



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Merial, Inc.
USDA Vet Biologics Establishment Number	298
Product Code	17H1.R1
True Name	Marek's Disease-Newcastle Disease Vaccine, Serotypes 2 & 3, Live Virus, Live Marek's Disease Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	NEWXXITEK HVT+ND & SB1 - No distributor specified
Date of Compilation Summary	November 06, 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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Marek's disease virus
<b>Study Purpose</b>	Demonstrate efficacy against very virulent Marek's Disease virus
<b>Product Administration</b>	1 dose by in ovo route
<b>Study Animals</b>	18- to 19-day-old embryos were divided into 4 groups  Group 1 vaccinated with test product and challenged Group 2 sham vaccinated and challenged (control) Group 3 sham vaccinated non-challenged (control) Group 4 vaccinated with HVT vaccine and challenged
<b>Challenge Description</b>	Serotype 1, RB1B very virulent Marek's disease virus
<b>Interval observed after challenge</b>	Birds observed daily for clinical signs for 45 days post challenge
<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).  Birds with clinical signs and/or observable lesions: Group 1: 5/28 Group 2: 34/34 Group 3: 0/25 Group 4: 18/34  Requirements of 9 CFR 113.330(c) were met.  Raw data on attached page
<b>USDA Approval Date</b>	March 25, 2014

Group/Bird	Paralysis	Locomotive	Emaciation	De-pression	Liver	Spleen	Heart	Muscle	Gonads	Kidneys	Other Gross Lesions	Comments
1/1			X						X			
1/2									X	X		
1/3		X	X						X	X		
1/4									X			
1/5									X	X		
2/1				X		X			X			
2/2				X	X	X	X			X		
2/3		X							X	X		
2/4				X	X		X					
2/5				X	X	X				X		
2/6										X		
2/7				X	X	X	X					
2/8			X			X				X		
2/9				X					X	X		
2/10			X			X	X		X	X		
2/11				X	X				X	X		
2/12				X	X	X	X			X		
2/13		X		X	X	X						
2/14				X	X	X	X					
2/15										X		
2/16			X	X				X	X	X		
2/17				X		X				X		
2/18				X	X		X		X	X		
2/19			X	X		X			X	X		
2/20				X				X	X			
2/21					X	X				X		
2/22			X	X		X			X	X		
2/23				X		X				X		
2/24				X			X		X	X		
2/25				X		X			X	X		
2/26				X								
2/27				X						X		
2/28		X		X						X		
2/29				X		X	X			X		
2/30				X		X	X			X	X	Intestinal tract
2/31		X	X					X	X	X		
2/32				X	X	X				X		
2/33				X		X				X		
2/34				X	X	X				X		
4/1					X	X	X		X	X		

Group/Bird	Paralysis	Locomotive	Emaciation	De- pression	Liver	Spleen	Heart	Muscle	Gonads	Kidneys	Other Gross Lesions	Comments
4/2								X	X	X	X	Intestinal tract (other)
4/3									X			
4/4	X								X			
4/5			X	X			X			X	X	Intestinal tract
4/6				X		X		X	X			X Intestinal tract
4/7												X Intestinal tract
4/8									X			X Intestinal tract
4/9			X	X		X			X	X		
4/10										X		
4/11		X							X			
4/12			X									X Intestinal tract
4/13		X		X			X		X			
4/14		X		X			X	X		X		
4/15		X		X			X	X		X		
4/16		X							X	X		
4/17							X			X		
4/18					X	X	X			X		

No clinical signs or lesions were observed in remaining birds in study.

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Marek's disease virus
<b>Study Purpose</b>	Demonstrate efficacy against very virulent Marek's Disease virus
<b>Product Administration</b>	1 dose by Subcutaneous route
<b>Study Animals</b>	Day-old chicks divided into 4 groups  Group 1 vaccinated with test product and challenged Group 2 sham vaccinated and challenged (control) Group 3 sham vaccinated non-challenged (control) Group 4 vaccinated with HVT vaccine and challenged
<b>Challenge Description</b>	Serotype 1, RB1B very virulent Marek's disease virus
<b>Interval observed after challenge</b>	Birds observed daily for clinical signs for 45 days post challenge
<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).  Birds with clinical signs and/or observable lesions: Group 1: 5/35 Group 2: 35/35 Group 3: 0/25 Group 4: 9/34  Requirements of 9 CFR 113.330(c) were met.  Raw data on attached page
<b>USDA Approval Date</b>	April 3, 2014

