

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1525.21
True Name	Equine Rhinopneumonitis Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Prodigy with Havlogen - Merck Animal Health Prestige Prodigy - Merck Animal Health
Date of Compilation Summary	February 06, 2018

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	Equine Herpesvirus-Subty	pe 1 (EHV-	1), AB69	strain		
Study Purpose	Efficacy against respirator	y disease an	d abortio	n caused b	y EHV-1	
Product	Three doses, administered	intramuscul	larly at th	e 5 th , 7 th a	nd 9 th months	of
Administration	gestation.					
Study Animals	22 vaccinates and 22 contr	ols pregnan	t mares.	3 vaccinat	es were open	at the
	end of the study.					
Challenge	Horses were challenged wi	th EHV-1,	20 days p	ost-third v	accination.	
Description						
Interval	Observed for 11 days post	challenge f	or clinical	l signs of 1	espiratory dis	sease
observed after	and through foaling for neo	onatal delive	ery observ	vations.		
challenge						
Results	Delivery Observations		r			
	Treatment Group		Vacc	inates	Controls	s
	# of aborted, EHV-1 positiv	ve fetuses	2/19 or	: 10.5%	7/22 or 31.	8%
	Vince lealetion from need on	h				
	virus isolation iroin nasal sw	abs				
	Treatment Crown	Vacain	otos	Co	ntrole	
	Treatment Group	Vaccin 2/22 or	ates	Co	ntrols	
	Treatment Group Virus Isolation	Vaccin 2/22 or	ates 9.1%	Co 13/22	ntrols or 59.1%	
	Treatment Group Virus Isolation	Vaccin 2/22 or	ates 9.1%	Co 13/22	ntrols or 59.1%	
	Treatment GroupVirus IsolationBody Temperatures $\geq 101.0^{\circ}$	Vaccin 2/22 or F were consi	ates 9.1%	Co 13/22 e elevated.	ntrols or 59.1%	
	Treatment GroupVirus IsolationBody Temperatures ≥ 101.0°Treatment Group	Vaccin 2/22 or F were consi Vaccir	ates 9.1% dered to b nates	Co 13/22 e elevated. Cont	ntrols or 59.1% rols	
	Treatment GroupVirus IsolationBody Temperatures ≥ 101.0°Treatment GroupHyperthermia Affected	Vaccin 2/22 or F were consi Vaccin 3/22 or	ates 9.1% dered to b nates 13.6%	Co 13/22 e elevated. Cont 13/22 or	ntrols or 59.1%	
	Treatment Group Virus Isolation Body Temperatures ≥ 101.0° Treatment Group Hyperthermia Affected	Vaccin 2/22 or F were consi Vaccin 3/22 or	ates 9.1% dered to b nates 13.6%	Co 13/22 e elevated. Cont 13/22 or	ntrols or 59.1% rols 59.1%	
	Treatment Group Virus Isolation Body Temperatures ≥ 101.0° Treatment Group Hyperthermia Affected	Vaccin 2/22 or F were consi Vaccin 3/22 or	edered to be nates 13.6%	Co 13/22 e elevated. Cont 13/22 or	ntrols or 59.1% rols 59.1%	
	Treatment Group Virus Isolation Body Temperatures ≥ 101.0° Treatment Group Hyperthermia Affected Nasal Exudate – Individual d	Vaccin 2/22 or F were consi Vaccin 3/22 or aily nasal ex	ates 9.1% dered to b nates 13.6% udate scor	Co $13/22$ e elevated.Cont $13/22$ ores of ≥ 4 in	ntrols or 59.1% rols 59.1%	ificant
	Treatment Group Virus Isolation Body Temperatures ≥ 101.0° Treatment Group Hyperthermia Affected Nasal Exudate – Individual d level of respiratory disease.	Vaccin 2/22 or F were consi Vaccin 3/22 or aily nasal ex	ates 9.1% dered to b nates 13.6% udate scor	Co $13/22$ e elevated.Cont $13/22$ ores of ≥ 4 in	ntrols or 59.1% rols 59.1%	ificant
	Treatment Group Virus Isolation Body Temperatures ≥ 101.0° Treatment Group Hyperthermia Affected Nasal Exudate – Individual d level of respiratory disease. Treatment Group	Vaccin 2/22 or F were consi Vaccin 3/22 or aily nasal ex	edered to be nates 13.6% Udate scor	Co $13/22$ e elevated.Cont $13/22$ ores of ≥ 4 ines	ntrols or 59.1% rols 59.1% dicated a signi	ificant
	Treatment GroupVirus IsolationBody Temperatures $\geq 101.0^{\circ}$ Treatment GroupHyperthermia AffectedNasal Exudate – Individual dlevel of respiratory disease.Treatment GroupNasal exudate score \geq	Vaccin 2/22 or F were consi Vaccin 3/22 or aily nasal ex 4	ates 9.1% dered to b nates 13.6% udate scor Vaccinat 2/22 or 9.1	Co $13/22$ e elevated.Cont $13/22$ ores of ≥ 4 ines 1%	ntrols or 59.1% rols 59.1% dicated a signi Controls 9/22 or 40.19	ificant
	Treatment GroupVirus IsolationBody Temperatures $\geq 101.0^{\circ}$ Treatment GroupHyperthermia AffectedNasal Exudate – Individual dlevel of respiratory disease.Treatment GroupNasal exudate score $\geq 100000000000000000000000000000000000$	Vaccin 2/22 or F were consi Vaccin 3/22 or aily nasal ex 4	ates 9.1% dered to b nates 13.6% udate scor Vaccinat 2/22 or 9.1	Co $13/22$ e elevated.Cont $13/22$ ores of ≥ 4 ines1%	ntrols or 59.1% rols 59.1% dicated a signi Controls 9/22 or 40.1	ificant %
	Treatment GroupVirus IsolationBody Temperatures $\geq 101.0^{\circ}$ Treatment GroupHyperthermia AffectedNasal Exudate – Individual dlevel of respiratory disease.Treatment GroupNasal exudate score $\geq -$	Vaccin 2/22 or F were consi Vaccin 3/22 or aily nasal ex 4	ates 9.1% dered to b nates 13.6% udate scor Vaccinat 2/22 or 9.1	Co $13/22$ e elevated.Cont $13/22$ ores of ≥ 4 ines1%	ntrols or 59.1% rols 59.1% dicated a signi Controls 9/22 or 40.19	ificant %
	Treatment GroupVirus IsolationBody Temperatures $\geq 101.0^{\circ}$ Treatment GroupHyperthermia AffectedNasal Exudate – Individual dlevel of respiratory disease.Treatment GroupNasal exudate score ≥ 4 Raw data shown on attached	Vaccin 2/22 or F were consi Vaccin 3/22 or aily nasal ex 4 ed pages.	ates 9.1% dered to b nates 13.6% udate scor Vaccinat 2/22 or 9.1	Co $13/22$ e elevated.Cont $13/22$ ores of ≥ 4 ines 1%	ntrols or 59.1% rols 59.1% dicated a signi <u>Controls</u> 9/22 or 40.19	ificant
USDA Approval	Treatment GroupVirus IsolationBody Temperatures $\geq 101.0^{\circ}$ Treatment GroupHyperthermia AffectedNasal Exudate – Individual dlevel of respiratory disease.Treatment GroupNasal exudate score $\geq -$ Raw data shown on attachedNovember 30, 1992	Vaccin 2/22 or F were consi Vaccin 3/22 or aily nasal ex 4 ed pages.	ates 9.1% dered to b nates 13.6% udate scor Vaccinat 2/22 or 9.1	Co $13/22$ e elevated.Cont $13/22$ ores of ≥ 4 ines 1%	ntrols or 59.1% rols 59.1% dicated a signi Controls 9/22 or 40.1	ificant %

