

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	4845.33
True Name	Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Prestige 5 - 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.

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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

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Study Type	Efficacy			
Pertaining to	Eastern Equine E	Encephalomyelitis (l	EEE)	
Study Purpose	Demonstrate effi	cacy against EEE		
Product Administration	Two doses admir	nistered intramuscul	larly 3 weeks ap	art.
Study Animals	Twelve guinea p	igs, 10 vaccinates a	nd 2 controls, ea	ach 300-500g
Challenge Description	Not applicable	_		-
Interval observed after	14 days post 2nd	vaccination, guinea	a pigs were bled	for
challenge	serological testin	g.		
Results	according to 9CF Satisfactory test	was demonstrated if R 113.207(b). result is a Virus New 0 vaccinates (2 nd st	utralization Tite	r of ≥ 1:40 in
	Treatment		Test	
	group	Results	Disposition	
	Vaccinates	$17/20 \ge 1:40$	Satisfactory	
	Controls	2/2 <1:4	Satisfactory	
USDA Approval Date	June 15, 2010			_

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Study Type	Efficacy												
Pertaining to	Western Equine 1	Encephalomyelitis	(WEE)										
Study Purpose	Demonstrate effic	cacy against WEE											
Product Administration	Two doses admir	nistered intramuscu	ılarly 3 weeks ap	art.									
Study Animals	Twelve guinea pi	gs, 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	according to 9CF	result is a Virus Ne	, and the second										
	Treatment Test												
	group	Results	Disposition										
	Vaccinates Controls	$9/10 \ge 1:40$ $2/2 < 1:4$	Satisfactory										
		_,,1.1		1									
USDA Approval Date	June 15, 2010												

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	T											
Study Type	Efficacy											
Pertaining to	Equine Herpesvirus-S	, i										
Study Purpose	Efficacy against respir											
Product	Two doses, administer	red intramu	scularly, 21	days apar	t.							
Administration												
Study Animals	16 vaccinates and 16 p			rols, sero	negativ	e to EHV-1.						
	Horses were 11 month											
Challenge	Horses were challenge	ed with EH	V-1, 23 days	post seco	ond vac	cination.						
Description												
Interval	Observed for 14 days	post challe	nge for clinic	al signs o	of respi	ratory disease.						
observed after												
challenge												
Results	Animals displaying cl	_		ered to b	e affect	ed by the						
	challenge. Result sum	ımaries bel	ow.									
	Body Temperatures ≥	102.5°F w	ere considere	ed to be e	levated.	•						
			1		Π							
	Treatment Gro	up	Vaccina	ates	(Controls						
	Hyperthermia Aff	ected	15/16 or	94%	16/	16 or 100%						
	Observations of nasal di	scharged we	ere scored as:									
	0 - Normal											
	1 - Very Mild 2 - Moderate											
	3 - Severe											
	Treatment Group			Vaccin	natos	Controls						
	Treatment Group	Mildly	Affected	5/16 or		1/16 or 6%						
			ely Affected	7/16 or		2/16 or 13%						
	Nasal Discharge					13/16 or 80%						
	Nasal Discharge Severely Affected 4/16 or 25% 13/16 or 80%											
	Observations of cough	ing were c	cored as:									
	0 - No coughing or co											
	2 - Coughed twice	agned one	,									
	3 - Coughed three time	es or more										
	Animals were scored a		for coughing									
	Treatment Group	15 4 2 01 5	Vaccinates		Contro	ols						
	Coughing Affected		0/16 or 0%		4/16 or							
	Coughing Affected		0/10 01 0/0		-7/10 OI	23/0						
	Treatment Gro	up	Vaccina	ates	(Controls						
	Abnormal Respiration	Affected	3/16 or	19%	12	/16 or 75%						

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Animals were considered postive for Virus Isolation (VI) with recovery of at least one positive nasal swab. **Treatment Group** Vaccinates Controls 12/16 or 75% Virus Isolation Recovery 6/16 or 37% **Treatment Group** Vaccinates Controls 0 Days 10/16 or 63% 4/16 or 25% 1 Day 5/16 or 31% 6/16 or 38% Virus Isolation, Duration \geq 2 Days 1/16 or 6% 6/16 or 38% Raw data shown on attached pages.

USDA Approval

September 26, 2006 **Date**

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Rectal body temperatures of horses on days -1 to 14 post-challenge with virulent EHV-1 Table 2.

