



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	48W5.R1
True Name	Encephalomyelitis-West Nile Virus Vaccine, Eastern & Western, Killed Virus, Killed Flavivirus Chimera, Tetanus Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Encevac-T + WNV with Havlogen - 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	<i>Clostridium tetani</i>		
Study Purpose	Demonstrate efficacy against <i>C. tetani</i>		
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 challenge	Six weeks after vaccination, guinea pigs were bled for serological testing.		
Results	<p>Efficacy of <i>C. tetani</i> was demonstrated in laboratory animals according to 9CFR 113.114(c).</p> <p>Satisfactory result is an antitoxin titer of at least 2.0 A.U. per mL for the serum pool.</p> <table border="1" data-bbox="580 920 989 1037"> <tr> <td>Pooled Guinea Pig Antitoxin titer (A.U./mL)</td> </tr> <tr> <td>2.082</td> </tr> </table>	Pooled Guinea Pig Antitoxin titer (A.U./mL)	2.082
Pooled Guinea Pig Antitoxin titer (A.U./mL)			
2.082			
USDA Approval Date	June 15, 2010		

Study Type	Efficacy								
Pertaining to	Eastern Equine Encephalomyelitis (EEE)								
Study Purpose	Demonstrate efficacy against EEE								
Product Administration	Two doses administered intramuscularly 3 weeks apart.								
Study Animals	Twelve guinea pigs, 10 vaccinates and 2 controls, each 300-500g								
Challenge Description	Not applicable								
Interval observed after challenge	14 days post 2nd vaccination, guinea pigs were bled for serological testing.								
Results	<p>Efficacy of EEE was demonstrated in laboratory animals according to 9CFR 113.207(b).</p> <p>Satisfactory test result is a Virus Neutralization Titer of $\geq 1:40$ in at least 9 out of 10 vaccinates (2nd stage - at least 17 out of 20 vaccinates).</p> <table border="1" data-bbox="577 920 1252 1072"> <thead> <tr> <th>Treatment group</th> <th>Results</th> <th>Test Disposition</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>17/20 $\geq 1:40$</td> <td rowspan="2">Satisfactory</td> </tr> <tr> <td>Controls</td> <td>2/2 $<1:4$</td> </tr> </tbody> </table>	Treatment group	Results	Test Disposition	Vaccinates	17/20 $\geq 1:40$	Satisfactory	Controls	2/2 $<1:4$
Treatment group	Results	Test Disposition							
Vaccinates	17/20 $\geq 1:40$	Satisfactory							
Controls	2/2 $<1:4$								
USDA Approval Date	June 15, 2010								

Study Type	Efficacy								
Pertaining to	Western Equine Encephalomyelitis (WEE)								
Study Purpose	Demonstrate efficacy against WEE								
Product Administration	Two doses administered intramuscularly 3 weeks apart.								
Study Animals	Twelve guinea pigs, 10 vaccinates and 2 controls, each 300-500g								
Challenge Description	Not applicable								
Interval observed after challenge	14 days post 2nd vaccination, guinea pigs were bled for serological testing.								
Results	<p>Efficacy of WEE was demonstrated in laboratory animals according to 9CFR 113.207(b).</p> <p>Satisfactory test result is a Virus Neutralization Titer of $\geq 1:40$ in at least 9 of the vaccinates.</p> <table border="1" data-bbox="587 884 1259 1037"> <thead> <tr> <th>Treatment group</th> <th>Results</th> <th>Test Disposition</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>9/10 $\geq 1:40$</td> <td rowspan="2">Satisfactory</td> </tr> <tr> <td>Controls</td> <td>2/2 $<1:4$</td> </tr> </tbody> </table>	Treatment group	Results	Test Disposition	Vaccinates	9/10 $\geq 1:40$	Satisfactory	Controls	2/2 $<1:4$
Treatment group	Results	Test Disposition							
Vaccinates	9/10 $\geq 1:40$	Satisfactory							
Controls	2/2 $<1:4$								
USDA Approval Date	June 15, 2010								

