, c	υ	N	N	N	z
4		N	N	z	z	z	z	c'c	c, c	c, c	c,c	c, c	υ	N	N	z	N
_		N	N	z	z	N	z	N	N	N	N	υ	N	Z	N	z	N
6		z	N	N	z	υ	z	N	N	z	z	N	N	N	'	z	z
6		z	N	N	z	z	z	N	N	z	N	N	N	N	N	z	z
		z	z	N	N	z	z	N	N	N	z	N	N	N	N	N	N
		z	z	z	N	z	z	z	υ	υ	N	N	υ	N	N	N	N
6		z	z	z	z	N	N	z	z	N	U.	C, C	N	N	z	N	N
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		z	z	z	N	z	z	N	N	o'o	υ	c,c	υ	N	N	z	z
		z	z	z	υ	c'c	c'c	c'c	0'0	c, c	c,c	c,c	υ	N	N	N	z
5	CONTROLS	Z	z	z	z	C'C	υ	0'0	c'c	c, c	N	N	c, c	Z	N	N	z
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4		z	z	N	z	c,c	υ	υ	c'c	N	z	υ	N	c, c	z	z	z
	oughing , C-	=coug	hing	1 ti	me di	uring	the	bserv	ration	peri	od, C,	C=COL	ghing	2 or	more	times	

4 n N=no cougning , U=cougning 1 t during the observation period Nasal discharge observations of horses vaccinated with vaccine 111103 on days post-challenge with virulent EIV KY99. Table 3.

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discharge (score of 2), CM=copious mucopurulent discharge (score of 4)

Tab	le 4. Abnor	mal r	l1111	U3 o	n day	ys pos	t-chal	on ops lenge	ervati with	ons or virule	nt EIV	KY99.	-			1
					C	the other	tione	on da	800 an	t-chal	landa	with	ETV KV	.00		
NO	Group	ī	0	٦	2	3	4	2	9	2	8	6	10	Ħ	12	13
-		z	Z	z	z	z	z	N	z	N	N	N	z	z	N	z
0		z	z	N	N	z	z	N	N	N	N	N	N	z	N	z
4		N	z	z	N	N	N	N	N	z	N	N	N	N	z	z
14		z	z	N	z	z	N	N	N	N	N	N	N	N	N	z
16		z	z	Z	Ω	z	N	N	z	z	N	N	N	N	N	z
19		z	z	z	z	Z	N	z	N	z	N	N	N	N	z	z
29		z	N	z	z	Z	N	z	N	N	N	N	N	N	N	z
30		z	z	N	Ω	D, Ab	D	D, Ab	D, Ab	N	D, Ab	N	N	N	z	z
32		z	z	z	z	N	N	z	N	N	N	N	N	N	z	z
33	- Vaccinates	z	z	N	Ab	z	z	N	z	N	N	N	N	N	N	z

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> lethargy or inappetence (score of 1) Observations were scored as not observed (score of 0) and observed per minute, D=depression, N=normal, Ab=abnormal respiration of >36

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Virus isolation from nasal swabs from horses vaccinated with vaccine 111103 on days post-challenge with virulent EIV KY99. Table 5.

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	Group										Vaccinates									記書のこれに行いたい					CONTROLS		1	
Horse	оу Х		2	4	14	16	19	29	30	32	33	34	35	36	39	40	41	43	47	の語がないのな	e	8	11	13	25	38	44	

TTOM FUR HEAST SMAD DATAAODAT SNITA = (-) = no virus isolated from the nasal swab, (+)