1	3	-	7	m	3	so.	9 1 8	7	00	6	10	11	12	13	14
102.3	101.3	102.3	102.4	102.1	102.5	103.0	104.0	102.5	101.0	100.2	100.2	100.2	100.6	100.8	101.1
101.6	101.9	100.6	103.1	103.2	103.2	102.1	102.4	105.1	103.3	100.0	99.4	0.66	100.2	100.2	8.66
Н	101.3	100.0	102.8	103.8	101.9	101.4	102.1	101.4	101.2	100.0	99.5	98.9	100.5	6.66	99.7
101.5	101.2	99.2	102.4	102.2	102.2	102.7	102.3	100.8	100.7	6.66	99.3	99.9	100.2	6.86	8.66
100.7	101.2	102.0	103.5	103.7	103.6	102.0	102.4	102.3	101.6	100.1	6.66	99.5	100.8	100.1	99.3
100.8	101.6	100.2	102.4	101.4	101.9	102.5	101.1	6.66	100.1	100.0	99.1	99.0	100.2	100.1	100.1
01.3	101.1	100.8	102.9	101.6	102.0	102.1	102.1	101.1	100.9	100.5	6.66	98.9	100.2	100.0	100.0
102.0	102.4	100.0	103.1	102.4	101.9	102.9	102.4	101.9	101.0	100.7	99.3	98.1	101.1	100.1	99.4
101.8	102.1	100.8	101.9	101.0	100.3	100.9	102.6	101.5	100.7	100.5	100.2	6.66	100.1	100.8	100.2
01.0	103.6	102.4	105.5	103.6	102.1	102.8	102.1	103.1	100.2	100.5	99.2	100.9	101	100.2	99.5
102.5	101.8	101.5	102.4	102.0	104.0	101.0	104.3	103.5	105.4	100.3	100.0	99.5	100.7	100.0	99.7
100.9	102.7	100.2	103.1	101.6	101.9	102.9	105.0	105.8	100.2	100.5	6.66	39.5	100.8	100.0	100.0
02.5	103.0	102.5	102.4	101.9	102.6	103.4	102.3	101.4	101.3	101.2	100.4	101.0	101.7	100.2	100.8
01.5	101.2	101.7	101.9	102.1	102.2	102.9	101.4	102.4	100.3	100.2	99.1	266	101.6	100.3	100.0
02.0	103.2	101.8	104.0	102.2	102.4	103.1	104.0	102.9	101.0	100.0	1001	100.0	100.5	1001	100.3
103.0	102.1	100.6	104.0	103.3	104.3	101.7	104.0	102.7	102.5	101.1	99.7	98.6	99.7	99.5	8.66
01.4	101.0	102.3	105.1	103.5	102.5	101.4	100.6	1001	100.0	100.9	100.2	26.5	666	100.8	100.1
01.4	101.0	101.1	106.8	104.1	103.4	100.2	101.7	100.3	100.7	100.0	100.0	99.2	101.2	1001	101.1
01.5	101.0	101.0	106.9	102.6	Died	Died	Died	Died	Died	Died	Died	Died	Died	Died	Died
01.2	102.3	101.3	105.3	102.4	104.9	102.9	102.6	101.4	100.7	6.66	8.66	100.2	100.2	99.0	100.0
01.0	101.7	99.3	106.3	103.7	104.1	102.7	102.8	103.0	101.5	100.3	100.2	99.3	100.2	100.9	100.1
02.1	101.1	100.1	106.1	103.5	102.7	100.2	2.66	1001	103.0	100.5	6.66	99.4	100.3	100.0	99.9
103.1	102.8	101.8	105.1	102.6	104.3	103.5	100.9	104.0	101.4	100.2	99.9	99.2	100.6	100.0	100.0
101.2	101.5	100.6	104.2	102.1	104.9	102.9	103.5	103.9	100.2	6.66	8.66	99.2	99.7	99.4	666
102.5	103.5	100.2	105.0	104.5	103.4	103.3	102.7	103.8	103.8	100.8	101.1	98.5	100.1	8.66	8.66
100.4	102.7	101.6	106.2	103.1	102.4	100.2	101.6	1001	101.3	99.5	100.0	98.4	100.4	0.66	98.8
02.0	103.2	103.4	104.5	103.3	103.6	103.9	102.6	102.5	101.5	101.1	100.9	100.2	100.2	100.2	100.0
01.9	101.1	101.8	106.2	103.5	103.9	102.7	103.6	102.0	101.6	99.7	99.4	8.86	100.2	99.4	99.3
101.9	101.8	100.9	106.1	104.8	103.7	103.8	103.2	102.8	102.7	101.3	100.1	99.7	100.1	2.66	100.0
102.8	102.9	100.7	105.2	103.7	104.1	102.3	103.8	102.3	101.0	101.7	100.7	101.8	100.4	100.1	100.0
101.1	101.8	100.8	107.0	104.2	104.5	104.1	104.5	102.2	102.7	100.4	99.0	98.7	99.7	99.2	99.5
102.4	102.5	101.8	101.5	104.2	104.9	104.6	102.9	105.4	103.4	100.8	8.66	9.66	101.9	101.2	101.0
	101.3 102.0 102.0 102.5 100.9 102.5 101.2 101.2 101.2 101.9 101.9 101.9 101.9	- - - 	101.1 102.4 102.1 103.6 101.8 101.2 102.7 101.0 101.0 101.1 102.3 101.1 102.3 101.5 103.5 103.5 103.5 101.6 101.6 101.6 102.7 101.6 102.7 103.7 101.6 101.6 101.6 102.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 103.7 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102.3 101.4 100.2 100.2 102.4 100.2 102.0 101.4 102.0 100.2 100.2 102.4 102.2 102.0 101.4 102.0 100.2 100.2 102.4 102.2 102.0 101.4 102.0 100.2 100.2 102.4 102.2 102.4 102.0 101.4 100.2 102.4 <	101.1 100.8 102.9 101.6 102.0 102.1 100.1 100.9 102.4 100.0 103.1 102.4 101.9 102.4 101.9 100.0 102.1 100.0 101.0 100.2 102.9 102.6 101.0 100.0 102.1 100.2 102.4 102.1 102.1 100.2 100.2 100.2 103.0 102.2 102.4 102.0 102.3 101.4 101.3 103.0 102.5 102.4 102.1 102.2 102.9 101.4 101.3 103.0 101.2 102.1 102.2 102.4 102.3 101.4 101.3 103.1 101.2 102.2 102.4 102.3 101.4 101.3 103.2 101.8 104.0 102.2 102.4 102.3 101.0 103.1 102.1 102.2 102.4 102.1 102.4 100.3 101.0 102.1 102.2 102.4	101.1 100.8 102.9 101.6 102.0 102.1 100.1 100.9 100.2 101.1 100.9 100.5 102.4 100.0 100.2 100.2 101.6 101.0 100.7 100.5 102.1 100.2 100.2 100.2 100.2 100.5 100.5 100.5 103.6 102.4 102.0 102.1 102.1 100.7 100.2 100.5 103.7 100.2 102.4 102.0 101.0 102.1 100.2 100.2 103.0 102.5 102.4 102.0 101.0 102.0 100.2 100.2 103.7 100.2 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Body Temperatures $\geq 102.5^{\circ}F$ were considered to be elevated.

