

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1995.R2
True Name	West Nile Virus Vaccine, Killed Flavivirus Chimera
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	EquiNile - Merck Animal Health
Date of Compilation Summary	December 19, 2017

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

Study Type	Efficacy			
Pertaining to	West Nile Viru	15		
Study Purpose			gainst West Nile	Virus
Product Administration			ntramuscularly 3	
Study Animals				used at 6 months of
	age			
Challenge Description	20 horses (10 v West Nile Viru	us 61 days p		vere challenged with on. The remaining ^d vaccination.
Interval observed after	Horses were of	bserved for	21 days post cha	llenge for clinical
challenge	signs. Blood s	amples wei	e taken at days (-14 and 21 post
	challenge for w	virus isolatio	on. Histopatholo	gy was performed on
	samples taken			
Results	signs of neurol	logical dise	efined as the den ase observed in h field conditions	
	paresis, muscle			(,
	Group	# of	Presence of	
	oroup	Animals	clinical signs	
	Vaccinates	20	7	
	Controls	20	13	
	Viremia was d of serum on an		-	virus titer \geq 5 PFU/mL
		# of		
	Group	Animals	Viremia	
	Vaccinates	20	14	
	Controls	20	20	
	showing histor	oathologica minimal ch	l lesions of at lea	ulla or cervical cord st a "mild" ssues were classified as
		# of		
	Group	Animals	Encephalitis	
	Vaccinates	20	9	
	Controls	20	19	
	Raw data show	vn on attach	ed pages.	
USDA Approval Date	March 27, 200			

		Challenge	Challenge Day
Group	Horse No.	Group	Post 2 nd -Vacc
Vaccinate	206	1	61
Vaccinate	214	2	91
Vaccinate	301	1	61
Vaccinate	316	1	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	322	2	91
Control	323	1	61
Control	325	2	91
Control	396	1	61
Control	611	2	91
Control	613	1	61
Control	616	2	91
Control	617	1	61
Control	625	2	91
Control	626	2	91

Overview of Challenge Groups

1	Table 1.		inic	Clinical scores	COLE	BOL		vaccinate		Orses	TW E	E D	horses with mentation	Ton	on de	days I	post	chal	challenge	e wit	with WNV.	≥.	
Treatment	Horse								š	Scores [*]	on de	bd sys	on days post-challenge with WNV	llenge	with	NNN							
Group	No.	7	0	۰	2	3	4	ŝ	9	7	ø	6	P	÷	12	13	14 15		16 1	17 18	19	20	21
Vaccinate	206	0	0	0	0	0	0	0	0	0	0	5	0	-	0	0	0	0	0	0	0	0	0
Vaccinate	214	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	0	0	0	0	0	0	0
Vaccinate	301	0	0	0	0	0	0	0	0	0	0	0	0	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
Vaccinate	318	0	0	0	0	0	0	0	٥	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	8		•	•	•	•	•		
Vaccinate	326	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0 0	0	•	•	•	٥	0
Vaccinete	331	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	•	٥	0
Vaccinate	333	0	0	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	0	•	0	0
Vaccinate	334	0	0	0	0	0	0	0	0	0	0	0	0	0	0	•			_	•			
Vaccinate	335	0	0	0	0	0	0	0	0	•	0	0	0	0	0	•	0 0	0		0	•	۰	0
Vaccinate	609	0	0	0	0	0	0	0	0	•	0	0	0	0	0	0	0 0	0	•	•	•	•	0
Vaccinate	614	۰	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	•	0	0	0
Vaccinate	615	۰	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	0	0	0
Vaccinate	620	0	0	0	0	0	0	0	0	0	0	0	0	0	0	•	° 0	0	•	•	•	0	0
Vaccinate	622	۰	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	0	0
Vaccinate	624	۰	0	0	0	0	0	0	-	0	R	0	0	0	0	0	0	•	_	0	•	0	0

post challenge with WNV. Aave ŝ ŝ mantati with horeas wanni nata ĉ 100 100 5141 ٣ Table

