



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Merial, Inc.
USDA Vet Biologics Establishment Number	298
Product Code	16L1.R0
True Name	Marek's Disease Vaccine, Serotype 1, Live Herpesvirus Chimera
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Prevexxion RN - No distributor specified
Date of Compilation Summary	July 17, 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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	vvMDV serotype 1
<b>Study Purpose</b>	Demonstrate efficacy against very virulent Marek's disease
<b>Product Administration</b>	One dose administered subcutaneously
<b>Study Animals</b>	Day-old chicks divided into 4 groups Group 1 vaccinated with Code 16L1.R0 and challenged Group 2 sham vaccinated and challenged (control) Group 3 sham vaccinated non-challenged (control) Group 4 vaccinated with a serotype 3 Marek's vaccine and challenged (control)
<b>Challenge Description</b>	Serotype-1 (SR-1) RB1B strain administered at 4 days post vaccination
<b>Interval observed after challenge</b>	Observed daily for 7 weeks and then evaluated for internal lesions
<b>Results</b>	Vaccinates and controls were evaluated in terms of Marek's disease clinical signs and/or grossly observable lesions per the criteria in 9 CFR 113.330(c)(4) & (5).  Birds with clinical signs and/or observable lesions: Group 1: 5/34 Group 2: 31/34 Group 3: 0/35 Group 4: 8/33  Requirements of 9 CFR 113.330(c)(4) & (5) were met.  Raw data on attached page
<b>USDA Approval Date</b>	December 20, 2011

Raw data shown below for birds classified as positive. All other birds normal.

Group/Bird	Emaciation	Locomotor/ Paralysis	Tumors In					Heart	Ascites	Yolk Sac Infection	Reason Not Given
			Kidney	Spleen	Gonads	Breast	Liver				
Group 1/1		x									
Group 1/2	x										
Group 1/3											x
Group 1/4	x			x							
Group 1/5			x								
Group 2/1	x										
Group 2/2		x			x						
Group 2/3		x			x						
Group 2/4	x		x	x							
Group 2/5			x	x		x					
Group 2/6	x		x		x						
Group 2/7	x										
Group 2/8	x		x								
Group 2/9	x		x								
Group 2/10	x										
Group 2/11	x		x								
Group 2/12	x				x						
Group 2/13	x		x								
Group 2/14	x		x		x		x				
Group 2/15	x										
Group 2/16	x										
Group 2/17		x									
Group 2/18		x			x						
Group 2/19	x				x						
Group 2/20	x		x								
Group 2/21	x										
Group 2/22					x						
Group 2/23			x				x				
Group 2/24	x		x								
Group 2/25	x		x								
Group 2/26											x
Group 2/27											x
Group 2/28											x
Group 2/29											x
Group 2/30											x

Group/Bird	Emaciation	Locomotor/ Paralysis	Tumors In						Heart	Ascites	Yolk Sac Infection	Reason Not Given
			Kidney	Spleen	Gonads	Breast	Liver	Intestine				
Group 2/31											x	
Group 4/1	x											
Group 4/2	x		x									
Group 4/3								x		x		
Group 4/4			x		x	x						
Group 4/5	x		x					x				
Group 4/6	x											
Group 4/7		x										
Group 4/8											x	

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	vvMDV serotype 1
<b>Study Purpose</b>	Demonstrate efficacy against very virulent Marek's disease
<b>Product Administration</b>	Administered <i>in ovo</i> to embryonated eggs at 18-19 days of embryonation
<b>Study Animals</b>	Embryonated eggs divided into 4 groups Group 1 vaccinated with Code 16L1.R0 and challenged Group 2 sham vaccinated and challenged (control) Group 3 sham vaccinated non-challenged (control) Group 4 vaccinated with a serotype 3 Marek's vaccine and challenged (control)
<b>Challenge Description</b>	Serotype-1 (SR-1) RB1B strain administered at 5 days post vaccination
<b>Interval observed after challenge</b>	Observed daily for 45 days and then evaluated for internal lesions
<b>Results</b>	Vaccinates and controls were evaluated in terms of Marek's disease clinical signs and/or grossly observable lesions per the criteria in 9 CFR 113.330(c)(4) & (5).  Birds with clinical signs and/or observable lesions: Group 1: 7/35 Group 2: 35/35 Group 3: 0/35 Group 4: 20/33  Requirements of 9 CFR 113.330(c)(4) & (5) were met.  Raw data on attached page
<b>USDA Approval Date</b>	June 12, 2015

Raw data shown below for birds classified as positive. All other birds normal.