Study Type	Efficacy																											
Pertaining to	West Nile Virus																											
Study Purpose	To demonstrate efficacy against West Nile Virus																											
Product Administration	Two doses administered intramuscularly 3 weeks apart																											
Study Animals	20 vaccinates and 20 controls horses were used at 6 months of age																											
Challenge Description	20 horses (10 vaccinates and 10 control) were challenged with West Nile Virus 61 days post-2 nd vaccination. The remaining 20 horses were challenged 91 days post-2 nd vaccination.																											
Interval observed after challenge	Horses were observed for 21 days post challenge for clinical signs. Blood samples were taken at days 0-14 and 21 post challenge for virus isolation. Histopathology was performed on samples taken at the end of the study.																											
Results	<p>Disease prevalence was defined as the demonstration of clinical signs of neurological disease observed in horses naturally affected with WNV under field conditions (i.e. mentation, paresis, muscle fasciculation, ataxia).</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th>Presence of clinical signs</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>20</td> <td>7</td> </tr> <tr> <td>Controls</td> <td>20</td> <td>13</td> </tr> </tbody> </table> <p>Viremia was defined as the presence of a virus titer ≥ 5 PFU/mL of serum on any testing occasion.</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th>Viremia</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>20</td> <td>14</td> </tr> <tr> <td>Controls</td> <td>20</td> <td>20</td> </tr> </tbody> </table> <p>Encephalitis was defined as the pons, medulla or cervical cord showing histopathological lesions of at least a "mild" classification; minimal changes in these tissues were classified as unaffected.</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th>Encephalitis</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>20</td> <td>9</td> </tr> <tr> <td>Controls</td> <td>20</td> <td>19</td> </tr> </tbody> </table> <p>Raw data shown on attached pages.</p>	Group	# of Animals	Presence of clinical signs	Vaccinates	20	7	Controls	20	13	Group	# of Animals	Viremia	Vaccinates	20	14	Controls	20	20	Group	# of Animals	Encephalitis	Vaccinates	20	9	Controls	20	19
Group	# of Animals	Presence of clinical signs																										
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Group	# of Animals	Viremia																										
Vaccinates	20	14																										
Controls	20	20																										
Group	# of Animals	Encephalitis																										
Vaccinates	20	9																										
Controls	20	19																										
USDA Approval Date	March 27, 2009																											

Overview of Challenge Groups

Group	Horse No.	Challenge Group	Challenge Day Post 2nd-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

Table 1. Clinical scores of vaccinate horses with mentation on days post challenge with WNV.

Treatment Group	Horse No.	Scores* on days post-challenge with WNV																						
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Vaccinate	206	0	0	0	0	0	0	0	0	0	2	0	1	0	0	0	0	0	0	0	0	0	0	0
Vaccinate	214	0	0	0	0	0	0	0	0	0	0	2	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	1	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	0
Vaccinate	324	0	0	0	0	0	0	0	0	0	1	0	0	2
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	2	2	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	0	0	0	2
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	2	0	0	0	0	0	0	0	0	0	0	0	0	0

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

Table 1a. Clinical scores of control horses with mentation on days post challenge with WNV.

Treatment Group	Horse No.	Scores ^a on days post-challenge with WNV																						
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Control	205	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	222	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	300	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	302	0	0	0	0	0	0	0	0	0	3
Control	307	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	308	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	310	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	311	0	0	0	0	0	0	0	0	0	2	2	0
Control	313	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	321	0	0	0	0	0	0	0	1	2	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	0
Control	323	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	325	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	396	0	0	0	0	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	2	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	613	0	0	0	0	0	0	0	2	2
Control	616	0	0	0	0	0	0	0	0	0	2	2
Control	617	0	0	0	0	0	0	0	0	0	0	3
Control	625	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	626	0	0	0	0	0	0	0	2	3

(a) Observations were scored as 0= Normal, 1=Mild, 2=Moderate, 3=Severe

(.) Euthanized for humane reasons

Table 2. Clinical scores of vaccinate horses with paresis on days post-challenge with WNV.