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

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-	Treatment	Horse								ŝ	Scores [*]	on di	on days post-challenge with WNV	st-ch	alleng	e with	VNV								
	Group	No.	7	•	-	8	8	4	ŝ	9	7	80	6	5	÷	12	13	14	15	16	17	18	19 2	20	5
	Control	205	0	۰	0	۰	0	۰	۰	0	٥	۰	0	0	•	0	0	0	0	0	0	0	0	0	0
	Control	222	0	0	0	٥	0	0	0	0	0	0	0	0	0	0	0	0	•	•	0	•	•	0	0
	Control	300	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
	Control	302	0	0	0	0	0	0	0	0	0	0	0	en											
	Control	307	0	0	0	0	0	0	ø	0	٥	0	0	-	0	0	0	0	0	0	0	0	0	0	•
	Control	306	0	0	0	0	0	0	0	0	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	•
	Control	310	0	0	0	0	0	0	0	0	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	•
	Control	311	0	0	0	0	0	0	0	0	0	0	0	N	2	0									
	Control	313	0	0	0	0	0	0	0	0	0	0	0	N	0	0	0	0	0	0	0	0	0	0	0
	Control	321	0	0	0	0	0	0	0	0	0	-	8	0	0	0	2								
	Control	322	0	0	0	0	0	0	0	0	0	0	0	0	•	0	0	0	0	0	0	0	0	0	0
	Control	323	0	0	0	0	0	0	0	0	0	0	0	0	۰	0	0	0	0	0	0	0	•	0	0
	Control	325	0	0	0	0	0	0	0	0	0	0	-	0	•	0	0	0	0	0	0	0	•	0	0
	Control	396	0	0	ø	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	•
	Control	611	0	0	0	0	0	0	0	0	0	2	ø	N	0	0	0	0	0	0	0	0	•	0	0
	Control	613	0	0	0	0	0	0	0	0	0	2	2												
	Control	616	0	0	٥	٥	0	0	0	٥	٥	0	5	N											
	Control	617	0	0	٥	0	0	0	0	0	٥	0	0	m									-		
	Control	33	0	0	0	0	0	0	0	0	۰	0	0	N	•	0	0	0	0	0	0	0	0	0	0
	Control	828	0	0	0	0	0	0	0	0	0	N	3												
(a)		Observation were scored as 0= Suthanized for humane reasons	e sco	scored mane re	as 0= basons	Normal		1-M11	1d, 2	2=Moder	rate,	ň	Severe												

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	Wo. -1 0 1 2 3 4 5 6 7 8 9 10 11 15 16 15 16 17 16 15 16 17 16	Treatment	Horse								Š	Scores"	on de	ays po	st-ch	alleng	on days post-challenge with WNV	WNV								
	faconate 206 0	Group	No.	7	۰	-	8	8	4	ъ	9	~	8	6	9	÷	12	13	4	15	16	1	8	19	8	2
	Associate 214 0 <th< td=""><td>Vaccinate</td><td>206</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>2</td><td>•</td><td>0</td><td>0</td><td>•</td><td>•</td><td>0</td><td>¢</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></th<>	Vaccinate	206	0	0	0	0	0	0	0	0	0	0	2	•	0	0	•	•	0	¢	0	0	0	0	0
	Associate 301 0 <th< td=""><td>Vaccinate</td><td>214</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>•</td><td>o</td><td>0</td><td>0</td><td>0</td><td>0</td><td>•</td><td>۰</td></th<>	Vaccinate	214	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	•	o	0	0	0	0	•	۰
	Accontate 316 0 <th< td=""><td>Vaccinate</td><td>301</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>o</td><td>0</td><td>¢</td><td>o</td><td>0</td><td>0</td><td>0</td><td>0</td></th<>	Vaccinate	301	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	o	0	¢	o	0	0	0	0
	Ascolnation 316 0 Associnate 331 0	Vaccinate	316	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	¢	ø	0	0	0	0
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	Associnate 326 0 </td <td>Vaccinate</td> <td>324</td> <td>0</td> <td>5</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>•</td>	Vaccinate	324	0	0	0	0	0	0	0	0	0	0	0	0	0	5									•
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	faccinate 609 0 </td <td>Vaccinate</td> <td>335</td> <td>0</td>	Vaccinate	335	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Maccinate 614 0 <t></t>	Vaccinate	609	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	٥	0	•
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618 0	Vaccinate 618 0 <t></t>	Vaccinate	615	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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623 0	Vaccinate 623 0 <th< td=""><td>Vaccinate</td><td>622</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>•</td></th<>	Vaccinate	622	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	•
624 0 0 0 0 0 0 0 0 0 2 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	Vaccinate	623	0	۰	0	0	٥	۰	0	0	0	۰	0	0	٥	0	0	•	۰	0	0	0	0	0	•
	Observation were scored as D= Normal, 1=Mild, 2=Moderate, 3= Buthanized for humane reasons	Vaccinate	624	0	•	0	0	0	0	0	0	0	N	0	0	0	0	0	•	0	0	0	0	0	0	۰