Study Type	Efficacy													
Pertaining to	West Nile Viru	IS												
Study Purpose	To demonstrat	e efficacy a	gainst West Nile	Virus										
Product Administration	Two doses adm	ninistered in	ntramuscularly 3	weeks apart										
Study Animals	20 vaccinates a	and 20 cont	rols horses were	used at 6 months of										
	age													
Challenge Description	20 horses (10 v	vaccinates a	and 10 control) w	ere challenged with										
	West Nile Viru	us 61 days p	oost-2 nd vaccinati	on. The remaining										
	20 horses were	e challenged	191 days post-2 ⁿ	^d vaccination.										
Interval observed after	Horses were of	bserved for	21 days post cha	llenge for clinical										
challenge	signs. Blood s	amples wer	e taken at days 0	-14 and 21 post										
	challenge for v	virus isolatio	on. Histopatholo	gy was performed on										
	samples taken	at the end c	of the study.											
Results	Disease preval	ance was d	efined as the dem	ionstration of clinical										
	signs of neurol	logical dise	ase observed in h	orses naturally										
	affected with V	NNV under	field conditions	(i.e. mentation,										
	paresis, muscle	e tasiculato	in, ataxia).											
	Group	# of	Presence of											
	X7	Animals	clinical signs											
	Vaccinates	20	12											
	Controls	20	13											
	Viromia was d	afinad as th	a presence of a x	virus titor > 5 $PEII/mI$										
	of serum on any testing occasion. # of													
	Viremia was defined as the presence of a virus titer ≥ 5 PFU/mL of serum on any testing occasion. # of Group Animals Viremia													
	Viremia was defined as the presence of a virus titer \geq 5 PFU/mLof serum on any testing occasion.# ofGroupAnimalsViremia													
	Vaccinates	20	14											
	Controls	20	20											
	Controls	20	20											
	Encephalitis w	as defined	as the pons, med	ulla or cervical cord										
	showing histor	oathological	l lesions of at lea	st a "mild"										
	classification;	minimal ch	anges in these tis	sues were classified as										
	unaffected.		C											
		# of												
	Group	Animals	Encephalitis											
	Vaccinates	20	9											
	Controls	20	19											
	Raw data show	vn on attach	ed pages.											
USDA Approval Date	March 27, 200	9												

Crown	Hange No.	Challenge	Challenge Day
Group	Horse No.	Group	Post 2^{na} -vacc
Vaccinate	206	1	01
Vaccinate	214	2	91
Vaccinate	301	l	61
Vaccinate	316	l	61
Vaccinate	318	1	61
Vaccinate	324	1	61
Vaccinate	326	2	91
Vaccinate	331	1	61
Vaccinate	332	2	91
Vaccinate	333	2	91
Vaccinate	334	2	91
Vaccinate	335	2	91
Vaccinate	609	2	91
Vaccinate	614	1	61
Vaccinate	615	1	61
Vaccinate	618	1	61
Vaccinate	620	2	91
Vaccinate	622	1	61
Vaccinate	623	2	91
Vaccinate	624	2	91
Control	205	2	91
Control	222	2	91
Control	300	1	61
Control	302	1	61
Control	307	1	61
Control	308	1	61
Control	310	1	61
Control	311	2	91
Control	313	1	61
Control	321	2	91
Control	321	2	01
Control	322	1	61
Control	325	1	01
Control	323	<u> </u>	91
Control	<u> </u>	1	01
Control	612	<u> </u>	<u> </u>
Control	013		01
Control	010	2	91
Control	617		61
Control	625	2	91
Control	626	2	91

Overview of Challenge Groups

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	Treatment	Horse	•		[Ē	1							i,	ľ	ļ.	Ŀ		h		ŀ	Ŀ
	Group	No.	7	•	-	~	۳	4	ŝ	۵	~		•	₽	F	12	33	4	12	9	-	200	19	2 2	-
	Vaccinate	206	0	0	0	0	0	0	0	0	0	0	2	0	-	0	0	0	0	0	0	0	0	0	~
	Vaccinate	214	0	0	0	0	0	0	0	0	0	0	0	~	0	0	0	0	0	0	0	0	0	0	~
	Vaccinate	301	0	0	0	0	0	0	0	0	0	0	0	0	٥	0	0	0	0	0	0	0	0	0	_
	Vaccinate	316	0	0	0	0	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0	_
	Vaccinate	318	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	_
	Vaccinate	324	0	0	0	0	0	0	0	0	0	0	-	0	0	~									
	Vaccinate	326	0	0	0	0	0	0	0	0	0	0	0	0	•	0	0	0	0	0	0	0	0	0	_
	Vaccinete	331	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	_
	Vaccinate	332	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	_
	Vaccinate	333	0	0	0	0	0	0	0	0	0	8	2	0	0	0	0	0	0	0	0	0	0	0	_
	Vaccinate	334	0	0	0	0	0	0	0	۰	0	0	0	0	٥	0	0	~							
	Vaccinate	335	٥	0	0	۰	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	Vaccinate	609	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
_	Vaccinate	614	0	0	0	0	0	0	0	0	0	0	0	0	٥	0	0	0	0	0	0	0	0	0	
	Vaccinate	615	0	0	0	0	0	0	0	0	0	0	0	0	٥	0	0	0	0	0	0	0	0		_
	Vaccinate	618	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	~
	Vaccinate	620	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	~
	Vaccinate	622	0	0	0	0	0	0	0	0	•	0	0	0	0	0	0	•	0	0	0	0	0	•	_
	Vaccinate	623	0	0	۰	0	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	~
_	Vaccinate	624	0	0	۰	0	0	0	0	-	0	Q	0	0	0	0	0	0	0	0	0	0	0	0	0
2.) Observat	tion were	e sco	bred o	as 0=	Nori	wal,	1=Mi1	d, 2:	Mode	rate,	3 S	evere												

