



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-Subtype 1 (EHV-1), AB69 strain																								
Study Purpose	Efficacy against respiratory disease and abortion caused by EHV-1																								
Product Administration	Three doses, administered intramuscularly at the 5 th , 7 th and 9 th months of gestation.																								
Study Animals	22 vaccinates and 22 controls pregnant mares. 3 vaccinates were open at the end of the study.																								
Challenge Description	Horses were challenged with EHV-1, 20 days post-third vaccination.																								
Interval observed after challenge	Observed for 11 days post challenge for clinical signs of respiratory disease and through foaling for neonatal delivery observations.																								
Results	<p>Delivery Observations</p> <table border="1"> <thead> <tr> <th>Treatment Group</th> <th>Vaccinates</th> <th>Controls</th> </tr> </thead> <tbody> <tr> <td># of aborted, EHV-1 positive fetuses</td> <td>2/19 or 10.5%</td> <td>7/22 or 31.8%</td> </tr> </tbody> </table> <p>Virus Isolation from nasal swabs</p> <table border="1"> <thead> <tr> <th>Treatment Group</th> <th>Vaccinates</th> <th>Controls</th> </tr> </thead> <tbody> <tr> <td>Virus Isolation</td> <td>2/22 or 9.1%</td> <td>13/22 or 59.1%</td> </tr> </tbody> </table> <p>Body Temperatures $\geq 101.0^{\circ}\text{F}$ were considered to be elevated.</p> <table border="1"> <thead> <tr> <th>Treatment Group</th> <th>Vaccinates</th> <th>Controls</th> </tr> </thead> <tbody> <tr> <td>Hyperthermia Affected</td> <td>3/22 or 13.6%</td> <td>13/22 or 59.1%</td> </tr> </tbody> </table> <p>Nasal Exudate – Individual daily nasal exudate scores of ≥ 4 indicated a significant level of respiratory disease.</p> <table border="1"> <thead> <tr> <th>Treatment Group</th> <th>Vaccinates</th> <th>Controls</th> </tr> </thead> <tbody> <tr> <td>Nasal exudate score ≥ 4</td> <td>2/22 or 9.1%</td> <td>9/22 or 40.1%</td> </tr> </tbody> </table> <p>Raw data shown on attached pages.</p>	Treatment Group	Vaccinates	Controls	# of aborted, EHV-1 positive fetuses	2/19 or 10.5%	7/22 or 31.8%	Treatment Group	Vaccinates	Controls	Virus Isolation	2/22 or 9.1%	13/22 or 59.1%	Treatment Group	Vaccinates	Controls	Hyperthermia Affected	3/22 or 13.6%	13/22 or 59.1%	Treatment Group	Vaccinates	Controls	Nasal exudate score ≥ 4	2/22 or 9.1%	9/22 or 40.1%
Treatment Group	Vaccinates	Controls																							
# of aborted, EHV-1 positive fetuses	2/19 or 10.5%	7/22 or 31.8%																							
Treatment Group	Vaccinates	Controls																							
Virus Isolation	2/22 or 9.1%	13/22 or 59.1%																							
Treatment Group	Vaccinates	Controls																							
Hyperthermia Affected	3/22 or 13.6%	13/22 or 59.1%																							
Treatment Group	Vaccinates	Controls																							
Nasal exudate score ≥ 4	2/22 or 9.1%	9/22 or 40.1%																							
USDA Approval Date	November 30, 1992																								

