



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	1A89.R0
True Name	Bursal Disease-Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Poulvac Procerta HVT-IBD-ND - No distributor specified
Date of Compilation Summary	June 22, 2022

**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>	Infectious Bursal Disease Virus (IBDV)
<b>Study Purpose</b>	Demonstrate efficacy against Infectious Bursal disease
<b>Product Administration</b>	One dose by the <i>in ovo</i> route
<b>Study Animals</b>	Chicken eggs at 18 days of embryonation, divided into 3 groups: Group 1 vaccinated with product and challenged. Group 2 placebo vaccinated and challenged (positive control) Group 3 sham vaccinated non-challenged (negative control)
<b>Challenge Description</b>	USDA STD strain given at 34 days of age
<b>Interval observed after challenge</b>	The birds were observed daily for 4 days then bursa were examined
<b>Results</b>	Vaccines and controls were evaluated in terms of Infectious Bursal disease grossly observable lesions per the criteria in 9 CFR 113.331(c).  Birds with gross observable lesions: Group 1: 0/30 Group 2: 28/30 Group 3: 0/30  Requirements of 9 CFR 113.331(c) were met.  Raw data on attached page
<b>USDA Approval Date</b>	23 April 2020

### Evaluation of Bursal Lesions

Group	Animal	Edema	Edema & Hemorrhage
1	210		
1	212		
1	227		
1	228		
1	232		
1	240		
1	246		
1	247		
1	251		
1	253		
1	255		
1	270		
1	272		
1	276		
1	279		

1	280		
1	282		
1	283		
1	286		
1	292		
1	295		
1	301		
1	303		
1	306		
1	311		
1	315		
1	316		
1	328		
1	332		
1	344		
2	201	X	
2	204		
2	205	X	
2	207	X	
2	222		X
2	223	X	
2	229	X	
2	230	X	
2	233	X	
2	238	X	
2	242	X	
2	243	X	
2	254	X	
2	261	X	
2	263	X	
2	264	X	
2	288	X	
2	289	X	
2	304	X	
2	307	X	
2	308	X	
2	317		X
2	318	X	
2	320	X	
2	323	X	
2	330	X	
2	333	X	
2	336		

2	340	X	
2	342	X	
3	208		
3	216		
3	217		
3	224		
3	231		
3	236		
3	239		
3	248		
3	256		
3	258		
3	259		
3	260		
3	267		
3	268		
3	269		
3	277		
3	278		
3	285		
3	287		
3	294		
3	297		
3	299		
3	300		
3	309		
3	313		
3	321		
3	324		
3	331		
3	339		
3	343		

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious Bursal Disease Virus (IBDV)
<b>Study Purpose</b>	Demonstrate efficacy against Infectious Bursal disease
<b>Product Administration</b>	One dose by the subcutaneous route
<b>Study Animals</b>	Day-old chicks divided into three groups Group 1 vaccinated with product and challenged Group 2 placebo vaccinated and challenged (positive control) Group 3 sham vaccinated non-challenged (negative control)
<b>Challenge Description</b>	USDA STD IBDV strain given at 34 days of age
<b>Interval observed after challenge</b>	The birds were observed daily for 4 days then bursa were examined
<b>Results</b>	Vaccines and controls were evaluated in terms of Infectious Bursal disease grossly observable lesions per the criteria in 9 CFR 113.331(c).  Birds with grossly observable lesions: Group 1: 0/30 Group 2: 30/30 Group 3: 0/30  Requirements of 9 CFR 113.331(c) were met.  Raw data on attached page
<b>USDA Approval Date</b>	24 April 2020