Control		Days		Foal	Cause	Vaccinated		Days		Foal	Cause
Mare	Foaling	Post	Type	Delivery	õ	Mare	Foaling	Post	Type	Delivery	ō
No.	Date	Challenge	Delivery	Status	Death	No.	Date	Challenge	Delivery	Status	Death
830	3-8-92	20	Abortion	Dead	EHV-1	804	3-4-92	16	Abnornal	Dead	Dystocia
845	3-14-92	26	Abortion	Dead	EHV-1	814	3-12-92	24	Abortion	Dead	EHV-1
831	3-15-92	27	Abortion	Dead	EHV-1	837	3-27-92	39	Abortion	Dead	EHV-1
817	4-3-92	46	Normal	Live		798	3-31-92	43	Normal	Live	
825	4-4-92	47	Normal	Live		832	4-5-92	48	Normal	Live	
819	4-9-92	52	Normal	Live		860	4-10-92	53	Normal	Live	
741	4-10-92	53	Normal	Live		833	4-11-92	54	Normal	Live	
801	4-10-92	53	Normal	Live		818	4-13-92	56	Normal	Live	
838	4-10-92	53	Normal	Live		803	4-14-92	57	Normal	Live	
796	4-11-92	5	Abortion	Dead	EHV-1	807	4-16-92	59	Normal	Live	
808	4-11-92	54	Normal	Live		835	4-18-92	61	Normal	Live	
752	4-12-92	55	Abortion	Dead	EHV-1	824	4-19-92	62	Normal	Live	
822	4-12-92	55	Normal	Live		812	4-25-92	68	Normal	Live	
861	4-13-92	56	Normal	Live		862	4-27-92	70	Normal	Live	
802	4-15-92	58	Normal	ill-Died	EHV-1	815	4-29-92	72	Normal	Live	
836	4-20-92	63	Normal	Live		799	5-4-92	77	Normal	Live	
811	4-23-92	67	Normal	Live		813	5-5-92	78	Normal	Live	
858	4-26-92	69	Normal	Live		834	5-7-92	80	Normal	Live	
842	5-1-92	77	Normal	Live		826	5-14-92	87	Normal	Live	
828	5-4-92	74	Normal	Dead	EHV-1	908	5-29-92	Open	AN	٩N	
859	5-13-92	86	Normal	Live		823	5-29-92	Open	AN	٩N	
857	5-15-92	88	Normal	Live		829	5-29-92	Open	٩N	٩N	
Mean		56				Mean		58			
Range		20-83			_	Range		16-87			
EHV-1 D	eaths: 7/2:	2 (31.8%)			_	EHV-1 Deat	hs: 2/19 (1	0.5%)			
Normal F	oals: 15/22	2 (68.2%)				Normal Foal	s: 16/19 (8	4.2%)			