Table 3.	Nasal	discharge	ge scores	- 1	in horses	an I	7	, , ,		alleng	e with	virulent	ent EHV-1	1-1			
Horse	Group					뒮	Discharge	sezoze e	on day	a post	-cnalleng	5	EHV-1:				
No	diore	-1	0	1	2	3	4	2	9	7	00	ď	10	11	12	13	14
280		0	0	0	0	2	7	-1	0	0	0	63	0		0	0	0
282		0	0	0	0	1	1	1	1	2	7	1	2	2	0	0	0
284		0	٥	0	0	0	1	0	7	T	0	1	0	2	0	0	0
287		٥	٥	٥	0	7	0	1	1	1	0	0	0	0	0	7	0
291		0	0	0	0	1	-1	п	1	2	0	1	3	1	۰	0	0
294		٥	0	٥	0	1	0	0	0	0	0	0	0	0	0	0	0
295		0	0	0	1	-	7	0	0	0	0	0	0	0	0	0	0
296		0	0	۰	٥	-1	0	0	0	0	1	2	0	0	0	0	0
297	Vaccinates	0	٥	٥		0	0	0	1	0	0	0	0	0	0	0	0
298		0	۰	0	۲		-	0	0	0	1	0	0	0	0	0	0
299		0	0	۰	-1	-	1	1	1	1	1	0	2	2	0	0	0
305		0	0	0	0	7	2	7	1	1	1	0	o	0	0	0	0
307		0	۰	0		-1	-	Cq.		64	3	2	2	1	1	0	0
308		0	٥	0	0	1	-	m	11	٥	7	0	1	-	0	0	0
313		0	0	٥	0	-	1	-	ı	2	2	2	2	1	1	0	0
315		٥	0	0	0	-		1	-	23	2	2	3	23	2	Q	0
285		۰	0	٥	0	62	2	1	3	1	1	0		0	0	٥	0
286		0	0	٥	-	7	3	57	3	2	0	0	0	0	0	0	0
288		٥	0	0	1	٦	Died	Diec	Died	Died	Died	Died	Died	Died	Died	Died	Died
290		0	0		0	C4	C4	2	2	1	1	0	0	0	0	0	0
293		0	٥	0	1	e	m	m	3	3	3	2	2	2	2	0	0
300		0	٥	0	-	-	ч	2	33	1	0	0	0	0	0	0	0
302		0	٥	0	0	24	m	2	3	3	3	1	2	2	0	0	0
303	Placebo	0	0	0		2	ч	3	2	2	2	1	2	2	1	0	0
304	Controls	1	0	-4	٦	23	m	3	2	2	2	2	e	2	1	0	0
306		0	0	0	0	н	24	2	1	2	1	2	0	0	0	0	0
309		o	0	0	C4	m	m	6	3	3	2	2	1	2	0	0	0
310		٥		0	7	m	2	3	3	3	3	3	3	2	2	2	0
311		0	0	0	1	е	2	3	2	3	3	2	2	1	2	2	1
312		0	٥	0	1	3	1	2	2	3	2	0	0	0	0	0	0
314		0	٥	0	1	3	2	ca	2	3	3	3	7	2	1	0	0
316		0	0	0	0	ť	0	2	2	e	m	3	2	2	0	0	0
0.00	mel leabnormal	ormal garons.		2=slight mucopur	copurulent,	t. 3=cor	ojus muco	opurulent	1								

(0-normal, 1-abnormal serous, 2-slight mucopurulent, 3-copi

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Animals were scored as a 2 or 3 for coughing

an Lore						Š	condurad sc	Scores on	the Comp	post-custrende		WIER BHV-I	-7.				
No	Group	7-	0	7	2	3	4	2	9	7	00	σ.	10	11	12	13	14
280		0	0	0	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	0	٥
284		0	0	0	0	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	0	0	0	0	0
294		0	0	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	0	0	0
Т		0	0	0	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	0	0	0
298		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
299		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
305		٥	٥	0	o	0	0	٥	0	0	0	0	0	0	0	0	0
307		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
308		0	0	0	°	0	0	0	0	0	0	0	0	0	0	0	0
313		0	0	٥	0	0	0	0	0	0	0	0	0	0	0	0	0
315		٥	0	0	0	٥	0	0	0	0	0	0	٥	0	0	0	0
285		0	0	0	0		0	۰	0	0	0	0	0	0	0	0	0
286		0	0	٥	0	0		•	0	0	0	0	0	0	0	0	0
288		0	0	٥	o	0	Died	Died	Died	Died	Died	Died	Died	Died	Died	Died	Dred
290		°	0	0	0	0	0	0	0	٥	0	0	0	0	0	0	0
293		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
300		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
302			0	0	٥	0	0	0	0	0	0	0	0	0	0	0	0
303	Placebo	0	0	0	0	٥	0	0	2	0	0	0	0	0	0	0	0
304	Controls	0	0	٥	0	0	0	2	3	33	3	3	3	2	2	2	5
306		0	0	0	٣	0	0	0	0	0	0	Q	0	0	0	0	0
308		٥	٥	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		0	0	o
311		٥	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Q
310		0	0	0	0	0	٥	0	0	0		0	٥		0	0	0
314		0	0	٥	0	0	0	0	0	0	0	0	0	0	0	0	0
		<	0	0	o	0	0	0	2	0		0	0	0	0	0	0