Group/Bird	Emaciation	Locomotor/ Paralysis	Tumors In							Depression	Reason Not Given
			Kidney	Spleen	Gonads	Breast	Liver	Heart	Skin		
Group 1/1		x								x	
Group 1/2		x		x				x		x	
Group 1/3		x	x		x	x	x			x	
Group 1/4		x								x	
Group 1/5			x	x				x		x	
Group 1/6	x		x	x	x			x		x	
Group 1/7	x			x				x			
Group 2/1				x				x		x	
Group 2/2				x				x		x	
Group 2/3		x		x					x	x	
Group 2/4		x	x	x				x		x	
Group 2/5	x	x	x	x	x			x		x	
Group 2/6		x						x		x	
Group 2/7				x						x	
Group 2/8			x		x	x				x	
Group 2/9				x				x	x	x	
Group 2/10				x				x		x	
Group 2/11			x	x				x		x	
Group 2/12				x					x	x	
Group 2/13			x	x				x		x	
Group 2/14		x							x	x	
Group 2/15		x	x			x				x	
Group 2/16	x		x	x						x	
Group 2/17	x		x	x				x	x	x	
Group 2/18	x		x	x	x					x	
Group 2/19			x	x				x	x	x	
Group 2/20	x							x		x	
Group 2/21				x		x		x		x	
Group 2/22	x		x	x	x	x	x	x		x	
Group 2/23		x	x	x	x	x			x	x	
Group 2/24		x	x	x				x		x	
Group 2/25	x		x	x							
Group 2/26			x	x						x	
Group 2/27		x	x	x	x	x	x	x		x	

Group/Bird	Emaciation	Locomotor/ Paralysis	Tumors In							Depression	Reason Not Given	
			Kidney	Spleen	Gonads	Breast	Liver	Heart	Skin			
Group 2/28				x				x			x	
Group 2/29	x			x				x			x	
Group 2/30										x	x	
Group 2/31			x		x						x	
Group 2/32										x	x	
Group 2/33				x				x			x	
Group 2/34		x		x			x	x				
Group 2/35		x	x	x				x				
Group 4/1											x	
Group 4/2		x					x					
Group 4/3	x											
Group 4/4			x								x	
Group 4/5	x	x									x	
Group 4/6		x	x					x			x	
Group 4/7	x										x	
Group 4/8			x		x							
Group 4/9		x										
Group 4/10		x	x	x							x	
Group 4/11		x	x									
Group 4/12		x		x								
Group 4/13		x	x	x				x				
Group 4/14			x		x			x				
Group 4/15		x										
Group 4/16		x	x		x	x			x			
Group 4/17			x		x	x						
Group 4/18						x						
Group 4/19			x		x							
Group 4/20			x	x	x			x				

<b>Study Type</b>	Safety																																																						
<b>Pertaining to</b>	ALL																																																						
<b>Study Purpose</b>	Demonstrate safety of product under typical use conditions																																																						
<b>Product Administration</b>	1 dose (0.05 mL) by the in ovo route																																																						
<b>Study Animals</b>	Chickens, 18 to 19 day-old embryos 1/2 were vaccinated by in ovo route and 1/2 kept as controls. Animals were observed daily for mortality through 21 days after vaccination.																																																						
<b>Challenge Description</b>	Not applicable																																																						
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<b>Study Purpose</b>	Demonstrate safety of product under typical use conditions																																																						
<b>Product Administration</b>	1 dose (0.2 mL) by the subcutaneous (SQ) route																																																						
<b>Study Animals</b>	Chickens, day-old chicks 1/2 by the subcutaneous route and 1/2 kept as controls. Animals were observed daily for mortality through 21 days after vaccination.																																																						
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