Group/ Bird	Paralysis	Locomotive	Emaciation	Depression	Other Clinical Signs	Liver	Spleen	Heart	Muscle	Gonads	Kidneys	Other Gross Lesions	Comments
1/1												X	Intestinal tract
1/2						X	X	X		X	X		
1/3								X		X			
1/4										X			
1/5		X		X		X				X	X		
2/1				X			X				X		
2/2		X		X		X		X			X		
2/3				X			X			X			
2/4				X			X						
2/5		X		X						X			
2/6				X			X	X					
2/7				X		X	X	X					
2/8											X		
2/9				X	X								Torticollis
2/10							X				X		
2/11			X	X							X		
2/12				X						X	X		
2/13				X									
2/14				X			X				X		
2/15				X									
2/16		X		X			X	X					
2/17				X			X						
2/18			X	X			X	X	X		X		
2/19		X		X									
2/20				X		X	X				X		
2/21				X		X	X				X		
2/22								X		X		X	Intestinal tract
2/23				X			X		X		X		
2/24		X				X	X	X		X	X		
2/25				X							X		
2/26				X									Large retained yolk
2/27				X			X				X		
2/28	X												
2/29				X			X				X		
2/30				X				X	X	X	X		
2/31				X			X				X		
2/32				X				X			X		
2/33				X		X	X		X				
2/34				X			X			X			
2/35				X	X								Torticollis
4/1												X	Intestinal tract
4/2		X											

Group/ Bird	Paralysis	Locomotive	Emaciation	Depression	Other Clinical Signs	Liver	Spleen	Heart	Muscle	Gonads	Kidneys	Other Gross Lesions	Comments
4/3										X			
4/4											X		
4/5							X	X		X	X		
4/6				X					X	X	X		
4/7		X	X	X				X	X		X		
4/8										X	X		
4/9		X		X		X			X	X	X		

No clinical signs or lesions were observed in remaining birds in the study.

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Newcastle disease virus (NDV)
<b>Study Purpose</b>	Demonstrate efficacy against virulent Newcastle disease
<b>Product Administration</b>	1 dose by subcutaneous route
<b>Study Animals</b>	Day old chicks were divided into 2 groups  Group 1 vaccinated and challenged Group 2 sham vaccinated and challenged (control)
<b>Challenge Description</b>	NDV Texas GB
<b>Interval observed after challenge</b>	Birds observed daily for clinical signs for 14 days post challenge
<b>Results</b>	Vaccinates and controls were evaluated in terms of Newcastle disease clinical signs per the criteria in 9 CFR 113.329(c)(4).  Birds with clinical signs: Group 1: 0/30 Group 2: 30/30  Requirements of 9 CFR 113.329(c)(4) were met.  Raw data on attached page
<b>USDA Approval Date</b>	March 10, 2014



<b>Group/Bird</b>	<b>NDV Result based on clinical signs</b>
2/1	Positive
2/2	Positive
2/3	Positive
2/4	Positive
2/5	Positive
2/6	Positive
2/7	Positive
2/8	Positive
2/9	Positive
2/10	Positive
2/11	Positive
2/12	Positive
2/13	Positive
2/14	Positive
2/15	Positive
2/16	Positive
2/17	Positive
2/18	Positive
2/19	Positive
2/20	Positive
2/21	Positive
2/22	Positive
2/23	Positive
2/24	Positive
2/25	Positive
2/26	Positive
2/27	Positive
2/28	Positive
2/29	Positive
2/30	Positive

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Newcastle disease virus (NDV)
<b>Study Purpose</b>	Demonstrate efficacy against virulent Newcastle disease
<b>Product Administration</b>	1 dose by <i>in ovo</i> route
<b>Study Animals</b>	18 to 19 day old embryos were divided into 2 groups  Group 3 vaccinated and challenged Group 4 sham vaccinated and challenged (control)
<b>Challenge Description</b>	NDV Texas GB
<b>Interval observed after challenge</b>	Birds observed daily for clinical signs for 14 days post challenge
<b>Results</b>	Vaccinates and controls were evaluated in terms of Newcastle disease clinical signs per the criteria in 9 CFR 113.329(c)(4).  Birds with clinical signs: Group 3: 2/39 Group 4: 40/40  Requirements of 9 CFR 113.329(c)(4) were met.  Raw data on attached page
<b>USDA Approval Date</b>	March 27, 2014

Group/Bird	Paralysis	Muscular Tremors	NDV Result
3/1		X	Positive
3/2			Positive
4/1			Positive
4/2		X	Positive
4/3			Positive
4/4			Positive
4/5		X	Positive
4/6		X	Positive
4/7		X	Positive
4/8			Positive
4/9			Positive
4/10			Positive
4/11		X	Positive
4/12			Positive
4/13		X	Positive
4/14			Positive
4/15		X	Positive
4/16		X	Positive
4/17		X	Positive
4/18			Positive
4/19		X	Positive
4/20			Positive
4/21		X	Positive
4/22		X	Positive
4/23			Positive
4/24		X	Positive
4/25		X	Positive
4/26			Positive
4/27		X	Positive
4/28			Positive
4/29			Positive
4/30			Positive
4/31			Positive
4/32			Positive
4/33			Positive
4/34		X	Positive
4/35			Positive
4/36		X	Positive
4/37			Positive
4/38			Positive
4/39			Positive
4/40			Positive