Table 15. Parturition Summary For 22 Non-vaccinated Control Mares And 22 EHV-1 Vaccinated Mares Following Intranasal Challenge Inoculation With EHV-1 Subtype 1 Virus

	_																		-		- · · ·				_	_		
Positive	Days	0/11	0/11	0/11	0/11	0/11	0/11	0/11	0/11	0/11	0/11	0/11	0/11	0/11	1/11	1/11	0/11	0/11	0/11	0/11	0/11	0/11	0/11		2/242		0.826%	
	÷																								0/22		0	
	10																								0/22		0	
	6																								0/22		0	
	80																								0/22		0	
	7																								0/22		0	
96	9																								0/22		0	
Challer	5														>										1/22		4.5	
Post (4																								0/22		0	
re and	e															>									1/22		4.5	
Days F	N																								0/22		0	
	-																								0/22		0	
	0																								0/22		0	
	٦																								0/22		0	
	Ň																								0/22		0	1.
Vaccinated Horse	No.	798	799	803	804	806	807	812	813	814	815	818	823	824	826	829	832	833	834	835	837	860	862	Group	Total	Per Cent	Recovery	ALC: NO REAL PROPERTY OF

Table 2.	Results Of Viral Isolation Studies Performed On Pre And Post Challenge Nasal Swab Cultures
	From 22 Non-vaccinated Control Mares Following Intranasal Challenge With EHV-1 Subtype 1
	Virus

Control Days Pre and Post Chaltene Postive Lucton Horeo Days Pre and Post Chaltene Postive Ritene PostiveRitene Postive Ritene Postive R															_	_	_	_	_	_		_	_	_			_	_	_	
Control No. -2 -1 0 1 2 3 4 5 6 7 8 10 11 Yat 732 -2 -1 0 1 2 3 4 5 6 7 8 10 11 732 786 8 1 2 3 4 5 6 7 8 10 11 732 786 8 7 8 7 8 7 8 10 11 801 801 7 8 7 8 7 8 10 11 817 80 7 7 7 7 7 7 7 7 7 7 813 814 7 7 7 7 7 7 7 7 7 7 7 7 7 813 8 1 7 7		Positive	Days	8/11	0/11	0/11	0/11	2/11	1/11	2/11	0/11	0/11	0/11	4/11	6/11	4/11	6/11	2/11	0/11	4/11	0/11	1/11	6/11	5/11	0/11		51/242		21.07	
Control Antical Days Pro and Post Challenge No. -2 -1 0 1 2 3 4 5 6 7 8 9 10 721 752 7 8 9 70 7 8 9 10 751 7 7 7 7 7 8 9 10 752 7 7 7 7 7 8 9 10 803 801 7 7 7 7 7 7 7 7 803 801 7 </td <td></td> <td></td> <td>:</td> <td></td> <td>0/22</td> <td></td> <td>0</td> <td></td>			:																								0/22		0	
Control Horse -2 -1 0 1 2 3 4 5 6 7 8 9 731 752 1 2 3 4 5 6 7 8 9 731 752 1 2 3 4 5 6 7 8 9 752 1 1 2 3 4 5 6 7 8 9 802 802 1 1 2 3 4 5 6 7 8 9 803 801 1 2 2 4 5 7 8 9 813 813 1 2 2 4 5 7 8 9 813 1 1 2 2 4 2 4 2 9 813 833 8 1 2 2			9	>																							1/22		4.5	
Control Horse -2 -1 0 1 2 3 4 5 6 7 8 732 1 0 1 2 3 4 5 6 7 8 752 76 7 V <td< td=""><td></td><td></td><td>a</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>0/22</td><td></td><td>0</td><td></td></td<>			a																								0/22		0	
Control -2 -1 0 1 2 3 4 5 6 7 741 - -1 0 1 2 3 4 5 6 7 752 7 7 7 7 7 7 7 7 7 752 7 7 7 7 7 7 7 7 7 752 7 7 7 7 7 7 7 7 762 811 7 7 7 7 7 7 7 817 81 7 7 7 7 7 7 7 813 81 7 7 7 7 7 7 7 813 1 1 1 1 1 1 1 7 7 813 81 1 1 1 1 1 1			8	>											>								>	~			4/22		18.2	
Control -2 -1 0 1 2 3 4 5 6 741 - -1 0 1 2 3 4 5 6 741 - -1 0 1 2 3 4 5 6 752 76 - 0 1 2 3 4 5 6 752 - - 0 1 2 3 4 5 6 752 - - 0 1 2 3 4 5 6 801 - <td></td> <td>ľ</td> <td>7</td> <td>N</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>></td> <td>></td> <td></td> <td>٨</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>٧</td> <td>></td> <td></td> <td></td> <td>6/22</td> <td></td> <td>27.3</td> <td></td>		ľ	7	N										>	>		٨						٧	>			6/22		27.3	
Control Horse Days Pre and Post Challen No. Days Pre and Post Challen No. Control No. -2 -1 0 1 2 3 4 5 741 -2 -1 0 1 2 3 4 5 796 801 - - 0 1 2 3 4 5 801 - - 0 1 2 3 4 5 802 - - 0 1 2 3 4 5 803 - - 0 1 2 3 4 5 813 - - - 0 1 0		9e	9	۷										۷	>		>						>	>			6/22		27.3	
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Control -2 -1 0 1 2 3 741 -2 -1 0 1 2 3 741 -2 -1 0 1 2 3 752 71 0 1 2 3 752 796 0 1 2 3 796 801 0 1 2 3 801 0 1 0 1 2 3 803 1 0 1 0 1 2 3 819 1 1 1 1 1 1 1 813 1		Post	4	>						>				>	>	>	>			>							7/22		31.8	
Control -2 -1 0 1 2 741 -2 -1 0 1 2 741 -2 -1 0 1 2 741 -2 -1 0 1 2 752 796 - - - - 796 801 - - - - - 801 80 - - - - - - 803 811 81 - - - - - 813 81 - - - - - - 813 81 - - - - - - 813 81 -<		re and	e	>				>							>	>	>			>			>				7/22		31.8	
Control Horse -2 -1 0 1 741 - - 1 0 1 752 71 - 0 1 0 1 752 796 801 90 1 0 1 796 801 90 1 0 1 0 1 801 80 1 90 1 1 1 1 803 81 1		Days F	Q	>												>		>		>		>	>	>			8/22		36.4	
Control -2 -1 0 741 - -1 0 752 796 901 90 796 901 90 90 802 802 80 90 819 817 1 1 813 813 1 1 813 819 1 1 813 819 1 1 813 813 1 1 813 813 1 1 814 1 1 1 825 836 1 1 831 833 1 1 842 836 1 1 833 857 1 1 845 8 1 1 858 859 1 1 851 1 1 1 854 1 1 1 858 1 1			-																								0/22		•	
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	Control	Horse	No	741	752	796	801	802	608	811	817	819	822	825	828	830	831	836	838	842	845	857	858	859	861	Group	Total	Per Cent	Recovery	V: EHV-1 /