post challenge with WNV. Aave 5 mentation with horead wanni nata ŝ 1000 5 61 i ni ٣ Table

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Table

	6 17 18 19 20 21	0 0 0 0	0 0 0 0 0	0 0 0 0	-	0 0 0 0	0 0 0 0 0	0 0 0 0	-	0 0 0 0 0	-	0 0 0 0 0	0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0	-	-	-	0 0 0 0 0	
	15	0	0	0		0	0	0		0		0	0	0	0	0				0	t
	14	0	0	0		0	0	0		0		0	0	0	0	0				0	ľ
WNN	13	0	0	0		0	0	0		0	2	0	0	0	0	0				0	ľ
le with	12	0	0	0		0	0	0	0	0	0	0	0	0	0	0				0	ľ
alleng	÷	0	0	0		0	۰	0	2	0	0	0	٥	٥	0	0				0	ľ
ost-ch	9	۰	0	0	en	-	0	0	N	N	0	0	0	0	0	N		N	8	N	
lays p	6	0	۰	2	0	0	٥	o	0	0	2	0	٥	-	0	0	2	R	0	0	
" on d	80	۰	۰	٥	0	٥	۰	0	0	0	-	0	0	0	0	8	8	٥	0	0	
scores	~	•	۰	•	0	۰	۰	۰	٥	0	0	۰	0	0	۰	۰	0	۰	٥	0	
ß	9	0	۰	0	0	۰	0	٥	0	0	0	0	0	¢	0	ø	0	٥	٥	0	
	ŝ	•	۰	0	0	٥	۰	٥	٥	•	٥	٥	•	•	•	•	0	0	۰	0	
	4	•	۰	•	0	•	•	•	•	0	0	•	0	•	0	0	0	•	۰	•	
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	~	•	۰	۰	0	۰	۰	۰	۰	۰	0	۰	۰	•	۰	۰	•	۰	۰	•	
	-	•	•	0	0	•	•	٥	٥	•	•	٥	•	•	ø	0	0	٥	ø	0	ļ
	•	•	۰	•	0	•	•	0	0	0	0	0	0	0	0	0	0	0	0	0	
	7	۰	۰	0	0	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Horse	No.	205	222	300	302	307	308	310	311	313	321	322	323	325	396	611	613	616	617	53	
Treatment	Group	Control	Control	Control	Control	Control	Control	Control	Control	Control	Control	Control	Control	Control	Control	Control	Control	Control	Control	Control	

(a) Observation were scored as 0= Normal, 1=Mild, 2=Moderate, 3=Severe (.) Euthanized for humane reasons