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

Control		Days		Foal		Cause	
Mare No.	Foaling Date	Post Challenge	Type Delivery	Status	Delivery	Of	Death
830	3-8-92	20	Abortion	Dead	EHV-1		
845	3-14-92	26	Abortion	Dead	EHV-1		
831	3-15-92	27	Abortion	Dead	EHV-1		
817	4-3-92	46	Normal	Live			
825	4-4-92	47	Normal	Live			
819	4-9-92	52	Normal	Live			
741	4-10-92	53	Normal	Live			
801	4-10-92	53	Normal	Live			
838	4-10-92	53	Normal	Live			
796	4-11-92	54	Abortion	Dead	EHV-1		
809	4-11-92	54	Normal	Live			
752	4-12-92	55	Abortion	Dead	EHV-1		
822	4-12-92	55	Normal	Live			
861	4-13-92	56	Normal	Live			
802	4-15-92	58	Normal	ill-Died	EHV-1		
836	4-20-92	63	Normal	Live			
811	4-23-92	67	Normal	Live			
858	4-26-92	69	Normal	Live			
842	5-1-92	77	Normal	Live			
828	5-4-92	74	Normal	Dead	EHV-1		
859	5-13-92	86	Normal	Live			
857	5-15-92	88	Normal	Live			
Mean		56					
Range		20-83					
EHV-1 Deaths: 7/22 (31.8%)							
Normal Foals: 15/22 (68.2%)							
Vaccinated		Days		Foal		Cause	
Mare No.	Foaling Date	Post Challenge	Type Delivery	Status	Delivery	Of	Death
804	3-4-92	16	Abnormal	Dead	Dystocia		
814	3-12-92	24	Abortion	Dead	EHV-1		
837	3-27-92	39	Abortion	Dead	EHV-1		
798	3-31-92	43	Normal	Live			
832	4-5-92	48	Normal	Live			
860	4-10-92	53	Normal	Live			
833	4-11-92	54	Normal	Live			
818	4-13-92	56	Normal	Live			
803	4-14-92	57	Normal	Live			
807	4-16-92	59	Normal	Live			
835	4-18-92	61	Normal	Live			
824	4-19-92	62	Normal	Live			
812	4-25-92	68	Normal	Live			
862	4-27-92	70	Normal	Live			
815	4-29-92	72	Normal	Live			
799	5-4-92	77	Normal	Live			
813	5-5-92	78	Normal	Live			
834	5-7-92	80	Normal	Live			
826	5-14-92	87	Normal	Live			
806	5-29-92	Open	NA	NA			
823	5-29-92	Open	NA	NA			
829	5-29-92	Open	NA	NA			
Mean		58					
Range		16-87					
EHV-1 Deaths: 2/19 (10.5%)							
Normal Foals: 16/19 (84.2%)							

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

Vaccinated Horse No.	Days Pre and Post Challenge													Positive Days	
	-2	-1	0	1	2	3	4	5	6	7	8	9	10		11
798															0/11
799															0/11
803															0/11
804															0/11
806															0/11
807															0/11
812															0/11
813															0/11
814															0/11
815															0/11
818															0/11
823															0/11
824															0/11
826								V							1/11
829					V										1/11
832															0/11
833															0/11
834															0/11
835															0/11
837															0/11
860															0/11
862															0/11
Group Total	0/22	0/22	0/22	0/22	0/22	1/22	0/22	1/22	0/22	0/22	0/22	0/22	0/22	0/22	2/242
Per Cent Recovery	0	0	0	0	0	4.5	0	4.5	0	0	0	0	0	0	0.826%

V: EHV-1 Virus Isolated

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 Horse No.	Days Pre and Post Challenge											Positive Days			
	-2	-1	0	1	2	3	4	5	6	7	8		9	10	11
741					V	V	V	V	V	V			V		8/11
752															0/11
796															0/11
801															0/11
802				V				V							2/11
809								V							1/11
811							V	V							2/11
817															0/11
819															0/11
822															0/11
825							V	V	V	V					4/11
828							V	V	V	V	V				6/11
830					V	V	V	V							4/11
831					V	V	V	V	V						6/11
836					V			V							2/11
838															0/11
842					V	V	V								4/11
845															0/11
857					V										1/11
858					V	V		V	V	V	V				6/11
859					V			V	V	V	V				5/11
861															0/11
Group Total	0/22	0/22	0/22	0/22	8/22	7/22	7/22	12/22	6/22	6/22	4/22	0/22	1/22	0/22	51/242
Per Cent Recovery	0	0	0	0	36.4	31.8	31.8	54.5	27.3	27.3	18.2	0	4.5	0	21.07

V: EHV-1 Virus Isolated

Table 4. Individual And Group Mean Pre And Post Challenge Daily Rectal Temperatures Recorded For 22 EHV-1 Vaccinated Mares Following Intranasal Challenge Inoculation With EHV-1 Subtype 1 Virus