i de la	vidual A	Mare	roup M	ean Pre wind Int	And Pot	st Challen	enge Da	ily Rectu	al Temp	eratures	Record	fed For 2	22 EHV-	÷
				R	000	Rectal 1	Tempera	ture.			- odk	2		
					Days Pr	e and P	ost Chal	llenge						
~	1	-	0	-	8	e	4	5	9	7	8	6	10	1
9.6	ð	9.8	100.1	99.1	98.6	99.8	99.7	99.9	99.7	99.6	99.1	99.9	99.7	99.3
9.6	5	0.1	99.7	99.8	99.3	99.7	100.3	99.6	99.5	100.6	100.1	100.8	99.5	99.4
5.0	10	0.4	100	100.4	100.3	98.8	99.4	100.1	100.3	100.4	100	99.7	100	99.9
66	ð	9.4	99.4	9.66	100	99.2	39.5	99.2	99.4	99.1	100.3	98.8	99.1	66
9.6	ð	9.4	99.3	99.8	100	98.4	99.1	66	99.1	99.9	99.6	99.5	99.7	99.5
9.6	ę	0.3	99.8	9 .66	99.4	9 9.6	9 .6	66	9 .66	99.4	99.3	99.3	99.9	99.9
N	ð	8.9	99.1	99.1	99.8	99.9	9.66	98.8	98.8	99.3	99.8	99.3	99.1	99.8
6.0	ő	9.6	99.4	99.7	100	99.8	9 .66	98.8	98.8	99.8	100.2	66	99.3	66
4	ð	9.7	98.9	99.7	100.7	99.6	99.8	100.2	100.6	100.1	99.9	99.5	99.8	100.4
2	9	1.4	100	101.1	100.8	100.1	100.3	100.1	99.9	100.3	99.5	99.9	99.9	98.7
2	6	9.6	99.5	99.2	99.9	99.4	99.9	98.9	99.1	100	98.9	99.3	66	99.7
-	ő	9.4	98.9	99.2	99.4	99.1	99.4	99.4	98.8	99.6	99.7	99.7	99.1	99.5
4	6	9.4	99.4	100	99.4	66	99.7	99.2	100	100.6	99.7	100.1	100	100
9.0	ð	9.5	98.9	99.5	99.2	99.3	99.4	98.9	99.2	99.4	98.9	99.8	99.2	99.6
2	ð	9.5	100.1	99.4	98.9	99.5	99.7	99.4	99.3	99.3	99.3	99.2	99.1	99.8
8	5	0.2	99.6	99.8	100.6	99.3	99.9	99.9	99.66	100.3	101	9.66	99.8	99.4
8	Ø	8.9	98.5	99.2	99.3	100	99.3	99.3	99.8	99.2	100	99.2	99.1	98.9
4	5	0.1	100	100	100.7	99.7	99.3	99.8	99.4	99.8	99	99.6	99.1	98.6
9.5	6	9.5	99.7	99.2	99.5	99.1	100	99.2	99.8	100	100.3	99.66	99.2	100.3
9.6	-	0	99.2	99.8	66	99.1	99.8	99.2	9 9.6	100.2	99.8	66	98.8	99.7
2	9	0.1	100.1	100.3	99.8	100.4	99.2	100.7	100.6	102.3	101.5	66	99.5	100.1
3.5	6	9.2	99.5	100.1	100.3	99.7	99.66	99.1	98.6	99.3	99.5	99.5	99.8	66

Degrees Fahrenheit

Non-vaccinated Control Mares Following Intranasal Challenge Inoculation With EHV-1 Subtype 1 Virus Individual And Group Mean Pre And Post Challenge Daily Rectal Temperatures Recorded For 22 Table 5.