	E4	Table 2.		linic	al 8	SCOLE	s of	Vaco	inat	e ho	IL Be	B Wİ	Ch Dé	ares:	B OI	day	's po	st-c	hall	enge	with	NW C			
Trea	tment	Horse								ŝ	ores"	on dâ	ys po	st-chi	lleng	e with	WNV								
້ອ	dno,	No.	$\overline{\gamma}$	0	-	~	8	4	5	9	7	8	6	₽	÷	12	13	14	15	16	1	80	9	5 0	-
Vao	cinate	206	0	0	0	0	0	0	0	0	0	0	~	0	•	0	•	•	0	0	0		•	0	
Vao	cinate	214	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	•	0	0	0		•	•	
Vao	cinate	301	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			0	
Vao	cinate	316	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		•	0	
Vac	cinate	318	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		•	0	
Vao	cinate	324	0	0	0	0	0	0	0	0	0	0	0	0	0	5								•	
Vao	cinate	326	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			0	
Vao	cinate	331	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			0	
Vao	cinate	332	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	
Vao	cinale	333	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	
Vac	cinale	334	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	-	e							
Vac	cinate	335	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			0	0	
Vao	cinate	609	0	0	0	0	0	•	0	0	0	0	0	0	0	0	0	0	0	0			0	•	
Vao	cinale	614	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			0	•	
Vac	cinate	615	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	_
Vac	cinate	618	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			~ ~	0	_
Vac	cinate	620	0	0	0	0	0	•	•	•	•	•	•	•	0	0	0	•	0	0	°	~	•	°	
Vac	cinate	622	0	۰	0	•	0	•	•	0	•	0	•	•	•	0	0	•	0	0	о о	~	~	°	_
Vao	cinate	623	0	۰	0	0	•	•	0	0	0	•	•	0	•	0	0	•	0	0	~	~		°	
Vao	cinate	624	0	0	0	0	0	0	0	0	0	N	0	0	0	0	0	•	0	0	0	0	- -	°	
(a) Ob (.) Bu	servat	tion were	e sc	ored d	as 0=	Norm	al, i	I=Mild	2	Moder	ate,	n n n	evere												

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						_	_		_	_	_	_	_	_	_	_	_	_	_	_	_	_
		21	0	0	0		0	0	0		0		0	0	0	0	0				0	
		20	0	0	0		•	•	•		0		0	0	0	0	0				0	
2		19	0	0	0		0	0	0		0		0	0	0	0	0				0	
IN NI		18	0	0	0		0	0	0		0		0	0	0	0	0				0	
TTM D		17	0	0	0		0	0	0		0		0	0	0	0	0				•	
reng.		16	0	0	0		0	0	0		0		0	0	0	0	0				•	
UDA1.		15	0	0	0		0	0	0		0		0	0	0	0	0				0	
		14	0	0	0		0	0	0		0		0	0	0	0	0				0	
ň	NNN L	13	0	•	0		0	0	0		0	e	0	0	0	0	0				0	
(ab)	je witt	12	0	0	0		0	0	0	0	0	-	0	0	0	0	0				0	
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1108	st-ch	10	0	0	0	8	0	0	0	0	N	0	0	0	0	0	0		0	~	~	
n pe	ays po	6	0	0	0	0	0	0	0	0	0	0	٥	0	0	0	0	-	0	0	0	e
DTM I	on di	80	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N	0	0	0	0	0
DIBOR	cores.	۲	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10	ŭ	9	0	•	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ontro		6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DI CO		4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
88		8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BCOI		8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Cal		-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CUTTO		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
aDle Z	Horse	No.	205	222	300	302	307	308	310	311	313	321	322	323	325	396	611	613	616	617	825	83
A	Treatment	Group	Control																			

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⁽a) Observation were scored as 0= Normal, 1=Mild, 2=Moderate, 3=Severe (.) Euthanized for humane reasons

Table 3.Clinical scores of vaccinate horses with fasciculation on days post-challenge with WNV.