Vaccinated Horse No.	Rectal Temperature*													
	Days Pre and Post Challenge													
	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11
798	99.6	99.8	100.1	99.1	98.6	99.8	99.7	99.9	99.7	99.6	99.1	99.9	99.7	99.3
799	99.6	100.1	99.7	99.8	99.3	99.7	100.3	99.6	99.5	100.6	100.1	100.8	99.5	99.4
803	99.5	100.4	100	100.4	100.3	98.8	99.4	100.1	100.3	100.4	100	99.7	100	99.9
804	99	99.4	99.4	99.6	100	99.2	99.5	99.2	99.4	99.1	100.3	98.8	99.1	99
806	99.6	99.4	99.3	99.8	100	98.4	99.1	99	99.1	99.9	99.6	99.5	99.7	99.5
807	99.6	100.3	99.8	99.6	99.4	99.6	99.6	99	99.6	99.4	99.3	99.3	99.9	99.9
812	99.2	98.9	99.1	99.1	99.8	99.9	99.6	98.8	98.8	99.3	99.8	99.3	99.1	99.8
813	99.9	99.6	99.4	99.7	100	99.8	99.6	98.8	98.8	99.8	100.2	99	99.3	99
814	99.4	99.7	98.9	99.7	100.7	99.6	99.8	100.2	100.6	100.1	99.9	99.5	99.8	100.4
815	102.2	101.4	100	101.1	100.8	100.1	100.3	100.1	99.9	100.3	99.5	99.9	99.9	98.7
818	99.2	99.6	99.5	99.2	99.9	99.4	99.9	98.9	99.1	100	98.9	99.3	99	99.7
823	99.1	99.4	98.9	99.2	99.4	99.1	99.4	99.4	98.8	99.6	99.7	99.7	99.1	99.5
824	99.4	99.4	99.4	100	99.4	99	99.7	99.2	100	100.6	99.7	100.1	100	100
826	99.9	99.5	98.9	99.5	99.2	99.3	99.4	98.9	99.2	99.4	98.9	99.8	99.2	99.6
829	99.2	99.5	100.1	99.4	98.9	99.5	99.7	99.4	99.3	99.3	99.3	99.2	99.1	99.8
832	100	100.2	99.6	99.8	100.6	99.3	99.9	99.9	99.6	100.3	101	99.6	99.8	99.4
833	99	98.9	98.5	99.2	99.3	100	99.3	99.3	99.8	99.2	100	99.2	99.1	98.9
834	99.4	100.1	100	100	100.7	99.7	99.3	99.8	99.4	99.8	99	99.6	99.1	98.6
835	99.5	99.5	99.7	99.2	99.5	99.1	100	99.2	99.8	100	100.3	99.6	99.2	100.3
837	99.6	100	99.2	99.8	99	99.1	99.8	99.2	99.6	100.2	99.8	99	98.8	99.7
860	100.2	100.1	100.1	100.3	99.8	100.4	99.2	100.7	100.6	102.3	101.5	99	99.5	100.1
862	99.5	99.2	99.5	100.1	100.3	99.7	99.6	99.1	98.6	99.3	99.5	99.5	99.8	99

Degrees Fahrenheit

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

Control Horse No.	Rectal Temperature*														
	Days Pre and Post Challenge														
	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	
741	99.6	99.9	99.5	100.2	103.2	100.3	99.1	100.2	100.2	100.3	98.8	100.2	100	99.7	
752	99.9	100	100.3	99.9	103.4	100.8	100.6	99.1	99.6	99.7	99.8	100.2	99.2	99.9	
796	99.4	99.6	99.4	99.7	99.2	98.6	100	99.5	99.4	99.7	99.3	98.8	100	99.6	
801	99.4	99.3	99.2	99.9	99.7	99.4	99.3	99.6	99.6	100.1	99.8	99.3	99.4	99.6	
802	99.3	99.2	99.6	99.3	100	99.1	99.7	99.5	99.7	99.4	99.8	98.8	99	98.8	
809	101	100.5	99.2	100.3	102.6	99	99.6	100.1	99.9	100	99.4	98.9	100	100.1	
811	99.6	99.3	99.4	99.6	99.1	99.7	99.7	99.4	98.8	99.7	99.8	99.2	99.4	99.5	
817	99.7	100	98.9	99.4	102.1	99.3	99.5	99.1	99.6	98.4	99.5	98.8	98.8	99.8	
819	99.4	99.8	99.7	99.5	100.8	98.8	99.3	98.8	99.2	99.4	99.2	99.1	98.5	99.3	
822	99.6	99.8	99.9	99.2	103.1	102.2	99.5	99.4	99.2	99.3	99.8	99.4	98.9	99.1	
825	99.6	99.8	99.2	100	102	99.5	99.9	99.4	99.8	99.7	99.5	99.6	100.1	100	
828	99.8	99.3	99.3	99.5	101	99	99.7	99.9	99	100.6	99.8	99	99.9	98.8	
830	98.5	99.4	98.3	99.1	100.8	98.8	98.8	98.5	99.1	99.7	99.2	98.9	99.3	99.7	
831	100.2	100.2	99.5	99.9	104.2	104.1	100.7	100.3	99.9	100.3	99.9	100.1	100	100	
836	98.9	99.6	99.7	99.8	99.9	99.1	99.6	100.4	99.3	99.1	98.9	99	99.3	99	
838	99.3	99.3	98.7	99	99.9	98.8	99.3	99.7	99.9	99.7	99	98.9	99.8	99.8	
842	98.8	98.9	98.4	99.5	102.2	99.6	99	99	98.7	98.7	99.5	99.4	99.6	99.3	
845	99.3	99.3	99.5	100	101.8	99.7	99.5	100.2	100.8	99.5	100.3	99.8	100.2	100.1	
857	100.1	99.8	99.4	99.4	99.4	99.4	99.6	99.2	98.8	98.4	99.7	98.9	99.6	99.3	
858	100.9	100.6	99.7	99.3	101	98	99.3	99.3	99.5	99.5	98.9	99.5	99.4	99.7	
859	99.7	99.8	99.5	100.3	101.8	100.2	100.1	99.7	98.9	100.1	99.3	99.4	99.5	99.3	
861	99.3	99.8	99.6	99.5	101	99.9	99.2	99.2	100	99.7	99.7	99.4	99.2	99	