	14	0	0	0	0	0	0	0	0	6	0	0	0	0	0	0	0	0	0	Died	0	0	0	0	0	0	0	0	0	0	0	0	0
	13	0	0	0	0	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	Died	0	0	0	0	0	0	0	0	0	0	0	0	0
	12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Died	0	0	0	0	٥	0	0	0	0	0	0	0	0
	11	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Died	0	0	0	0	0	0	0	0	٥	٥	0	0	٥
EHV-1:	10	0	0	0	0	٥	٥	0	0	0	0	0	0	0	0	0	0	0	0	Died	0	0	0	0	0	0	0	0	0	0	0	0	0
with	ø	0	0	0	0	0	0	0	0	0	0	0	0		0	0	•	0		Died	0	0	0	0	0	0	0	0	0	0	0	0	0
post-challenge		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Died	0	0	0	0	0	0	0	0	0	٥	0	0	0
ys post-	-	0	0	0	0	0	o	0	0	0	0	0	0	0	0	0	0	0	0	Died	0	0	0	0	0	0	0	0	0	0	0	0	0
s° on days	9	0	٥	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Died	٥	0	0	0	0	0	o	0	0	0	0	0	0
se Scores	r.	0	0	0	0	0	0	0	0	0	0	0	0	0	٥	0	0	0		Diet	0	0	٥	0	0	0	0	0	0	0	0	0	0
tion Rate	•	0	0	0	0	0	0	0	0	0	0	0		٥	0	0	0	0	0	Died	0	7	0	0	0	0	0	0	0	0	0	0	0
Respiration	m	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	1	г	1	0	1	0
	2	0	0	0	0	0	0	п	0	0	0	0	0	0	0	п	0	0	н	rt	0	1	0	1	1	7	rt	0	п	ч	п	1	0
	-			0	0	0	0	0	0	0	0	0	0	٥	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	٥	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	٥		0	0	0	0	0	0	0	0	0	0	0	0	0
	dnozg									Vaccinates															Placebo	Controls							
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

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swabs on days post-challenge with RHV-1	9	-			٠	-	,	,	,	,		,	,	,	,			,		Died					-	,	-				-		,
m nasal	2	•			,	,	,	,	,	,	,	,	,	,	-	,	,	-	,	Died		,			-		-		,	-	h	,	-
isolation from nasal	4			,	,	,	-		,	,		ı	,	,	,	,		,	,	Died	1	-		-	-	+	-	,		-	+	,	
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Virus	2	,			+	+	-	,	,	,		١.		-	,	,		,	+	+			,	h		+	+		+	,			,
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-	dnozo									Vaccinates															Placebo	Controls							
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	216

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Study Type	Efficacy														
Pertaining to	Equine Herpes	virus-Subty	pe 4 (EHV-4)												
Study Purpose	Efficacy agains	st respirator	ry disease cause	d by EHV-4											
Product	Two doses, adr	ninistered i	intramuscularly,	, 3 weeks apart											
Administration															
Study Animals	21 vaccinates a	nd 11 cont	rols, seronegativ	ve to EHV-4. Horses were 6											
	months of age,	mixed sex.	•												
Challenge	Horses were ch	allenged w	rith EHV-4, 21 o	days post second vaccination.											
Description															
Interval	Observed for 1	4 days post	challenge for c	linical signs of respiratory disease.											
observed after															
challenge															
Results				nsidered to be affected by the											
	_		-	ounts of nasal discharge for two or											
	more consecuti	ve days, an	nd exhibit cough	ning for two or more consecutive											
	days.														
	[~			1											
	Group	# of	Presence of												
		Animals	clinical signs												
	Vaccinates	21	2												
	Controls 11 8														
	Controls 11 8														
	.		•												
TIOD 1 1	Raw data show	n on attach	ed pages.												
USDA Approval	April 7, 2004														
Date															

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Nasal Discharge

Horse	_			Nasa	l dis	charge	obse	rvatio	ns on	days	post	challe	nge w	ith EH	V-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	N	SM	N	CM	N	N	N	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	N	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 /scc	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					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		N	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		N	N	N	N	N	N	N	N	N	N	-C	N	N	N	N	N
14		N	N	N	. N	C ₁	C	C	N	N	C	N	N	N	N	C	N
15		N	N	N	N	- IC	C	C	- C	C	C	C	N	C	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	N	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		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		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
83		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		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
40		N	N	N	N	N	C	C	N	N	N	N	N	N	N	N	N
43		N	N	N	N	N	N	C	C. t	N	N	N	N	N	N	N	N
59	Controls	N	N	N	N	N	C	N	/G.C	N	N	N	N	N	N	N	N
63		N	N	N	N	N	Ç	N	N	N	- N	N	N	N	N	N	N
65		N	N	N	N	N	N	C	. C	N	N	N	N	N	N	N	N
71		N	N	N	N	N	C	C	-c	N	N	И	N	N	N	N	N
79		N	N	N	N	N	C	N	°C:	C	N	N	N	N	N	N	N
91		N	N	N	N	N	C	C	N	N	N	N	N	- N	N	N	N