	21	•	0	0	۰	۰		0	0	0	0		0	0	0	0	0	0	0	0	0
	20	0	0	0	0	0		0	0	0	0		0	0	0	0	0	0	0	0	0
	19	0	0	0	0	0		0	0	0	0		0	0	0	0	0	0	0	0	0
	18	0	0	0	0	0		0	0	0	0		0	0	0	0	0	0	0	0	0
	17	0	0	0	0	0		0	0	0	0		0	0	0	0	0	0	0	0	0
	16	0	0	0	0	0		0	0	0	0		0	0	0	0	0	0	0	0	0
	15	0	۰	0	0	0		0	•	0	0		•	•	0	•	۰	0	۰	0	0
	14	0	0	0	۰	۰		0	0	0	0	-	0	•	0	۰	۰	۰	۰	0	•
NNN C	13	0	0	0	۰	۰		0	0	0	0	0	0	•	0	۰	٥	۰	۰	0	۰
e with	12	-	0	0	-	0	~	0	0	0	0	0	0	0	0	0	0	0	0	0	0
alleng	÷	-	0	0	N	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ost-ch	10	2	0	0	0	0	0	0	0	0	0	0	۰	•	0	0	۰	0	0	0	0
ays po	6	~	0	0	0	0	-	0	0	0	2	0	0	0	0	0	0	۰	0	0	0
ond	8	0	0	0	0	0	0	0	0	٥	0	۰	٥	٥	0	۰	0	0	0	0	0
cores	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ö	9	0	0	0	0	0	0	0	0	0	o	۰	٥	0	0	۰	۰	¢	0	0	0
	s	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	e	0	0	0	0	0	0	0	0	0	0	0	0	0	0	۰	0	0	0	0	0
	N	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	•	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Ţ	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Horse	No.	206	214	301	316	318	324	326	331	332	333	334	335	609	614	615	618	620	622	623	624
Treatment	Group	Vaccinate																			

(a) Observation were scored as 0= Normal, 1=Mild, 2=Moderate, 3=Severe(.) Euthanized for humane reasons

	_	_	_	_	_	_	_	_	_			_	_		_	_	_	_		_	_	_
		21	0	0	0		0	0	0		0		0	0	0	0	0				0	
		20	0	0	0		0	0	0		0		0	0	0	0	0	-			0	
A N/M		19	0	0	0		0	0	0		0		0	0	0	0	0				0	
UT CU		18	0	0	0		0	0	0		0		0	0	0	0	0				0	
D		17	0	0	0		0	•	0		•		0	0	0	0	0				0	
9115		16	0	0	0		0	0	0		0		0	0	0	0	0				0	
00-0		15	0	0	0		0	0	0		0		0	0	0	0	0				0	
a D C C		14	0	0	0		0	0	0		0		0	0	0	0	0				0	
ayau	WNV	13	0	0	0		0	0	0	,	0	N	0	0	0	0	0				0	-
HO IIO	e with	12	0	0	0		0	0	0	0	-	N	0	0	0	0	0				0	
1011	alleng	1	0	0	0		0	0	0	e	N	0	0	0	0	0	0				0	
BTDO	st-chi	10	0	0	0	N	0	0	0	0	N	0	0	0	0	0	0		e	e	5	
TOST	ys po	8	0	0	-	-	•	0	0	0	N	N	0	0	0	0	0	~	0	٥	0	\$
Ĩ	on da	8	0	0	0	•	•	0	0	0	۰	0	0	•	•	0	-	0	0	0	0	0
	ores	7	0	0	0	۰	۰	۰	0	0	0	0	0	0	0	0	0	0	0	0	0	<
	ŝ	9	0	0	0	•	•	•	•	•	0	0	0	0	0	0	0	0	0	0	0	c
		5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	•
OUCE		4	0	0	0	•	0	•	0	0	0	0	0	0	0	0	0	0	0	0	٥	<
Č I		8	0	0	۰	•	0	0	0	0	0	0	٥	0	0	0	0	0	0	0	٥	<
88		2	0	0	0	•	0	•	0	0	0	0	0	0	0	0	0	0	0	0	0	<
BCO		-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	<
TCal		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	•	0	•		•	<
UTTO		7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	<
38.	esu	9	8	5	8	8	07	8	10	11	113	21	52	53	25	96	11	113	16	117	25	
eTq	H	2	~	in a	0	-0			-0	60	6)	-01	6)	-0	-0	-0	9	9	9	9	-	
18	Treatment	Group	Control																			

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(a) Observation were scored as 0= Normal, 1=Mild, 2=Moderate, 3=Severe (.) Euthanized for humane reasons