Treatment Group	Horse No.	Scores ^a on days post-challenge with WNV																						
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Vaccinate	206	0	0	0	0	0	0	0	0	0	2	0	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	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	0
Vaccinate	324	0	0	0	0	0	0	0	0	0	0	0	2	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	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	0
Vaccinate	334	0	0	0	0	0	0	0	0	0	0	0	0	1	3	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	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	2	0	0	0	0	0	0	0	0	0	0	0	0	0

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

Table 2a. Clinical scores of control horses with paresis on days post-challenge with WNV.

Treatment Group	Horse No.	Scores ^a on days post-challenge with WNV																						
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Control	205	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	222	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	302	0	0	0	0	0	0	0	0	3
Control	307	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	308	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	310	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	311	0	0	0	0	0	0	0	0	0	2	0
Control	313	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	321	0	0	0	0	0	0	0	0	0	0	1	3
Control	322	0	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	0	0	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	0	0	0
Control	396	0	0	0	0	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	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	613	0	0	0	0	0	0	0	0	1
Control	616	0	0	0	0	0	0	0	0	0
Control	617	0	0	0	0	0	0	0	0	0	2
Control	625	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	626	0	0	0	0	0	0	0	0	0	3

(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.

Treatment Group	Horse No.	Scores ^a on days post-challenge with WNV																						
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Vaccinate	206	0	0	0	0	0	0	0	0	0	2	2	1	1	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	2	1	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	0
Vaccinate	324	0	0	0	0	0	0	0	1	0	0	0	0	2
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	2	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	0	0	0	1
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	0	0	0	0	0	0	0	0

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

Table 3a. Clinical scores of control horses with fasciulation on days post-challenge with WNV.

Treatment Group	Horse No.	Scores ^a on days post-challenge with WNV																						
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Control	205	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	222	0	0	0	0	0	0	0	0	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	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	302	0	0	0	0	0	0	0	0	0	1	2
Control	307	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	308	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	310	0	0	0	0	0	0	0	0	0	0	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	3	0
Control	313	0	0	0	0	0	0	0	0	0	2	2	2	1	0	0	0	0	0	0	0	0	0	0
Control	321	0	0	0	0	0	0	0	0	0	2	0	0	2	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	0
Control	323	0	0	0	0	0	0	0	0	0	0	0	0	0	0	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	0	0	0
Control	396	0	0	0	0	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	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	613	0	0	0	0	0	0	0	0	0	0	2
Control	616	0	0	0	0	0	0	0	0	0	0	0	3
Control	617	0	0	0	0	0	0	0	0	0	0	0	3
Control	625	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Control	626	0	0	0	0	0	0	0	0	0	2	0

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

Table 4. Clinical scores of vaccinate horses with ataxia on days post-challenge with WNV.

Treatment Group	Horse No.	Scores ^a on days post-challenge with WNV																						
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Vaccinate	206	0	0	0	0	0	0	0	0	0	2	0	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	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	0
Vaccinate	324	0	0	0	0	0	0	0	0	0	0	0	0	3
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	0
Vaccinate	334	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
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	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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

Table 4a. Clinical scores of control horses with ataxia on days post-challenge with WNV.

Treatment Group	Horse No.	Scores ^a on days post-challenge with WNV																						
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Control	205	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	222	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	302	0	0	0	0	0	0	0	0	0	3
Control	307	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	308	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	310	0	0	0	0	0	0	0	0	0	0	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	1	0
Control	313	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Control	321	0	0	0	0	0	0	0	0	0	0	0	0	1	3
Control	322	0	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	0	0	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	0	0	0
Control	396	0	0	0	0	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	0	0	0	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	0	0	0	0	0	0	0	0
Control	617	0	0	0	0	0	0	0	0	0	0	3
Control	625	0	0	0	0	0	0	0	0	0	0	2	0	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) Observation were scored as 0= Normal, 1=Mild, 2=Moderate, 3=Severe

(.) Euthanized for humane reasons

Table 5.