N=no coughing , C=coughing

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Study Type	Efficacy						
Pertaining to	Equine Herpe	svirus-Subtype	e 4 (EI	HV-4)			
Study Purpose	Efficacy agair	st respiratory	diseas	e and shed	ding ca	used by EHV-	4
Product	Two doses, ad	lministered int	ramus	cularly, 21	days a	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	n EHV	-4, 21 days	s post s	econd vaccina	tion.
Description							
Interval	Horses were o	•		· 1		_	signs.
observed after	Nasal swabs v	vere collected	daily 1	for virus iso	olation.		
challenge							
Results			-		ige day	s between the	last and
	first, inclusive	e, with a positi	ve tite	r.			
							1
			of Vi	rus Sheddi	ng		1
	Group	Minimum	Q1	Median	Q3	Maximum	1
	Vaccinates	3	5	6	8	14	1
	Controls	4	7	11	15	19	ı
	N1 D:1						
	Nasal Dischar	<u>ge</u>					
	Group	Unaffected	Af	fected			
	Vaccinates	4 (25%)	12	(75%)			
	Controls	0 (0%)	15 ([100%]			
	Coughing was	not observed	in vac	cinates or o	controls	S.	
	Raw data show	vn on attached	l nace	2			
USDA Approval	July 2, 2007	wii oii attaciice	i page	· ·			
Date	July 2, 2007						
Date							

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Nasal Discharge - Vaccinates

					Na	asal di	scharg	e score	es ^a on	oost-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)

Nasal Discharge - Controls

					1	Vasal d	ischa	arge sc	ores ^a (l	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)

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<u>Virus Isolation – Vaccinates</u>

								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	٧1	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

<u>Virus Isolation – Controls</u>

									Day	Post-	Challe	nge V	iral T	iters (L	.og ₁₀	TCID ₅₀	/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

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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	
C4	
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

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Study Type	Efficacy			
Pertaining to	Equine Influer	nza Virus (E	IV)	
Study Purpose	To demonstrat	te efficacy a	gainst EIV six	months after
	vaccination.			
Product Administration	Two doses ada	ministered ir	ntramuscularly	(IM) three weeks apart.
Study Animals	18 vaccinate a	nd 7 control	horses were u	sed at 6 months of
	age.			
Challenge Description			d with EIV stra	
				econd vaccination.
Interval observed after				oost-challenge for
challenge		Nasal swab	s were collecte	ed daily for virus
	isolation.			
Results		-		f any clinical sign at
	•	_		od (nasal discharge,
	coughing, resp	oiration, tem	perature >102.	5°F).
			Ţ	
		# of	Presence of	
	Group	Animals	clinical sign	S
	Vaccinates	18	14	
	Controls	7	7	
		- 1		considered negative for
	_	• •	_	vabs were virus
	negative, other	rwise it was	positive.	
		,, <u> </u>		
		# of	Virus	
	Group	Animals	Isolation	
	Vaccinates	18	12	
	Controls	7	7	
	Raw data show		ed pages.	
USDA Approval Date	August 8, 200	5		