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		20	0	0	0		0	0	0		0		0	0	0	0	0				0	
WNV.		19	0	0	0		0	0	0		0		0	0	0	0	0				0	
M H		18	0	0	0		0	0	0		0		0	0	0	0	0				0	
P wit		17	0	0	0		0	0	0		0		0	0	0	0	0				0	
eng		16	0	0	0		0	0	0		0		0	0	0	0	0				0	
days post-challenge with		15	0	0	0		0	0	0		0		0	0	0	0	0				0	
ost-c	_	14	0	0	0		0	0	0		0		0	0	0	0	0				0	
2 8/	post-challenge with WNV	13	•	0	0		0	0	0		0	m	0	0	0	0	0				0	
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	ays po	6	0	0	0	0	0	0	0	0	0	0	0	0	0	٥	0	-	0	0	0	0
with	on days	80	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N	0	0	0	0	0
horses	Scores [*]	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	ŵ	9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
control		6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0 f		4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		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
ical		-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Clinical scores		•	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
Table 2a.	Horse	No.	205	222	300	302	307	308	310	311	313	321	322	323	325	396	611	613	616	617	625	828
F	Treatment	Group	Control	Continol	Control	Control	Control	Control	Control	Control												

 ⁽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.

Horse									Š	ores"	on da	ys po	st-cha	Scores [®] on days post-challenge with WNV	with V	NNA								
Group	No.	Ţ	۰	-	2	s	4	5	9	7	8	6	10	=	12	3 14	-	5	16	17 1	18	19 20	21	
Vaccinate	206	0	0	0	0	0	0	0	0	0	0	~	CN	-	-	•	•	•		0	0	0	•	
Vaccinate	214	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	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	
Vaccinate	318	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	
Vaccinate	331	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	
Vaccinate	333	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0		0	0	0	0	
Vaccinate	334	0	0	0	0	0	0	0	0	0	0	0	0	0	•	-		,				•	•	
Vaccinate	335	0	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		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	
Vaccinate	615	٥	0	0	0	۰	0	0	o	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 0	0	
Vaccinate	620	0	٥	0	0	0	0	0	Ŷ	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	0	
Vaccinate	623	0	0	0	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	
ervat	(a) Observation were scored	8 SCC		as 0=	Normal	1.1	-Mild	d. 2	Mode	2=Moderate	8	Severe												1

3=Severe %=MOODELATE, T-MITCH-T (a) Observation were scored as 0= Normal,(.) Euthanized for humane reasons

a.	Table 3a. Clinical scores	800	Sel	of co	control		or sea	horses with		10SE	fasciculation	ion	ou	days	post	-ohe	11er	post-challenge with	ith	WNV.		
							Sc	Scores [®] on days post-challenge with WNV	on da	ys po	st-cha	llenge	with	WNV								
•		-	8	e	4	s	9	7	80	6	10	=	12	13	14	15	16	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
0		0	0	0	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	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	•	N	N	N	-	0	0	0	•	•	0	0	0	0
0	0	0	0	0	0	0	0	0	•	N	0	0	N	N								
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	o
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	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
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0	0	0	0	0	0	0	0	0	N	0												

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

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Treatment	Horse								5	2010		ad ad	10-10	Suamp	acores on uays post-crianenge with acore	ALLAN								
Group	No.	7	0	-	8	•	4	ю	ø	2	60	a	5	Ξ	12	13	14	15	16	17	5	19	8	3
Vaccinate	206	0	0	0	٥	0	0	0	0	0	0	N	0	0	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	0	0
Vaccinate	301	0	0	0	0	0	0	0	0	0	0	0	0	0	0	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	0	•
Vaccinate	316	0	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	0	e									
Vaccinate	326	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	331	0	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	0
Vaccinate	333	0	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	۰	0	0	0	e							
Vaccinate	335	0	0	0	0	0	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	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	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	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	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	0
Vaccinate	622	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	623	0	0	0	0	0	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