<b>Evaluation of Bursal Lesions</b>			
<b>Group</b>	<b>Animal</b>	<b>Edema</b>	<b>Edema &amp; Hemorrhage</b>
1	405		
1	414		
1	415		
1	417		
1	421		
1	428		
1	436		
1	440		
1	443		
1	444		
1	445		
1	446		
1	449		
1	452		
1	457		
1	460		
1	465		
1	468		
1	473		
1	479		
1	492		
1	493		
1	496		
1	504		
1	524		
1	525		
1	527		
1	528		
1	529		
1	534		
2	407	X	
2	409	X	
2	413	X	
2	416	X	
2	420	X	

2	423	X	
2	432	X	
2	433	X	
2	437	X	
2	438	X	
2	439	X	
2	447	X	
2	450	X	
2	463	X	
2	467	X	
2	469		X
2	474	X	
2	476	X	
2	480	X	
2	481	X	
2	487	X	
2	488	X	
2	495	X	
2	506	X	
2	509	X	
2	512	X	
2	515	X	
2	542	X	
2	543	X	
2	544	X	
3	401		
3	402		
3	406		
3	412		
3	422		
3	429		
3	430		
3	451		
3	454		
3	456		
3	458		
3	459		
3	462		
3	471		

3	475		
3	477		
3	484		
3	491		
3	494		
3	500		
3	503		
3	510		
3	513		
3	518		
3	521		
3	535		
3	537		
3	539		
3	540		
3	541		



<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious Bursal Disease Virus (IBDV)
<b>Study Purpose</b>	Demonstrate effectiveness against infectious bursal disease 63 days after vaccination
<b>Product Administration</b>	One dose by the <i>in ovo</i> route
<b>Study Animals</b>	Chicken eggs at 18 days of embryonation, divided into 3 groups: Group 1 vaccinated with product <i>in ovo</i> and challenged Group 2 placebo vaccinated and challenged (control) Group 3 placebo vaccinated and not challenged (control)
<b>Challenge Description</b>	USDA STD strain given at 63 days after vaccination
<b>Interval observed after challenge</b>	The birds were observed daily for 4 days post-challenge
<b>Results</b>	Vaccines and controls were evaluated in terms of infectious bursal disease grossly observable lesions per the criteria in 9 CFR 113.331(c).  Birds with gross observable lesions: Group 1: 0/30 Group 2: 28/30 Group 3: 0/30  Requirements of 9 CFR 113.331(c)(3)(ii) were met.  Raw data on attached page
<b>USDA Approval Date</b>	June 9, 2020

Group	Animal	Peri-Bursal Edema	Peri-Bursal Edema & Hemorrhage
1	108		
1	112		
1	120		
1	126		
1	134		
1	136		
1	141		
1	143		
1	153		
1	162		
1	168		
1	173		

1	180		
1	189		
1	192		
1	214		
1	222		
1	224		
1	251		
1	259		
1	272		
1	282		
1	291		
1	294		
1	303		
1	309		
1	314		
1	324		
1	328		
1	333		
2	101	X	
2	102	X	
2	110	X	
2	117		X
2	124	X	
2	127	X	
2	130		X
2	135		
2	151	X	
2	155	X	
2	160	X	
2	164		X
2	188	X	
2	193	X	
2	196		
2	198	X	
2	208	X	
2	217	X	
2	250	X	
2	252	X	
2	263	X	
2	264	X	
2	271	X	
2	287		X
2	288	X	

2	307	X	
2	308	X	
2	323		X
2	329		X
2	338	X	
3	123		
3	133		
3	138		
3	145		
3	149		
3	152		
3	156		
3	169		
3	172		
3	174		
3	183		
3	201		
3	202		
3	204		
3	216		
3	223		
3	239		
3	246		
3	261		
3	267		
3	276		
3	279		
3	285		
3	292		
3	310		
3	320		
3	327		
3	335		
3	339		
3	340		