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

	14	100.6	100.1	100.0	99.7	100.6	100.2	100.3	101.4	102.7	100.6	99.4	100.5	100.4	100.0	100.4	100.2	6.66	100.6	なるので	100.9	99.6	100.3	99.8	100.1	4	99.4
	13	100.1	100.3	101.7	100.2	100.0	100.9	100.2	102.1	100.4	100.9	99.8	100.3	6.66	100.9	99.9	1001	99.6	99.5	のなると	102.0	100.3		100.7	99.7	-	100.0
	12	6.66	93.6	66.6	99.9	99.4	100.6	100.9	101.3	100.0	93.6	1001	100.2	100.7	1001	99.2	0.66	99.9	99.7	のでは、	101.8	1001	6.66	100.1	99.8	99.5	100.6
	11	100.7	100.8	100.5	100.8	1001	100.0	100.5	102.4	101.2	100.6	100.4	101.6	100.6	100.5	100.3	100.2	93.6	99.3	THE PARTY	102.4	100.4	101.0	101.0	99.8	101.2	102.9
EIV KY99:	10	98.1	99.2	99.2	99.2	98.8	98.6	100.0	100.7	100.0	99.3	102.0	1001	99.0	99.6	99.5	98.8	99.66	99.5	ははの	102.7	99.3	99.2	98.8	99.5	101.6	102.6
with	6	100.2	8.66	99.2	100.3	98.3	100.0	99.8	101.5	93.6	99.0	102.9	1001	99.2	100.8	99.7	9.66	99.4	98.8	はいる	104.7	99.9	101.3	99.2	105.4	103.3	103.8
challenge	8	99.1	99.1	97.8	99.1	98.5	99.5	100.5	100.4	98.3	98.6	101.5	98.5	98.6	98.7	99.1	99.3	99.0	99.3	なると	102.4	98.9	100.6	99.5	102.3	103.6	104.6
post	-	100.2	100.0	98.9	99.5	98.8	99.7	99.2	93.6	99.7	100.8	102.1	98.8	100.4	99.4	99.1	99.7	98.7	9.66	1000年	102.6	100.2	99.2	100.4	103.2	103.0	100.4
on days	9	8.66	99.3	99.3	100.0	98.9	100.0	99.2	100.9	99.7	100.0	102.7	99.7	99.4	100.0	1001	9.66	99.8	100.5	な数を表する	103.6	100.7	1001	99.3	104.2	104.7	99.8
(a) (a)		100.0	6.86	98.9	6.66	1001	99.4	99.3	102.1	9.66	98.7	102.1	100.4	99.66	98.8	1001	99.4	98.6	99.9	影響學	103.7	99.1	100.9	99.5	103.1	104.6	97.2
temperatures	4	101.1	8.66	8.66	8.66	101.5	100.2	100.0	104.4	100.5	100.0	101.3	100.6	100.5	100.5	101.6	99.7	100.1	1001	を記録の	103.8	103.0	99.8	102.8	102.2	104.0	104.4
Body ter		101.5	99.5	98.6	99.8	100.5	93.6	99.7	102.6	99.3	100.0	100.0	99.5	100.0	100.3	99.9	99.7	8.8	99.2	の大学の大学の	103.1	100.8	99.9	102.4	103.6	103.7	102.6
	2	99.9			101.9	102.8	100.0	99.7	105.4	100.4	1.0	103.6				٠.				180	104.5	101.9		103.6	104.7	104.7	103.2
	-	9.66	99.7	6.66	100.6	99.3	99.9	9.66	100.5	100.0	99.4	7.66	99.1	8.66	100.0	99.9	99.4	8.66	100.1	の出版を記念	9.66	98.8	1001	100.3	99.5	99.0	L
		100.0	100.0	99.1	100.9	100.1	100.6	100.5	100.1	100.8	100.0	100.2	7.66	9.66	100.4	100.4	100.0	100.4	100.2	STATE OF STA	100.2	6.66	100.5	99.7	100.6	100.0	0.00
	7	100.3	99.2	8.86	8.66	99.1	99.7	100.3	101.2	8 86	99.2	8.66	2 66	7.99	49.7	99.4	66 2	000	100 2	の変数の対象を	99.5	0.66	100.4	9.66	100.1	99.2	00
	Group		-								Vaccinates									Total appropriate property and	CONTRACTOR CONTRACTOR				Controls		
	Notae		1	7	2	91	0	20	30	33	33 65	200	25	35	000	900		100	2	SAME BOOK ASS	2	٥	,	13	26	38	

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Coughing observations of horses vaccinated with vaccinated 111103 on days post-challenge with virulent EIV KY99. Table 2.

-1	Horse	Group			181	ghing	observa	rvati	tions on	day	8	171		171	>	KY99:	:	
Vaccinates N N N N N N N N N N N N N N N N N N N	_	ding	7	0	1	7	m	4	2	9	7	8	6	120	=	12	13	14
Vaccinates N N N N N N N N N N N N N N N N N N N	+		z	z	z	z	z	Ü	D	၁,၁	၁	υ	N	z	z	Z	z	z
Vaccinates N N N N N N N N N N N N N N N N N N N	Г		z	z	z	z	z	z	Z	N	Z	z	z	N	z	N	z	z
Vaccinates N	Τ		z	z	z	z	z	z	z	z	N	N		Z	ပ	N	N	Z
Vaccinates N N N N N N N N N N N N N N N N N N N	Т		z	z	z	z	z	z	z	S	z	N	U	ပ	N	z	z	z
Vaccinates N N N N N N N N N N N N N N N N N N N	Г		z	z	z		C,C	O		c,c	c,c	N		၁,၁	N	z	N	z
Vaccinates N N N N N N N C,C C,C C,C C,C N C,C N N N N	Γ		z	z	z		z	N	z	z	Z	N	Z	Z	z	z	z	z
Vaccinates N N N N N N C,C C,C C,C C,C N,C N C,C N N N N	Γ		z	z	z	z	z	z	z	z	z	0	z	N	N	N	z	z
Vaccinates N N N N N N N N N N N N N N N N N N N	Т		z	z	z	z	2,2	υ	2,2	0,0	2,2	N		N	z	z	z	z
Vaccinates N N N N N C,C C,C C,C C,C C,C C,C C,C C	T		z	z	z	z	z	z	Z	z	z	N	N	N	N	z	z	z
M N N N N N N N N N N N N N N N N N N N	Γ	Vaccinates	z	z	z	z	0,0	O	υ	Z	Z	N		۵	N	N	z	z
M N N N N N N N N N N N N N N N N N N N			z	z	z	z	z	z	0,0	0,0	C, C	2,2	0,0	ပ	z	Z	z	z
N	T		N	z	z	z	z	z	z	z	z	N	O	N	Z	N	Z	N
N	T		z	z	N	z	O	z	N	Z	z	z	N	N	N	z	z	z
Ontrols N N N N N N N N N N N N N N N N N N N	T		z	z	z	Z	z	z	z	z	z	Z	N	N	Z	Z	z	z
Ontrols N N N N N N N N N N N N N N N N N N N	Τ		z	z	z	z	z	z	z	N	z	z	N	N	N	N	Z	z
Controls N N N N N N N C,C C,C C,C C,C C,C C,C N N N N			z	z	z	z	z	z	z	υ	O	z	Z	၁	N	N	N	z
Controls N N N N N C,C C,C C,C C,C C,C C,C C,C N N N N	Τ		z	z	z	z	z	z	z	z	z	ပ	CCC	N	N	N	N	N
Controls N N N N C,C C,C C,C C,C C,C C,C C,C C,C	Τ		z	z	z	z	Z	z	z	z	z	N	C	N	Z	Z	z	z
Controls N N N N C,C C,C C,C C,C C,C C,C C,C C,C	100		10 10 S	の大変	A	250	のないのかの	The state of	を	がない	京 经税	地の	明確認定	北州 城		1000		
Controls N N N N C,C C,C C,C C,C C,C C,C N N N N			z	z	z	z	2,2	0,0	C,C		O	o.	ပ,်င		z	N	N	z
Controls N N N N C,C C,C C,C C,C C,C C N N N N N			z	z	z	z		ŭ			100	0,0	c,c	- 4	z	N	N	z
Controls N N N C,C C,C C,C C,C C,C C,C C,C N N N N	Τ		z	z	z	z	z	z	Z	z		S	2,2	C	N	z	z	z
Controls N N N N C,C C,C C,C N N C,C N N N N N N	T		z	z	z	υ		0,0		1.0		-	0,0	C	N	Z	N	z
N N N N C,C C,C C,C C,C C,C C,C C,C N N N N		Controls	z	z	z	z	-	Ü	0,0		_	N	z		z	z	z	z
N N D'C C C'C N N C'C N N			z	Z	z	z		2,2							z	z	Z	z
			z	z	z	z		υ	O	-	z	Z	S	N		z	z	z
	Τ																	