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		Table 4		Clini	cal	SCOL	es o	f va	ccin	ste 1	OLS	IW 89	th a	taxi	A OT	day	a po	st-cl	balle	ebue	with	VIEW			
_	Treatment	Horse								ŝ	cores	on da	ys po	st-chi	alleng	e with	WW								
	Group	No.	$\overline{\gamma}$	•	-	8	e	4	ю	ø	7	60	m	5	Ξ	12	13	14	15	16	1	80	9 24	21	
	Vaccinate	206	0	0	۰	٥	0	0	0	0	0	0	N	0	0	0	0	0	0	0	0	0	0	0	
	Vaccinate	214	0	0	۰	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	Vaccinate	301	0	0	۰	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	•	0	
	Vaccinate	316	0	0	۰	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	Vaccinate	316	0	0	۰	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		•	0	
	Vaccinate	324	0	0	٥	0	0	0	0	0	0	0	0	0	0	e							•	,	
	Vaccinate	326	0	0	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	•	0	
	Vaccinate	331	0	0	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	°	0	
	Vaccinate	332	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	•	0	
	Vaccinate	333	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	
	Vaccinate	334	0	0	0	0	0	0	0	0	0	0	0	o	0	0	0	e						•	
	Vaccinate	335	•	•	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		•	0	
	Vaccinate	609	•	0	0	0	0	•	0	0	0	0	0	•	0	0	0	0	0	0	0		•	0	
	Vaccinate	614	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	
	Vaccinate	615	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	Vaccinate	618	•	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		•	0	
	Vaccinate	620	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		•	0	
	Vaccinate	622	•	0	0	0	0	•	0	0	0	0	0	0	0	0	•	0	0	0	0		°	0	
	Vaccinate	623	۰	0	0	0	0	0	0	0	0	0	0	•	0	0	0	0	0	0	0		•	0	
	Vaccinate	624	0	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0		0	0	
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а.		7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	000
table 4	Horse	No.	205	222	300	302	307	308	310	311	313	321	322	323	325	396	611	613	616	617	625	828	on were
	Treatment	Group	Control	al Observati																			

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Table	5.	Summary for Prim	of Clinic ary Outco	cal Observation me/Case Defini	ns tion	
Horse	Vaccine	Horses that had of the categorie	d one or more es or that requ	days with mild, mode ired euthanasia	erate or seve	re scores in any
No.	Group	Mentation	Paresis	Fasciculations	Ataxia	Euthanasia
206		+	+	+	+	
214		+				
301						
316		+		+		
318						
324		+	+	+	+	+
326]					
331						
332	<					
333	300	+		+		
334	ina	+	+	+	+	+
335	8					
609	1					
614						
615						
618			1			
620	1					
622	1					
623						
624	1	+	+		+	
205						
222				and the second se		
300		+		+		
302		+	+	+	+	+
307		+				
308	1					
310						
311	1	+	+	+	+	+
313		+	+	+	+	
321	Co	+	+	+	+	+
322	ntro					
323	1					
325	1	+				
396						
611	1	+	+	+		
613	1	-		+		+
616	-	4		+		+
617	1	+	+	+		+
625	1	+	+	+		+
626	1	+	+	+		+