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious Bursal Disease Virus (IBDV)
<b>Study Purpose</b>	Demonstrate effectiveness against infectious bursal disease 63 days after vaccination
<b>Product Administration</b>	One dose by the subcutaneous route
<b>Study Animals</b>	Day old chicks divided into 3 groups: Group 1 vaccinated with product subcutaneously and challenged Group 2 placebo vaccinated and challenged (control) Group 3 placebo vaccinated and not challenged (control)
<b>Challenge Description</b>	USDA STD strain given at 63 days after vaccination
<b>Interval observed after challenge</b>	The birds were observed daily for 4 days post-challenge
<b>Results</b>	Vaccines and controls were evaluated in terms of infectious bursal disease grossly observable lesions per the criteria in 9 CFR 113.331(c).  Birds with gross observable lesions: Group 1: 0/30 Group 2: 28/30 Group 3: 0/30  Requirements of 9 CFR 113.331(c)(3)(3)(ii) were met.  Raw data on attached page
<b>USDA Approval Date</b>	June 9, 2020

<b>Group</b>	<b>Animal</b>	<b>Peri-Bursal Edema</b>	<b>Peri-Bursal Edema &amp; Hemorrhage</b>
1	105		
1	106		
1	122		
1	140		
1	142		
1	148		
1	161		
1	171		
1	190		
1	203		
1	207		
1	215		

1	226		
1	231		
1	237		
1	243		
1	244		
1	254		
1	257		
1	265		
1	266		
1	273		
1	283		
1	293		
1	295		
1	296		
1	299		
1	300		
1	325		
1	331		
2	101	X	
2	102	X	
2	110	X	
2	117		X
2	124	X	
2	127	X	
2	130		X
2	135		
2	151	X	
2	155	X	
2	160	X	
2	164		X
2	188	X	
2	193	X	
2	196		
2	198	X	
2	208	X	
2	217	X	
2	250	X	
2	252	X	
2	263	X	
2	264	X	
2	271	X	
2	287		X
2	288	X	

2	307	X	
2	308	X	
2	323		X
2	329		X
2	338	X	
3	123		
3	133		
3	138		
3	145		
3	149		
3	152		
3	156		
3	169		
3	172		
3	174		
3	183		
3	201		
3	202		
3	204		
3	216		
3	223		
3	239		
3	246		
3	261		
3	267		
3	276		
3	279		
3	285		
3	292		
3	310		
3	320		
3	327		
3	335		
3	339		
3	340		

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Marek's Disease Virus Serotype 3
<b>Study Purpose</b>	Demonstrate efficacy against Marek's Disease
<b>Product Administration</b>	One dose by the <i>in ovo</i> route
<b>Study Animals</b>	Chicken eggs at 18 days of embryonation, divided into 3 groups: Group 1 vaccinated with product and challenged Group 2 placebo vaccinated and challenged (positive control) Group 3 placebo vaccinated non-challenged (negative control)
<b>Challenge Description</b>	GA 22 strain given at 5 days of age.
<b>Interval observed after challenge</b>	The birds were observed daily for 49 days.
<b>Results</b>	Vaccines and controls were evaluated in terms of Marek's disease grossly observable lesions per the criteria in 9 CFR 113.330(c).  Birds with grossly observable lesions: Group 1: 6/30 Group 2: 27/29 Group 3: 0/30  Requirements of 9 CFR 113.330(c) were met.  Raw data on attached page
<b>USDA Approval Date</b>	May 13, 2021

Group	Animal	Eyes	Skin	Breast Muscle	Heart	Liver	Proventriculus	Spleen	Gonads	Kidney	Intestines	Pancreas	Nerves	Thymus
1	207													
1	209													
1	212													
1	224													
1	243								X					
1	251			X		X		X	X					
1	273			X		X				X			X	X
1	290													
1	296													
1	301													