Control Actal Temperature* Actal Temperature* Actal Temperature* Actal Temperature* Actal Temperature* Actal Temperature* Acta 39:5 100:2 100:2 39:4 39:1 100:2 39:4 39:1 100:2 39:4 39:1 100:2 39:4 39:1 100:2 39:4 39:1 100:2 39:2 39:2 <th colspa="</th"><th></th><th>_</th><th></th><th>_</th><th></th><th></th><th>_</th><th></th><th></th><th></th><th></th><th></th><th>_</th><th>_</th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th>_</th><th></th><th>_</th></th>	<th></th> <th>_</th> <th></th> <th>_</th> <th></th> <th></th> <th>_</th> <th></th> <th></th> <th></th> <th></th> <th></th> <th>_</th> <th>_</th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th>_</th> <th></th> <th>_</th>		_		_			_						_	_								_		_
Control Acontrol No. -2 -1 0 Operation of the text of the text of text		:	99.7	99.9	99.6	99.66	98.8	100.1	99.5	99.8	99.3	99.1	100	98.8	99.7	100	66	99.8	99.3	100.1	99.3	99.7	99.3	66	
Control Control Page 5 Days Pre and Post Challenge No. -2 -1 0 1 2 3 4 5 6 7 8 9 741 99.6 99.5 100.2 103.3 99.1 100.2 100.2 99.7 99.8 100.2 752 99.9 100 100.3 99.7 99.4 99.7 99.6 90.7 99.8 99.3 90.2 90.2 99.3 90.2 99.7 99.6 99.7 99.7 99.6 99.7 99.7 99.7 99.7 99.8 99.3 99.2 99.3 99.7 99.8 99.3 80.7 99.7 99.7 99.7 99.7 99.7		10	100	99.2	100	99.4	66	100	99.4	98.8	98.5	98.9	100.1	99.9	99.3	100	99.3	99.8	9.66	100.2	9.66	99.4	99.5	99.2	
Control Control Days Pre and Post Challenge No. -2 -1 0 1 2 3 4 5 6 7 8 741 99.6 99.5 100.2 103.2 100.2 103.2 99.1 100.2 100.2 99.2 99.6 100.2 99.2 99.6 100.2 99.7 99.8 99.7 99.8 99.7 99.8 99.2 99.8 99.7 99.4 99.7 99.4 99.7 99.8 99.7 99.8 99.7 99.7 99.8 99.7 99.8 99.7 99.8 99.7 99.8 99.7 99.8 99.7 99.8 99.7 99.8 99.7 99.8 89.7 99.7 99.8 89.7 99.8 89.7 99.7 99.8 89.7 99.8 89.7 99.7 99.8 89.7 99.8 89.7 99.8 88.8 99.7 99.8 88.8 89.7 99.8		6	100.2	100.2	98.8	99.3	98.8	98.9	99.2	98.8	99.1	99.4	9.66	66	98.9	100.1	66	98.9	99.4	99.8	98.9	99.5	99.4	99.4	
Control Days Pre and Post Challenge No. -2 -1 0 1 2 3 4 5 6 7 741 99.6 99.9 90.5 100.2 103.2 100.2 100.2 100.2 100.3 99.1 100.2 100.3 99.1 99.5 99.5 99.7 99		8	98.8	99.8	99.3	99.8	99.8	99.4	99.8	99.5	99.2	99.8	99.5	99.8	99.2	99.9	98.9	66	99.5	100.3	99.7	98.9	99.3	99.7	
Tentral Temperature* Days Pre and Post Challenge No. -2 -1 0 1 2 3 4 5 6 741 99.6 99.9 99.5 100.2 103.2 100.3 99.1 100.2 100.2 752 99.9 99.6 99.5 100.2 103.4 99.7 99.4 99.5 99.4 801 99.4 99.7 99.2 99.7 99.4 100.2 100.2 801 99.4 99.7 99.4 99.7 99.4 99.7 99.4 99.7 811 99.6 99.3 100.8 102.6 99.4 99.7 99.4 99.7 813 99.4 102.1 99.4 102.1 99.6 99.6 99.7 813 99.4 102.1 99.4 102.2 99.4 99.7 99.4 99.5 813 99.4 102.1 99.4 102.1 99.4 99.5<		~	100.3	99.7	99.7	100.1	99.4	100	99.7	98.4	99.4	99.3	99.7	100.6	99.7	100.3	99.1	99.7	98.7	99.5	98.4	99.5	100.1	99.7	
Control Horse -2 -1 0 1 2 3 4 5 741 99.6 99.9 99.5 100.2 103.2 100.3 99.1 100.2 752 99.9 100 100.3 99.5 100.2 103.2 99.1 100.2 796 99.4 99.5 100.2 103.4 100.8 100.6 99.1 100.2 801 99.4 99.5 100.3 99.4 99.7 99.4 99.7 99.6 801 99.4 99.7 99.4 99.7 99.7 99.4 99.7 99.4 811 99.6 99.4 102.1 99.7 99.7 99.7 99.4 99.7 99.4 99.7 99.4 817 99.6 99.7 99.4 102.1 99.7 99.7 99.4 99.7 99.4 817 99.4 102.1 99.4 102.1 99.7 99.4 9		9	100.2	9.66	99.4	9 .66	99.7	99.9	98.8	9 .66	99.2	99.2	99.8	66	99.1	99.9	99.3	99.9	98.7	100.8	98.8	99.5	98.9	100	
Flectal Tempera Days Fre and Post Chal No. -2 -1 0 1 2 3 4 741 99.6 99.9 99.5 100.2 103.2 100.3 99.1 741 99.6 99.9 99.5 100.2 103.2 100.3 99.1 752 99.9 100 100.3 99.6 99.7 99.4 99.7 99.1 99.3 801 99.4 99.3 99.2 99.3 100.6 99.3 99.3 100.6 99.3 99.7 99.7 99.7 99.7 99.7 89.7 99.3 99.5 100.6 99.4 99.3 99.7 99.7 99.7 99.7 99.7 99.7 99.7 99.7 99.7 99.7 89.7 99.5 100.6 99.4 99.3 99.7 99.7 99.7 99.7 89.7 89.7 99.7 99.7 89.7 89.7 99.5 89.6 99.3	ture" lence	2	100.2	99.1	99.5	9 .66	99.5	100.1	99.4	99.1	98.8	99.4	99.4	99.9	98.5	100.3	100.4	99.7	66	100.2	99.2	99.3	99.7	99.2	