(+) Clinical signs

Treatment	Horse		WNV	(pfu/m	L) detec	ted in s	serum o	f horse	s on da	ys post-	-challer	ige witi	h WNV	
Group	No.	0	1	2	3	4	5	6	7	8	9	10	14	21
Vaccinate	206	< 5	20	210	65	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	214	< 5	< 5	30	10	< 5	< 5	< 5	< 5	< 5	< 5	< 5	<5	< 5
Vaccinate	301	< 5	< 5	15	10	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	316	< 5	5	35	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	318	< 5	< 5	175	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	324	< 5	10	130	25	5	< 5	< 5	< 5	< 5	< 5	< 5		
Vaccinate	326	< 5	40	520	70	40	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	331	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	332	< 5	5	55	25	45	15	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	333	< 5	5	70	175	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	334	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	-
Vaccinate	335	< 5	< 5	15	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	609	< 5	< 5	15	45	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	614	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	<5
Vaccinate	615	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	<5
Vaccinate	618	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	620	< 5	< 5	20	20	45	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	622	< 5	< 5	10	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	623	< 5	< 5	95	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Vaccinate	624	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	205	< 5	5	80	155	30	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	222	< 5	< 5	165	45	75	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	300	< 5	55	265	45	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	302	< 5	< 5	5	5	10	15	< 5	< 5	< 5	< 5	< 5		-
Control	307	< 5	< 5	15	15	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	308	< 5	< 5	20	10	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	310	< 5	< 5	45	35	10	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	311	< 5	< 5	10	10	10	< 5	< 5	< 5	< 5	< 5	< 5		
Control	313	< 5	30	225	370	15	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	321	< 5	< 5	20	15	35	5	< 5	< 5	< 5	< 5	< 5		
Control	322	< 5	20	15	45	20	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	323	< 5	60	460	75	5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	325	< 5	25	235	70	30	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	396	< 5	5	55	20	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	611	< 5	< 5	50	30	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	613	< 5	< 5	95	35	5	< 5	< 5	< 5	< 5	< 5			-
Control	616	< 5	< 5	35	40	40	< 5	< 5	< 5	< 5	< 5	< 5		-
Control	617	< 5	5	45	40	40	10	< 5	< 5	< 5	< 5	< 5		-
Control	625	< 5	5	320	140	65	< 5	< 5	< 5	< 5	< 5	< 5	< 5	< 5
Control	626	< 5	15	470	225	175	< 5	< 5	< 5	< 5	< 5			

Table 1. Viremia in vaccinate and control horses on days post-challenge with WNV.

(.)Euthanized for humane reasons

Horse No.	Vaccine	Histopatho Post-ch	ology of neural tis allenge with WN	sue /*
	Group	Cervical Cord	Medulla	Pons
206		0	0	0
214		1	0	1
301		0	0	0
316		0	1	0
318		0	0	0
324		1	1	1
326		2	2	2
331		0	0	0
332	<	0	0	0
333	acc	1	0	1
334	ina	2	2	2
335	lle	0	0	0
609		0	0	1
614		0	0	0
615		0	0	0
618		0	0	0
620		0	0	0
622		0	0	0
623		0	1	0
624		0	1	1
205		1	1	0
222		1	1	1
300		1	1	0
302		3	3	3
307		1	1	0
308		0	0	0
310		1	1	1
311		2	2	2
313	_	0	1	1
321	ģ	1	1	2
322	tro	1	0	0
323	-	0	1	0
325		1	1	0
396		0	1	1
611		1	1	1
613		3	3	3
616		1	2	2
617		1	2	3
625		1	1	0
626		2	3	3

Table 1. Histopathology of neural tissues post-challenge with virulent WNV

*Histopathology scores: 0 = no apparent lesions in section or minimal changes apparent; 1 = mild changes present; 2 = moderate changes present; 3 = severe changes present or very severe lesions with extensive distribution

Study Type	Safety										
Pertaining to	ALL										
Study Purpose	To demonstrate safety under fiel	d condition	s								
Product Administration	Two doses administered intramu	scularly 3 t	o 4 weeks apart								
Study Animals	1,255 horses from 5 states. 570	horses were	e 6 months of age or								
	younger at time of the intial vacc	cination.									
Challenge Description	Not applicable										
Interval observed after	Horses were observed immediate	ely followir	ng vaccination and then								
challenge	daily for 21 days post-vaccinatio	n									
Results											
	Adverse Events	Number									
	Injection Site Swelling*	102									
	<1.5cm	24									
	1.5-5.0cm	57									
	>5.0cm	21									
	Injection site pain	17									
	Lethargy/Depression	6									
	Diarrhea	3									
	Soft Feces	1									
	Anorexia	6									
	Not Drinking 1 Increased Respiratory Rate 1										
	Not Drinking1Increased Respiratory Rate1										
	Nasal Discharge	1									
	Hoof Abscess	1									
	Enlarged Lymph Node	1									
	Hives	1									
	Unilateral Epistaxis	1									
	Colic Episode**	1									
	Horses with no reaction	1,149									
	*Injection site swellings resolved 3-7 d **Horse was euthanized; suspected due	ays post-vace to colon tors	ination. ion unrelated to vaccine								
USDA Approval Date	February 18, 2010										