Degrees Fahrenheit

Table 12. Individual And Group Mean Pre And Post Challenge Daily And Total Nasal Exudate Scores For 22 EHV-1 Vaccinated Mares Following Intranasal Challenge With EHV-1 Subtype 1 Virus

Vaccinate Horse No.	Nasal Exudate Score														Study Score
	Days Pre and Post Challenge														
	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	
798	0	0	0	1	1	0	1	2	1	1	1	2	1.5	1	12.5
799	2	1.5	1.5	2	2	1	2	1.5	2	2	2	2	2	1	24.5
803	0	0	0	0	0	0	1	2	2	2	0	1	0	0	6
804	0	0	0	1	2	1	2	0	1.5	1	2	1	0	0	11.5
806	0	0	0	1.5	1	1	1	1.5	0	1.5	1.5	2	0	1	12
807	0	1.5	2	2	3	2	2	1.5	2	1	2	1	2	1	23
812	0	0	0	0	2	0	1	0	0	1	2	0	0	0	6
813	1	0	0	2	1.5	1	1	2	2	1.5	2	2	1	2	19
814	0	0	1	1	1	1	0	1	1	2	2	1	1.5	0	12.5
815	0	0	0	1	2	2	2	1.5	0	1.5	1	1	1	1	14
818	0	0	0	0	1	1	1	0	1	1.5	1	1	0	0	7.5
823	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1
824	0	0	1	1	1.5	1	1	1	2	1	0	1.5	1	1	13
826	1	1	1.5	1	2	1	1	0	3	1.5	1	2	0	2	18
829	0	1	0	0	1	1	0	0	0	1.5	1	1	0	1	7.5
832	0	0	0	0	1	0	0	0	0	0	1	2	0	0	4
833	0	0	0	0	1	1	0	0	0	0	2	0	0	0	4
834	2	0	2	2	2	4	4	2	2	1	2	2	2	2	29
835	0	0	0	0	1	0	0	1	1	0	0	0	0	1	4
837	1	1	1.5	2	4	4	4	6	6	2	4	2	2	2	41.5
860	0	1.5	1	1	1	2	1	1.5	0	2	3	0	0	0	14
862	0	1.5	0	1	2	2	0	0	1	1	0	0	0	0	8.5

EN : Essential Normal (0)*
 C-1: Slightly Serous (1)
 C-2: Moderately Serous (2)
 C-3: Heavy Serous (3)
 VSM: Very Slightly Mucopurulent (1.5)
 SM : Slightly Mucopurulent (2)
 MM : Moderately Mucopurulent (4)
 HM : Heavy Mucopurulent (6)
 *: (Score)

Table 13. Individual And Group Mean Pre And Post Challenge Daily And Total Nasal Exudate Scores For 22 Non-vaccinated Control Mares Following Intranasal Challenge With EHV-1 Subtype 1 Virus