Control Page Free and F No. -2 -1 0 1 2 3 741 99.6 99.9 99.5 100.2 103.4 100.3 752 99.9 100 100.3 99.6 103.4 100.8 752 99.4 99.5 90.9 103.4 100.8 99.4 801 99.4 99.7 99.6 99.7 99.4 99.7 99.4 802 99.4 99.7 99.9 99.7 99.4 99.7 99.4 803 101 100.5 99.2 99.3 100.8 99.4 817 99.6 99.4 99.7 99.4 99.7 99.4 817 99.6 99.3 99.2 100.8 99.4 99.7 817 99.4 99.7 99.4 99.7 99.4 99.7 819 99.6 99.7 99.4 102.1 99.7 99.4 819<	fempera ost Chal	4	99.1	100.6	100	99.3	99.7	9.66	99.7	99.5	99.3	99.5	99.9	99.7	98.8	100.7	99.6	99.3	66	99.5	99.66	99.3	100.1	99.2	
Control Days Pr No. -2 -1 0 1 2 741 99.6 99.9 99.5 103.2 752 99.9 100 100.2 103.4 752 99.9 99.6 99.7 99.2 796 99.4 99.2 99.9 103.4 796 99.4 99.2 99.9 103.4 796 99.4 99.2 99.9 99.7 99.2 801 99.4 99.3 99.4 99.7 99.7 99.7 817 99.6 99.3 99.2 100.3 102.6 99.1 817 99.6 99.3 99.2 100.3 102.6 817 99.6 99.3 99.2 100.8 102.1 817 99.6 99.3 99.2 100.8 102.1 819 99.6 99.3 99.2 100.8 102.1 810 98.6 99.2 99.6	Rectal 7	3	100.3	100.8	98.6	99.4	99.1	66	99.7	99.3	98.8	102.2	99.5	66	98.8	104.1	99.1	98.8	99.66	99.7	99.4	98	100.2	99.9	
Control -2 -1 0 1 No. -2 -1 0 1 741 99.6 99.9 99.5 100.2 752 99.9 99.6 99.4 99.7 752 99.4 99.6 99.4 99.7 796 99.4 99.3 99.2 99.9 801 99.4 99.3 99.2 99.4 803 101 100.5 99.2 99.9 811 99.4 99.3 99.4 99.6 811 99.6 99.3 99.4 99.6 811 99.6 99.3 99.4 99.6 811 99.6 99.3 99.4 99.6 813 99.6 99.6 99.6 99.6 813 99.6 99.6 99.6 99.6 828 99.6 99.6 99.6 99.6 831 100.2 99.6 99.6 99.6	Davs Pr	~	103.2	103.4	99.2	99.7	100	102.6	99.1	102.1	100.8	103.1	102	101	100.8	104.2	99.9	99.9	102.2	101.8	99.4	101	101.8	101	
Control -2 -1 0 741 99.6 99.9 99.5 741 99.6 99.9 99.5 752 99.9 100 100.3 752 99.4 99.6 99.4 796 99.4 99.3 99.2 801 99.4 99.3 99.4 801 99.4 99.3 99.4 801 99.4 99.3 99.4 801 99.4 99.3 99.4 811 99.6 99.3 99.4 812 99.4 99.3 99.4 813 99.6 99.3 99.4 817 99.6 99.3 99.4 813 99.6 99.3 99.4 813 99.6 99.8 99.4 825 99.6 99.8 99.4 830 98.6 99.8 99.7 831 100.2 99.6 99.7 833		-	100.2	99.9	99.7	99.9	99.3	100.3	99.66	99.4	99.5	99.2	100	99.5	99.1	99.9	99.8	66	99.5	100	99.4	99.3	100.3	99.5	
Control -2 -1 741 99.6 99.9 741 99.6 99.9 752 99.9 100 752 99.4 99.6 752 99.4 99.6 796 99.4 99.3 801 99.4 99.3 802 99.4 99.3 811 99.6 99.3 812 99.3 99.3 813 99.4 99.3 817 99.4 99.3 819 99.4 99.3 810 99.4 99.3 811 99.6 99.3 812 99.4 99.3 825 99.4 99.3 825 99.6 99.3 830 98.5 99.3 831 100.2 100.2 833 99.3 99.3 845 99.3 99.3 859 99.3 99.3 859 <td></td> <td>0</td> <td>99.5</td> <td>100.3</td> <td>99.4</td> <td>99.2</td> <td>9.66</td> <td>99.2</td> <td>99.4</td> <td>98.9</td> <td>99.7</td> <td>99.9</td> <td>99.2</td> <td>99.3</td> <td>98.3</td> <td>99.5</td> <td>99.7</td> <td>98.7</td> <td>98.4</td> <td>99.5</td> <td>99.4</td> <td>99.7</td> <td>99.5</td> <td>99.66</td>		0	99.5	100.3	99.4	99.2	9.66	99.2	99.4	98.9	99.7	99.9	99.2	99.3	98.3	99.5	99.7	98.7	98.4	99.5	99.4	99.7	99.5	99.66	
Control -2 No. -2 741 99.6 752 99.9 752 99.4 801 99.4 801 99.4 801 99.4 801 99.4 801 99.4 802 99.4 811 99.6 812 99.6 813 90.3 814 99.6 815 99.6 817 99.6 818 99.6 819 99.6 825 99.6 830 99.6 831 100.2 836 98.9 845 98.9 857 100.1 858 99.3 859 99.3 850 99.3 851 99.3 852 99.3 853 99.3 854 99.3 95.3 99.3 <		7	99.9	100	99.6	99.3	99.2	100.5	99.3	100	99.8	99.8	99.8	99.3	99.4	100.2	99.6	99.3	98.9	99.3	99.8	100.6	99.8	99.8	
Control Horse No. 741 752 752 801 801 802 803 803 813 813 813 813 813 813 813 813 813 81		-2-	99.6	99.9	99.4	99.4	99.3	101	99.66	99.7	99.4	9 .66	99.66	99.8	98.5	100.2	98.9	99.3	98.8	99.3	100.1	100.9	99.7	99.3	
	Control Horse	No.	741	752	796	801	802	808	811	817	819	822	825	828	830	831	836	838	842	845	857	858	859	861	