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	Table 4a.	4a.	CLLD	Clinical		scores	fo	control	4 10	orse	iw a	horses with ataxia on	taxi	a on	days	a pos	st-cl	alle	days post-challenge with WNV.	with	NW U			
Treatment	t Horse								s	cores	ond	Scores" on days post-challenge with WNV	ost-ch	alleng	e with	WNV								\square
Group		7	•	-	2	3	4	5	9	7	8	6	10	:	12	13	14	15	16	17	18	19	20	51
Control	205	0	0	۰	0	0	0	0	0	0	0	0	٥	0	0	0	0	0	0	0	•	0	•	•
Control	222	0	۰	۰	0	0	0	0	0	0	0	0	۰	0	0	0	0	0	0	•	•	0	0	•
Control	300	0	•	۰	0	0	0	0	0	0	0	0	۰	0	0	0	•	•	0	•	•	0	0	0
Control	302	0	•	۰	0	0	0	0	0	0	0	0	9											
Control	307	0	•	•	0	0	0	0	0	٥	0	0	۰	0	0	0	0	0	0	0	0	•	0	0
Control	308	0	•	•	۰	0	0	۰	0	٥	0	0	۰	0	0	0	0	0	0	0	0	•	0	0
Control	310	0	•	•	0	0	0	0	0	0	0	0	۰	0	0	0	0	0	0	0	•	•	0	0
Control	311	0	•	۰	0	0	0	0	0	0	0	0	۰	-	0									
Control	313	0	۰	•	0	0	0	0	٥	0	0	0	-	-	0	0	0	0	0	•	•	0	0	0
Control	321	0	0	۰	0	0	0	0	0	0	0	0	۰	0	-	3								
Control	322	0	•	۰	0	0	0	0	0	0	0	0	۰	0	0	0	0	0	0	0	0	0	0	0
Control	323	0	0	۰	0	0	0	0	0	0	0	0	۰	0	0	0	0	0	0	0	0	0	0	0
Control	325	0	•	۰	0	0	0	0	0	0	0	0	۰	0	0	0	0	0	0	0	0	0	0	0
Control	396	0	0	۰	0	0	0	0	0	0	0	0	۰	0	0	0	0	0	0	0	0	0	0	0
Control	611	0	0	۰	0	0	0	0	0	0	0	0	۰	0	0	0	0	0	0	0	0	0	0	0
Control	613	0	0	•	0	0	0	0	0	0	0	0												
Control	616	0	0	۰	0	0	0	0	0	0	0	0	۰											
Control	617	0	0	۰	0	0	0	0	0	0	0	0	3			,			-					
Control	625	0	0	0	0	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0	0	0	0	0
Control	626	0	0	0	0	0	0	0	0	0	0	3			,									
(a) Observa	Observation were scored	os a.	ored	as 0=	Normal,		1=Mild,		2=Moderate,	tate		3=Severe												

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				me/Case Defini days with mild, mode		re scores in any
	Vaccine	of the categorie	s or that requ	ired euthanasia		
No.	Group	Mentation	Paresis	Fasciculations	Ataxia	Euthanasia
206		+	+	+	+	
214		+				
301					ļ	
316		+		+		
318						
324		+	+	+	+	+
326						
331						
332	<					
333	Vaccinate	+		+		
334		+	+	+	+	+
335	æ					
609						
614						
615						
618						
620						
622						
623						
624		+	+		+	
205		+	Ŧ		- T	
222						
300		+		+		
302		+	+	<u>+</u>	+	+
302						
308		+				
308						
310						*
313		+	+		+	•
1.12.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.	Control	+	+	+	+	
321 322		+	+	+	+	+
323						
325		+				
396						
611		+	+	+		
613		+	+	+		+
616		+		+		+
617		+	+	+	+	+
625		+	+	+	+	
625 626		+ +	++	+ +	•	+

(+) Clinical signs

Treatment	Horse			(pfu/m				e wit f horse			-chailer	nge wit	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			
Cantrol	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

		with virulent W		
	Vaccine	Histopatho	ology of neural tis	sue
Horse No.	Group	Post-ch	allenge with WNV	Para
		Cervical Cord	Medulla	Pons
206		0	0	0
214		1	0	1
301		0	0	0
316	í l	0	1	0
318		0	0	0
324		1	1	1
326		2	2	2
331		0	0	0
332	Va	0	0	0
333	Vaccinate	1	0	1
334	nat	2	2	2
335	e	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	Con	1	1	2
322	Itrol	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 conditior	18				
Product Administration	Two doses administered intramu						
Study Animals	1,255 horses from 5 states. 570		1				
Study / Milling	younger at time of the initial vaco		e o monuis or age or				
Challenge Description	Not applicable	induition.					
Interval observed after	Horses were observed immediate	elv followi	ng vaccination and then				
challenge	daily for 21 days post-vaccinatio	•	ing vaccination and then				
Results	durfy for 21 duys post vacematic	/11					
Results	Adverse Events	Number]				
	Injection Site Swelling*	102	-				
	<1.5cm	24	-				
	1.5-5.0cm	57					
	>5.0cm	21	-				
	Injection site pain	17	-				
	Lethargy/Depression6Diarrhea3						
	Soft Feces 1						
	Anorexia 6						
	Not Drinking 1						
	Increased Respiratory Rate 1						
	Hoof Abscess	1					
	Hoof Abscess 1						
	Enlarged Lymph Node1Hives1						
	Unilateral Epistaxis	1					
	Colic Episode**	1]				
	Horses with no reaction	1,149					
	*Injection site swellings resolved 3-7 d						
	**Horse was euthanized; suspected due affirmed by licensee.	e to colon tor	sion unrelated to vaccine				
USDA Approval Date	February 18, 2010						