**Summary of Clinical Observations
for Primary Outcome/Case Definition**

Horses that had one or more days with mild, moderate or severe scores in any of the categories or that required euthanasia

Horse No.	Vaccine Group	Mentation	Paresis	Fasciculations	Ataxia	Euthanasia
206	Vaccinate	+	+	+	+	
214		+				
301						
316		+		+		
318						
324		+	+	+	+	+
326						
331						
332						
333		+		+		
334		+	+	+	+	+
335						
609						
614						
615						
618						
620						
622						
623						
624		+	+			+
205	Control					
222						
300		+		+		
302		+	+	+	+	+
307		+				
308						
310						
311		+	+	+	+	+
313		+	+	+	+	
321		+	+	+	+	+
322						
323						
325		+				
396						
611		+	+	+		
613		+	+	+		+
616		+		+		+
617		+	+	+	+	+
625		+	+	+	+	
626		+	+	+	+	+

(+) Clinical signs

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

Treatment Group	Horse No.	WNV (pfu/mL) detected in serum of horses on days post-challenge with WNV												
		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	.	.	.
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	.	.	.
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	.	.	.
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
Control	616	< 5	< 5	35	40	40	< 5	< 5	< 5	< 5	< 5	.	.	.
Control	617	< 5	5	45	40	40	10	< 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

(.)Euthanized for humane reasons

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

Horse No.	Vaccine Group	Histopathology of neural tissue Post-challenge with WNV*		
		Cervical Cord	Medulla	Pons
206	Vaccinate	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		1	0	1
334		2	2	2
335		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	Control	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		1	1	2
322		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

*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 field conditions																																						
Product Administration	Two doses administered intramuscularly 3 to 4 weeks apart																																						
Study Animals	1,255 horses from 5 states. 570 horses were 6 months of age or younger at time of the initial vaccination.																																						
Challenge Description	Not applicable																																						
Interval observed after challenge	Horses were observed immediately following vaccination and then daily for 21 days post-vaccination																																						
Results	<table border="1"> <thead> <tr> <th>Adverse Events</th> <th>Number</th> </tr> </thead> <tbody> <tr> <td>Injection Site Swelling*</td> <td>102</td> </tr> <tr> <td> <1.5cm</td> <td>24</td> </tr> <tr> <td> 1.5-5.0cm</td> <td>57</td> </tr> <tr> <td> >5.0cm</td> <td>21</td> </tr> <tr> <td>Injection site pain</td> <td>17</td> </tr> <tr> <td>Lethargy/Depression</td> <td>6</td> </tr> <tr> <td>Diarrhea</td> <td>3</td> </tr> <tr> <td>Soft Feces</td> <td>1</td> </tr> <tr> <td>Anorexia</td> <td>6</td> </tr> <tr> <td>Not Drinking</td> <td>1</td> </tr> <tr> <td>Increased Respiratory Rate</td> <td>1</td> </tr> <tr> <td>Nasal Discharge</td> <td>1</td> </tr> <tr> <td>Hoof Abscess</td> <td>1</td> </tr> <tr> <td>Enlarged Lymph Node</td> <td>1</td> </tr> <tr> <td>Hives</td> <td>1</td> </tr> <tr> <td>Unilateral Epistaxis</td> <td>1</td> </tr> <tr> <td>Colic Episode**</td> <td>1</td> </tr> <tr> <td>Horses with no reaction</td> <td>1,149</td> </tr> </tbody> </table> <p>*Injection site swellings resolved 3-7 days post-vaccination. **Horse was euthanized; suspected due to colon torsion unrelated to vaccine affirmed by licensee.</p>	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	Nasal Discharge	1	Hoof Abscess	1	Enlarged Lymph Node	1	Hives	1	Unilateral Epistaxis	1	Colic Episode**	1	Horses with no reaction	1,149
Adverse Events	Number																																						
Injection Site Swelling*	102																																						
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