Degrees Fahrenheit

	22 EF	1V-1 V	accinat	ed Ma	res Fol	lowing	Intrana	Isal Ch	alleng	e With	EHV-1	Subty	pe 1 V	irus	
Vaccinate					ane C	Nasal	Exudation Doet C	e Scor							Chicke
No.	сч -	7	•	-	2	3	4	2	9	~	8	6	10	=	Score
798	0	0	0	-	-	0	-	2	-	-	-	~	1.5	-	12.5
799	2	1.5	1.5	2	2	-	2	1.5	~	~	2	~	~	-	24.5
803	0	•	0	0	0	0	-	2	2	0	-	0	•	0	9
804	0	•	0	-	2	-	N	0	1.5	-	~	-	0	0	11.5
806	•	•	0	1.5	-	-	-	1.5	0	1.5	1.5	~	•	-	12
807	•	1.5	2	Q	e	0	N	1.5	N	-	~	-	~	-	23
812	0	•	0	0	2	0	-	0	0	-	~	0	0	0	9
813	-	•	0	N	1.5	-	-	~	N	1.5	N	~	-	~	19
814	•	•	-	-	-	-	0	-	-	~	N	-	1.5	•	12.5
815	•	•	0	-	2	2	~	1.5	0	1.5	-	-	-	-	14
818	•	•	0	•	-	-	-	0	-	1.5	-	-	•	0	7.5
823	0	•	0	-	0	0	0	0	•	0	0	0	•	•	-
824	•	•	-	-	1.5	-	-	-	2	-	•	1.5	-	-	13
826	-	-	1.5	-	8	-	-	0	е	1.5	-	~	•	~	18
829	•	-	0	0	-	-	0	0	0	1.5	-	-	•	-	7.5
832	•	•	0	0	-	0	0	0	0	0	-	N	0	•	4
833	•	•	0	0	-	-	0	0	0	0	~	0	•	0	4
834	2	•	~	C1	~	4	4	~	~	-	N	~	~	~	29
835	•	•	0	0	-	0	0	-	-	0	0	0	0	-	4
837	-	-	1.5	2	4	4	4	9	9	~	4	N	~	~	41.5
860	•	1.5	-	7	-	N	-	1.5	0	N	e	0	0	•	14
862	•	1.5	0	-	N	2	0	•	-	-	•	•	•	0	8.5
EN : Essen	tial No	rmal (0			VSM:	Very SI	ightly N	Aucopt	Irulent	(1.5)			: (Sco	(e)	
C-1: Slight	ly Serc	(1) sno			S: MS	lightly	Mucopi	urulent	3						
C-2: Mode	rately :	Serous	(2)		MM :	Aodera	tely Mu	ncopur	ulent (4	(
C-3: Heavy	/ Seroi	us (3)			HM : H	leavy h	Aucopu	Irulent	(9)						