Group	Animal	Eyes	Skin	Breast Muscle	Heart	Liver	Proventriculus	Spleen	Gonads	Kidney	Intestines	Pancreas	Nerves	Thymus
1	303													
1	312													
1	318													
1	326				X	X		X	X	X	X			
1	329													
1	342													
1	345													
1	356							X	X	X	X			
1	362													
1	364													
1	366													
1	371													
1	378													
1	389													
1	390													
1	391				X	X		X	X	X				
1	397													
1	402													
1	415													
1	416													
2	206				X			X			X			
2	213					X				X	X			
2	214				X	X				X	X			
2	218				X	X								
2	219							X		X	X			
2	234				X			X			X			
2	242	X	X		X	X		X	X		X	X		X
2	279				X			X			X			
2	282												X	
2	286		X		X	X				X				
2	294				X	X			X		X			
2	298				X			X						
2	302				X	X			X		X			
2	306		X			X		X		X				
2	324													



Group	Animal	Eyes	Skin	Breast Muscle	Heart	Liver	Proventriculus	Spleen	Gonads	Kidney	Intestines	Pancreas	Nerves	Thymus
2	327				X	X				X				
2	337					X				X	X			
2	346					X		X		X	X			
2	355				X	X	X	X		X	X	X		
2	368				X	X		X			X			
2	374	X			X	X	X	X				X		
2	377		X		X	X			X					
2	383				X	X	X	X						
2	384		X		X	X					X			
2	386												X	
2	393					X		X						
2	403													
2	404		X			X		X						
2	407					X		X		X				
3	215													
3	222													
3	227													
3	229													
3	236													
3	239													
3	246													
3	252													
3	253													
3	254													
3	255													
3	258													
3	264													
3	266													
3	275													
3	297													
3	316													
3	320													
3	321													
3	331													
3	332													

<b>Group</b>	<b>Animal</b>	<b>Eyes</b>	<b>Skin</b>	<b>Breast Muscle</b>	<b>Heart</b>	<b>Liver</b>	<b>Proventriculus</b>	<b>Spleen</b>	<b>Gonads</b>	<b>Kidney</b>	<b>Intestines</b>	<b>Pancreas</b>	<b>Nerves</b>	<b>Thymus</b>
3	335													
3	336													
3	339													
3	357													
3	370													
3	373													
3	382													
3	401													
3	406													

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Marek's Disease Virus Serotype 3
<b>Study Purpose</b>	Demonstrate efficacy against Marek's Disease
<b>Product Administration</b>	One dose by the subcutaneous route
<b>Study Animals</b>	Day-old chicks divided into 3 groups Group 1 vaccinated with product and challenged Group 2 placebo vaccinated and challenged (positive control) Group 3 sham vaccinated non-challenged (negative control)
<b>Challenge Description</b>	Marek's Disease Virus GA 22 strain given at 5 days of age.
<b>Interval observed after challenge</b>	The birds were observed daily for 49 days, then evaluated for grossly observable lesions consistent with Marek's disease
<b>Results</b>	Vaccines and controls were evaluated in terms of Marek's disease grossly observable lesions per the criteria in 9 CFR 113.330(c).  Birds with grossly observable lesions: Group 1: 5/30 Group 2: 25/30 Group 3: 0/30  Requirements of 9 CFR 113.330(c) were met.  Raw data on attached page
<b>USDA Approval Date</b>	11 May 2020

Group	Animal	Skin	Breast Muscle	Heart	Liver	Spleen	Gonads	Kidney	Intestines	Nerves
1	404									
1	408									
1	410									
1	411									
1	416									
1	425									
1	428									
1	430									
1	434									
1	441					X				
1	445									
1	447				X	X		X	X	
1	456									
1	459		X		X			X		
1	461									
1	462									
1	470									
1	475				X				X	
1	476									
1	483									
1	496									
1	509									
1	518									
1	524									
1	532		X		X		X	X		
1	544									
1	545									
1	549									
1	550									
1	560									
2	402		X	X	X		X	X		
2	403			X	X	X	X	X		
2	415			X			X	X	X	
2	421						X	X		
2	427	X			X	X		X	X	
2	429	X		X	X	X		X		
2	433	X		X	X			X	X	