<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 by either the <i>in ovo</i> or subcutaneous route																																																																																									
<b>Study Animals</b>	Poultry, 18 to 19 day-old embryos or day-old chicks. 75,600 were vaccinated by <i>in ovo</i> route, 48,029 were vaccinated by subcutaneous route and 181,400 were kept as controls treated by the typical site vaccination program. Animals were observed daily for mortality through 21 days after vaccination.																																																																																									
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<b>Results</b>	<p>No adverse reactions attributable to the vaccine were noted.</p> <table border="1"> <thead> <tr> <th>Location</th> <th>Treatment</th> <th>Total Placed</th> <th>21 Day Mortality</th> <th>% Mortality</th> <th>% Hatchability</th> </tr> </thead> <tbody> <tr> <td>1</td> <td><i>In ovo</i></td> <td>22,600</td> <td>794</td> <td>3.5</td> <td>74.7</td> </tr> <tr> <td rowspan="2">1</td> <td>Control</td> <td rowspan="2">24,700</td> <td rowspan="2">721</td> <td rowspan="2">2.9</td> <td rowspan="6">87.4</td> </tr> <tr> <td><i>In ovo</i></td> </tr> <tr> <td rowspan="2">1</td> <td>Control</td> <td rowspan="2">24,700</td> <td rowspan="2">815</td> <td rowspan="2">3.3</td> </tr> <tr> <td><i>In ovo</i></td> </tr> <tr> <td rowspan="2">1</td> <td>Control</td> <td rowspan="2">24,700</td> <td rowspan="2">679</td> <td rowspan="2">2.7</td> </tr> <tr> <td><i>In ovo</i></td> </tr> <tr> <td>2</td> <td><i>In ovo</i></td> <td>20,200</td> <td>398</td> <td>2</td> <td rowspan="2">89.3</td> </tr> <tr> <td>2</td> <td><i>In ovo</i></td> <td>20,300</td> <td>369</td> <td>1.8</td> </tr> <tr> <td rowspan="2">2</td> <td>Control</td> <td rowspan="2">19,100</td> <td rowspan="2">410</td> <td rowspan="2">2.1</td> <td rowspan="2">86.6</td> </tr> <tr> <td><i>In ovo</i></td> </tr> <tr> <td rowspan="2">2</td> <td>Control</td> <td rowspan="2">19,100</td> <td rowspan="2">678</td> <td rowspan="2">3.5</td> <td rowspan="2">N/A</td> </tr> <tr> <td>SQ</td> </tr> <tr> <td rowspan="2">2</td> <td>Control</td> <td rowspan="2">19,100</td> <td rowspan="2">791</td> <td rowspan="2">4.1</td> <td rowspan="2">N/A</td> </tr> <tr> <td>SQ</td> </tr> <tr> <td>3</td> <td>SQ</td> <td>24,000</td> <td>542</td> <td>2.3</td> <td>N/A</td> </tr> <tr> <td>3</td> <td>SQ</td> <td>24,029</td> <td>267</td> <td>1.1</td> <td>N/A</td> </tr> <tr> <td rowspan="2">3</td> <td>Control</td> <td rowspan="2">25,000</td> <td rowspan="2">332</td> <td rowspan="2">1.3</td> <td rowspan="2">N/A</td> </tr> <tr> <td>SQ</td> </tr> <tr> <td rowspan="2">3</td> <td>Control</td> <td rowspan="2">25,000</td> <td rowspan="2">325</td> <td rowspan="2">1.3</td> <td rowspan="2">N/A</td> </tr> <tr> <td>SQ</td> </tr> </tbody> </table> <p>N/A is not applicable</p>	Location	Treatment	Total Placed	21 Day Mortality	% Mortality	% Hatchability	1	<i>In ovo</i>	22,600	794	3.5	74.7	1	Control	24,700	721	2.9	87.4	<i>In ovo</i>	1	Control	24,700	815	3.3	<i>In ovo</i>	1	Control	24,700	679	2.7	<i>In ovo</i>	2	<i>In ovo</i>	20,200	398	2	89.3	2	<i>In ovo</i>	20,300	369	1.8	2	Control	19,100	410	2.1	86.6	<i>In ovo</i>	2	Control	19,100	678	3.5	N/A	SQ	2	Control	19,100	791	4.1	N/A	SQ	3	SQ	24,000	542	2.3	N/A	3	SQ	24,029	267	1.1	N/A	3	Control	25,000	332	1.3	N/A	SQ	3	Control	25,000	325	1.3	N/A	SQ
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<b>USDA Approval Date</b>	October 19, 2017
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	SQ				N/A																																																																																								
3	SQ	24,000	542	2.3	N/A																																																																																								
3	SQ	24,029	267	1.1	N/A																																																																																								
3	Control	25,000	332	1.3	N/A																																																																																								
	SQ																																																																																												
3	Control	25,000	325	1.3																																																																																									
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<b>USDA Approval Date</b>	October 19, 2017																																																																																												