Table 12. Individual And Group Mean Pre And Post Challenge Daily And Total Nasal Exudate Scores For

trol Mares Following Intranasal Challenge With EHV-1 Subtype 1 Virus	Nasal Exudate Score Days Pre and Post Challenge	1 2 3 4 5 6 7 8 9 10 11 Score	1 0 0 0 1 0 2 0 0 4	0 1 0 0 1 0 2 2 1 0 0 8	2 2 1 3 1.5 4 2 1 1.5 1 0 20	1 2 1 0 0 1 3 2 1 0 0 1	1 3 0 2 1 2 2 2 1 2 0 17	2 3 4 4 2 2 2 2 2 1.5 0 28	1 2 0 1 0 0 1.5 2 2 0 0 9.5	1 2 1 1 1.5 2 1 1 1 0 1 13.5	2 2 2 2 4 3 1.5 1.5 2 2 2 1 24	0 2 2 2 0 0 0 1.5 1.5 0 0 8	2 2 1 1 1.5 4 2 4 2 0 1 23.5	2 1 1 1 0 1.5 0 1 1 0 1 10.5	1 2 4 1 1.5 4 4 4 1.5 2 1 27	1 2 4 6 6 6 6 6 7 1 46	1 2 3 3 4 1 2 2 3 1 1.5 0 21.5	1 3 0 0 2 0 1 2 0 1.5 0 13	1 2 1 1 1.5 2 2 2 2 0 1.5 17	0 0 0 0 0 1.5 0 0 1 0 0 2.5	1 3 1 4 2 0 1 2 1 1.5 0 17.5	2 4 4 3 1.5 2 2 4 2 2 0 29.5	0 0 0 0 0 1 0 1 0 0 2	0 1 1 1 0 0 2 1 2 2 0 11.5	VSM: Very Slightly Mucopurulent (1.5) • : (Score)	SM : Slightly Mucopurulent (2)	1111 - Hardenstein Museemerikan (A)	
With EF		8	0	0	~	en en	~	~	ŝ	-	ŝ	1.1	2	0	4	9	0	-	~	0	-	2	-	~	5)			
hallenge	9	9	-	0	4	-	~	~	0	~	1.5 1	0	4	1.5	4	9	8	0	2	1.5	0	8	0	0	rulent (1.	(2)	lent (4)	
asal Cl	e Score halleng	5	0	-	1.5	0	-	~	0	1.5	en	0	1.5	0	1.5	9	-	8	1.5	0	8	1.5	0	0	Aucopur	urulent	ICODUIU	
g Intrar	Exudate Post C	4	0	•	ო	0	~	4	-	-	4	0	-	-	-	9	4	•	-	0	4	e	0	-	ightly N	Mucopi	telv Mu	
ollowing	Nasal E	e	0	0	-	-	0	4	•	-	~	~	-	-	4	4	e	0	-	0	-	4	0	-	Very SI	lightly	Modera	
ares F(Days P	~	0	-	~	N	e	en	~	~	N	N	~	-	2	2	2	e	2	0	с	4	0	-	VSM: V	S: MS	MM : MM	
ntrol M		-	-	0	~	-	-	N	-	-	N	0	~	2	-	-	-	-	-	0	-	2	0	0	h			
ted Cor		•	0	0	-	0	0	~	0	0	0	-	1.5	0	0	0	-	1.5	-	0	0	1.5	0	0			(2)	ļ
accinat		7	0	-	0	0	0	1.5	0	-	0	0	0	0	0	0	0	0	0	0	0	1.5	0	0	mal (0	us (1)	Serous	
Non-v		ř	0	0	0	0	-	0	0	0	-	0	1.5	-	-	0	•	-	•	0	-	•	0	1.5	tial No	Ily Sero	rately 5	
	Control Horse	No.	741	752	796	801	802	808	811	817	819	822	825	828	830	831	836	838	842	845	857	858	859	861	EN : Essen	C-1: Slight	C-2: Mode	

Study Type	Safety												
Pertaining to	ALL												
Study Purpose	Safety in	oregnant mares											
Product Administration	1 to 3 dos	es administered int	ramuscularly a	at 60 day inte	ervals								
	starting at	5 months of gestat	tion. 213 mar	es received 3	doses, 16								
	mares rece	eived 2 doses and 7	7 mares receiv	ed 1 dose.									
Study Animals	236 pregn	ant mares of variou	us age and bre	ed in 6 differ	ent states.								
Challenge Description	Not applic	cable											
Interval observed after	Observed	through birth of fo	als.										
challenge		-											
Results	Vaccine H	Reactions – Doses	are reported d	ue to differen	nce in								
	vaccinatio	on schedule.		_									
	Score	# of Reactions	% of Total										
	0	664	97.94										
	1	7	1.03										
	2	2	0.29										
	2+	2	0.29										
	3	2	0.29										
	4	1	0.15										
	Total # of	Doses administere	d = 678										
	Score	Overview:											
	0 - Nc												
	1 - Nc												
	1 – Not clinically significant, parlpable swelling 2 – Non-painful, localized visible swelling												
	3 – Lo	calized, raised, pai	nful visible sv	velling									
	4 - Di	ffuse, very painful,	hot visible sw	velling									
	Pregnanc	y/Foaling Status											
	Total # o	bserved through ge	estation		230								
	Total # o	f live, healthly foal	ls		222								
	Total # o	f Abortions			6								
			Unkno	wn reasons	3								
		Indu	ced due to hyd	droallantois	1								
		I	Due to placent	itis/fibrosis	1								
		Due to place	ntitis/neonatal	septicemia	1								
	# of still	oorn foal (cause un	known)		1								
	# of foal	born week and die	d*		1								
	*EHV-1 was is	solated from the foal, mare h	ad aborted last year										
USDA Approval Data	00 1005												
USDA Approval Date	ca. 1995												