<b>Group</b>	<b>Animal</b>	<b>Skin</b>	<b>Breast Muscle</b>	<b>Heart</b>	<b>Liver</b>	<b>Spleen</b>	<b>Gonads</b>	<b>Kidney</b>	<b>Intestines</b>	<b>Nerves</b>
2	435			X	X		X	X		X
2	443	X		X	X	X				
2	453	X		X	X					
2	468			X		X	X	X		
2	472									
2	474			X			X	X		
2	477				X	X		X		X
2	484									
2	499			X	X	X				
2	502				X				X	
2	503					X		X	X	
2	506			X		X				
2	516					X		X	X	
2	517			X	X	X				X
2	523			X				X		
2	527									
2	529				X	X				X
2	531	X		X	X	X		X		
2	535	X		X		X		X		
2	543				X	X		X		
2	546			X		X		X		
2	548									
2	556									
3	406									
3	412									
3	414									
3	422									
3	431									
3	436									
3	437									
3	438									
3	442									
3	444									
3	446									
3	451									
3	455									
3	458									

<b>Group</b>	<b>Animal</b>	<b>Skin</b>	<b>Breast Muscle</b>	<b>Heart</b>	<b>Liver</b>	<b>Spleen</b>	<b>Gonads</b>	<b>Kidney</b>	<b>Intestines</b>	<b>Nerves</b>
3	464									
3	465									
3	473									
3	478									
3	481									
3	487									
3	488									
3	494									
3	501									
3	508									
3	537									
3	538									
3	541									
3	553									
3	554									
3	559									

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Newcastle disease Virus (NDV)
<b>Study Purpose</b>	Demonstrate efficacy against Newcastle disease
<b>Product Administration</b>	One dose by <i>in ovo</i> route
<b>Study Animals</b>	Chicken eggs at 18 days of embryonation, divided into 3 groups: Group 1 vaccinated with product and challenged Group 2 placebo vaccinated and challenged (positive control) Group 3 sham vaccinated non-challenged (negative control)
<b>Challenge Description</b>	Newcastle Disease Virus strain Texas GB given at 28 days of age.
<b>Interval observed after challenge</b>	Birds were daily observed for 14 days post challenge for clinical signs of NDV, including mortality.
<b>Results</b>	Vaccines and controls were evaluated in terms of Newcastle disease clinical signs per the criteria in 9 CFR 113.329(c).  Birds with clinical signs, including mortality: Group 1: 2/40 Group 2: 40/40 Group 3: 0/40  Requirements of 9 CFR 113.329(c) were met.  Raw data on attached page
<b>USDA Approval Date</b>	27 April 2020

Group	Animal	Clinical Signs of NDV		
		Paralysis	Respiratory	Mortality
1	101			
1	105			
1	116			
1	117			
1	120			
1	121			
1	129			
1	131			
1	132			
1	133			
1	138	X	X	
1	140			
1	143			
1	164	X	X	
1	173			
1	178			
1	182			
1	186			
1	189			
1	191			
1	196			
1	197			
1	198			
1	201			
1	204			
1	206			
1	213			
1	216			
1	220			
1	221			
1	232			
1	234			
1	239			
1	248			
1	253			
1	254			
1	255			
1	262			
1	270			
1	292			
2	114	X	X	



2	122	X	X	
2	125			X
2	136	X	X	
2	147	X	X	
2	148			X
2	149	X	X	
2	150	X	X	
2	161	X	X	
2	166	X	X	
2	167	X	X	
2	176			X
2	179	X	X	
2	181	X	X	
2	183	X	X	
2	187	X	X	
2	193	X	X	
2	199	X	X	
2	200	X	X	
2	217	X	X	
2	225	X	X	
2	226	X	X	
2	227	X	X	
2	231	X	X	
2	236			X
2	242	X	X	
2	243	X	X	
2	245	X	X	
2	246	X	X	
2	251			X
2	252	X	X	
2	258	X	X	
2	259	X	X	
2	260	X	X	
2	279	X	X	
2	280	X	X	
2	287	X	X	
2	288	X	X	
2	289	X	X	
2	291	X	X	
3	102			
3	103			
3	104			
3	115			
3	123			
3	124			