N=no coughing , C=coughing 1 time during the observation per during the observation period

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Nasal discharge observations of horses vaccinated with vaccine 111103 on days postchallenge with virulent EIV KY99. Table 3.

1			Look		discharge	- 1	observations	tions	8	davs	ost-c	post-challenge		with E	EIV KY	KX99:	
No.	Group	7	0	Jы	7		4	r,	9		8	6			12	13	14
-		z	Z	z	z	z	z	Œ	z	z	Σ	z	N	N	SM	N	z
10		z	z	z	z	z	z	z	z	z	z	z	z	Z	Z	N	N
4		z	z	z	z	z	z	z	z	z	z	N	N	Z	z	Z	Z
14		z	z	z	z	z	z	z	z	Z	Z	SM	ωO	SM	z	N	z
16		z	z	z	z	z	z	z	z	z	N	N	z	z	z	N	N
19		z	z	z	z	z	z	z	z	z	N	N	Z	z	z	z	N
29		z	z	z	z	z	z	z	SM	Z	SM	z	Z	N	N	N	z
30		z	z	z	z	z	SM	z	SM	SM	SM	Z	z	z	N	SM	N
32		z	z	z	z	z	z	z	z	Z	N	N	z	Z	Z	z	N
33	Vaccinates	z	z	z	z	z	z	z	Z	N	Z	z	N	N	N	Z	z
34		z	z	z	z	z	z	SM	SM	N	N	SM	z	SM	N	N	N
32		z	z	z	z	z	z	z	z	z	N	N	Z	z	z	SM	N
36		z	z	z	z	z	z	z	z	z	z	z	N	N	N .	z	Z
39		z	z	z	z	z	z	z	z	z	Z	z	Z	N	N	N	SM
40		z	z	z	z	z	z	z	z	z	SM	N	N	Z	z	z	N
41		z	z	z	z	Z	z	z	z	z	z	N	N	N	Z	N	Z
43		z	z	z	z	z	SM	z	z	Z	SM	z	Z	N	N	N	SM
47		z	z	z	z	z	z	z	z	SM	Z	z	z	z	z	N	N
	The state of the s		(教学	五百五四	のなる	東京の記	20000	新	1. 1877				海 里。		新典型的		
m		z	z	z	z	z	CM	E)	CM	CM	SM	SM	SM	SM	SM	SM	z
000		z	z	z	z	Z	SM	SM	Z	O.	SM	z	SM	z	z	N	SM
-		z	z	z	z	z	SM	Z	z	SM	SM	SM	SM	SM	z	N	N
13	,	z	z	z	z	z	SM	z	SM	SM	SM	SM	Z	CM	N	N	Z
	Controls	z	z	z	z	z	z	CM	SM	CM	CM	CM	CM	N	z	SM	z
38		z	N	z	z	SM	N	Z	SM	SM	ω	Σ	SM	Σ	z	z	SM
44	_	z	z	z	z	z	N	SM	N	N	SM	SM	z	S	Z	N	z
	_																
	100000	6	0	0000	000	0110	ed o	rae (s	SCOTE	of 1)	WS.	SM=slight	ı	mucopuru	lent		

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

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Abnormal respiration and depression observations of horses vaccinated with vaccine 111103 on days post-challenge with virulent EIV KY99. Table 4.