Control Horse No.	Nasal Exudate Score															Study Score
	Days Pre and Post Challenge															
	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11		
741	0	0	0	1	0	0	0	0	1	0	2	0	0	0	4	
752	0	1	0	0	1	0	0	1	0	2	2	1	0	0	8	
796	0	0	1	2	2	1	3	1.5	4	2	1	1.5	1	0	20	
801	0	0	0	1	2	1	0	0	1	3	2	1	0	0	11	
802	1	0	0	1	3	0	2	1	2	2	2	1	2	0	17	
809	0	1.5	2	2	3	4	4	2	2	2	2	2	1.5	0	28	
811	0	0	0	1	2	0	1	0	0	1.5	2	2	0	0	9.5	
817	0	1	0	1	2	1	1	1.5	2	1	1	1	0	1	13.5	
819	1	0	0	2	2	2	4	3	1.5	1.5	2	2	2	1	24	
822	0	0	1	0	2	2	0	0	0	0	1.5	1.5	0	0	8	
825	1.5	0	1.5	2	2	1	1	1.5	4	2	4	2	0	1	23.5	
828	1	0	0	2	1	1	1	0	1.5	0	1	1	0	1	10.5	
830	1	0	0	1	2	4	1	1.5	4	4	4	1.5	2	1	27	
831	0	0	0	1	2	4	6	6	6	6	6	6	2	1	46	
836	0	0	1	1	2	3	4	1	2	2	3	1	1.5	0	21.5	
838	1	0	1.5	1	3	0	0	2	0	1	2	0	1.5	0	13	
842	0	0	1	1	2	1	1	1.5	2	2	2	2	0	1.5	17	
845	0	0	0	0	0	0	0	0	1.5	0	0	1	0	0	2.5	
857	1	0	0	1	3	1	4	2	0	1	2	1	1.5	0	17.5	
858	0	1.5	1.5	2	4	4	3	1.5	2	2	4	2	2	0	29.5	
859	0	0	0	0	0	0	0	0	0	1	0	1	0	0	2	
861	1.5	0	0	0	1	1	1	0	0	2	1	2	2	0	11.5	

EN : Essential Normal (0)*

C-1: Slightly Serous (1)

C-2: Moderately Serous (2)

C-3: Heavy Serous (3)

VSM: Very Slightly Mucopurulent (1.5)

SM : Slightly Mucopurulent (2)

MM : Moderately Mucopurulent (4)

HM : Heavy Mucopurulent (6)

* : (Score)

Study Type	Safety																																							
Pertaining to	ALL																																							
Study Purpose	Safety in pregnant mares																																							
Product Administration	1 to 3 doses administered intramuscularly at 60 day intervals starting at 5 months of gestation. 213 mares received 3 doses, 16 mares received 2 doses and 7 mares received 1 dose.																																							
Study Animals	236 pregnant mares of various age and breed in 6 different states.																																							
Challenge Description	Not applicable																																							
Interval observed after challenge	Observed through birth of foals.																																							
Results	<p>Vaccine Reactions – Doses are reported due to difference in vaccination schedule.</p> <table border="1"> <thead> <tr> <th>Score</th> <th># of Reactions</th> <th>% of Total</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>664</td> <td>97.94</td> </tr> <tr> <td>1</td> <td>7</td> <td>1.03</td> </tr> <tr> <td>2</td> <td>2</td> <td>0.29</td> </tr> <tr> <td>2+</td> <td>2</td> <td>0.29</td> </tr> <tr> <td>3</td> <td>2</td> <td>0.29</td> </tr> <tr> <td>4</td> <td>1</td> <td>0.15</td> </tr> </tbody> </table> <p>Total # of Doses administered = 678</p> <p>Score Overview: 0 – No reaction 1 – Not clinically significant, palpable swelling 2 – Non-painful, localized visible swelling 3 – Localized, raised, painful visible swelling 4 – Diffuse, very painful, hot visible swelling</p> <p>Pregnancy/Foaling Status</p> <table border="1"> <tbody> <tr> <td>Total # observed through gestation</td> <td>230</td> </tr> <tr> <td>Total # of live, healthy foals</td> <td>222</td> </tr> <tr> <td>Total # of Abortions</td> <td>6</td> </tr> <tr> <td>Unknown reasons</td> <td>3</td> </tr> <tr> <td>Induced due to hydroallantois</td> <td>1</td> </tr> <tr> <td>Due to placentitis/fibrosis</td> <td>1</td> </tr> <tr> <td>Due to placentitis/neonatal septicemia</td> <td>1</td> </tr> <tr> <td># of stillborn foal (cause unknown)</td> <td>1</td> </tr> <tr> <td># of foal born week and died*</td> <td>1</td> </tr> </tbody> </table> <p>*EHV-1 was isolated from the foal, mare had aborted last year</p>	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 # observed through gestation	230	Total # of live, healthy foals	222	Total # of Abortions	6	Unknown reasons	3	Induced due to hydroallantois	1	Due to placentitis/fibrosis	1	Due to placentitis/neonatal septicemia	1	# of stillborn foal (cause unknown)	1	# of foal born week and died*	1
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