	14	z	Z	z	z	z	z	z	z	z	z	z	Z	Z	Z	z	z	N	N	経済	Δ	z	z	N	z	Ω	N	
	13	Z	z	z	z	z	z	z	z	z	z	z	z	z	z	z	z	N	N	1	۵	z	z	N	z	Ω	z	
	12	N	N	Z	N	z	z	z	z	z	z	z	z	z	z	z	Z	N	Z		Ω	z	N	N	z	Ω	Z	
:66	11	z	z	Z	N	z	z	N	z	z	z	Ab	N	z	z	N	N	N	z		Д	Z	N	N	Z	D	z	
EIV KY99:	10	z	Z	N	z	z	N	N	Z	N	Z	D, Ab	N	z	z	z	Z	N	z		D	N	N	N	N	D, Ab	z	
with 1	6	z	N	N	z	N	N	Z	N	N	N	N	Z	Z	N	z	Z	Z	Z		D	N	Z	Z	D, Ab	Z	z	
lenge	8	N	N	N	N	N	N	Z	D, Ab	Z	N	N	z	N	N	z	z	z	N	多数产业	Ω	z	Z	N	Z	z	N	
t-chall	7	Z	Z	z	N	N	N	N	N	N	N	D, Ab	N	z	z	N	N	z	z	が開発	D, Ab	Z	N	Z	z	Z	z	
ys post	١٣	z	z	N	N	Z	N	Z	D, Ab	Z	Z	D, Ab	Z	z	N	N	N	z	z	ははは	Ω	N	N	z	Z	D	z	
on days	1.0	z	N	z	N	N	Z	z	D, Ab	z	N	Z	z	N	z	z	z	z	z	を	D, Ab	z	z	z	Z	Q	N	
tions	4	z	z	z	Z	Z	N	z	۵	z	z	z	Z	Z	z	z	Z	Z	z	10 to 10 to	D, Ab	N	z	Ω	z	D, Ab	z	
Observations	3	z	z	z	z	z	z	z	D, Ab	Z	z	Z	z	z	z	z	z	z	z	1	Z	z	z	Ω	z	Z	Z	
O	2	z	z	z	z	Ω	z	z	Ω	z	Ab	z	z	z	z	z	z	z	z		z	z	z	z	z	z	z	
	7	z	z	z	z	z	z	z	z	z	z	z	z	z	z	z	z	z	z		z	z	z	z	z	z	Z	L
	0	z	z	z	z	z	z	Z	z	z	z	z	z	z	z	z	z	z	z	200	z	z	z	z	z	z	z	H
	7	z	z	z	z	z	z	z	z	z	z	z	Z	z	z	z	z	z	z	4	z	z	z	z	z	z	z	L
	Group										Vaccinates									· · · · · · · · · · · · · · · · · · ·					Controls			
Horse	No	-	0	P	14	16	19	29	30	32	33	34	35	36	39	40	4			100 A	3		11	13	25	38	44	

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

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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.

	Group	7	0 1 1 1 1 1 1 1 1 1 1 1 1 1	H 1 1 1 + 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Isolation 1 2 1 2 + + + + + + + + + + + + + + + +	g m + 1 1 1 + 1 1 + 1 1 + 1 1 1	virus	8 6 1 1 1 + 1 1 1 + 1 1 1 + 1 + 1 + 1		post-chal 7 8	Chall	1	4	.	112 12 12 12 12	13	
Trols		1 1 1	1 1 1	1 1	1 1 1	+ 1 +	+ + +	1 1 +	1 1 +	1 1 1	1 1	1 1 1		1 1		1 1	' ' '
11.	2	-	1	1 2000	To de la	1	129	1	1		1899年中华	1	1855	-		癫	1
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		1	1	+	+	+	+	51	+		1	-	in foliation has	1	-	ě	1
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		'	1	t	+	+	÷	+	ı	,	ı	,	1		ı	1	ı
		-	1	ı	+	+	+	+	+	,	ı	1	ı	1	1	ı	1
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		'	ı	'	+	+	+	+	+	1	ı	1	1	•	,	1	1
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	ontrols	'	-	1	+	+	+	+	+	+	ı	1	ı	1	1	ı	ı
		1	1	ı	+	+	+	+	+	ı	1	1	ι	1	-	,	ı
		ı	1	ı	1	+	+	+	+	ı	ı	ı	ı		ı	1	1

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Study Type	Safety					
Pertaining to	ALL					
Study Purpose	To demonstrate safety under field conditions					
Product Administration	298 horses received 2 doses intramuscularly 3 to 4 weeks apart for					
	primary immunization. 254 horses received 1 dose					
	intramuscularly.					
Study Animals	552 horses of various ages, breeds and sex in 5 different states.					
			hs of age or yo	unger at the time of the		
	initial vac					
Challenge Description	Not applic					
Interval observed after	Horses were observed immediately following vaccination and then					
challenge	daily for 3 days post-vaccination					
Results	Doses are reported due to difference in vaccination schedule.					
	Score	# of Cases	% of Total]		
	0	820	96.47			
	1	25	2.94			
	2 3 0.35					
	3 2 0.24					
	4 0 0					
	5 0 0					
	Total # of Doses administered = 850					
	Score Overview:					
	0 – No rea					
		_		jection site, which is not		
				n. Not clinically significant.		
			elling at or nea	ar the injection site. Not		
	painfu		111	4		
			-	r the injection site. Raised,		
		scribed and pa		a substantial area around		
				hot. Horse is stiff and/or		
		ant to move.	ary panniui anu	not. Horse is suit and/of		
			mic reaction i	ncluding anaphylaxis or		
	5 – Generalized or systemic reaction, including anaphylaxis or elevated temperature.					
USDA Approval Date	February					

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