3	145			
3	151			
3	157			
3	158			
3	159			
3	162			
3	163			
3	168			
3	169			
3	170			
3	172			
3	180			
3	184			
3	185			
3	194			
3	202			
3	211			
3	212			
3	214			
3	222			
3	223			
3	228			
3	229			
3	240			
3	250			
3	256			
3	257			
3	268			
3	269			
3	277			
3	278			
3	281			
3	284			
3	290			

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Newcastle Disease Virus (NDV)
<b>Study Purpose</b>	Demonstrate effectiveness against NDV 63 days after vaccination
<b>Product Administration</b>	One dose by the <i>in ovo</i> route
<b>Study Animals</b>	Chicken eggs at 18 days of embryonation, divided into 3 groups: Group 1 vaccinated with product <i>in ovo</i> and challenged Group 2 placebo vaccinated and challenged (control) Group 3 placebo vaccinated and not challenged (control)
<b>Challenge Description</b>	NDV Texas GB strain given at 63 days after vaccination
<b>Interval observed after challenge</b>	The birds were observed daily for 14 days post-challenge
<b>Results</b>	Vaccines 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, including mortality: Group 1: 0/28 Group 2: 29/29 Group 3: 0/30  Requirements of 9 CFR 113.329(c)(4) were met.  Raw data on attached page
<b>USDA Approval Date</b>	September 21, 2020

Group	Bird	Clinical Signs of NDV			
		Mortality	Depression	Paralysis	Respiratory
1	110				
1	111				
1	129				
1	132				
1	137				
1	169				
1	180				
1	186				
1	189				
1	192				
1	214				

1	218				
1	230				
1	235				
1	247				
1	248				
1	250				
1	264				
1	271				
1	272				
1	274				
1	296				
1	298				
1	300				
1	307				
1	322				
1	325				
1	339				
2	113	X			
2	139			X	
2	143				X
2	148			X	X
2	150			X	
2	152			X	X
2	153				X
2	155			X	
2	157			X	X
2	166			X	
2	172			X	
2	182			X	
2	190			X	X
2	191			X	X
2	195			X	
2	201	X			
2	217			X	
2	222	X			
2	225			X	
2	228			X	X

2	234				X
2	260			X	X
2	263			X	
2	266			X	X
2	269			X	
2	270			X	X
2	275			X	X
2	281				X
2	312			X	X
3	106				
3	117				
3	121				
3	133				
3	136				
3	140				
3	141				
3	149				
3	151				
3	154				
3	156				
3	163				
3	175				
3	176				
3	188				
3	194				
3	200				
3	202				
3	208				
3	243				
3	255				
3	291				
3	297				
3	302				
3	305				
3	313				
3	321				
3	327				

3	330				
3	331				

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Newcastle Disease Virus (NDV)
<b>Study Purpose</b>	Demonstrate effectiveness against NDV 63 days after vaccination
<b>Product Administration</b>	One dose by the subcutaneous route
<b>Study Animals</b>	Day old chicks divided into 3 groups: Group 1 vaccinated with product and challenged Group 2 placebo vaccinated and challenged (control) Group 3 placebo vaccinated not challenged (control)
<b>Challenge Description</b>	NDV Texas GB strain given at 63 days after vaccination
<b>Interval observed after challenge</b>	The birds were observed daily for 14 days post-challenge
<b>Results</b>	Vaccines 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, including mortality: Group 1: 1/30 Group 2: 29/29 Group 3: 0/30  Requirements of 9 CFR 113.329(c)(4) were met.  Raw data on attached page
<b>USDA Approval Date</b>	September 21, 2020

Group	Bird	Clinical Signs of NDV			
		Mortality	Depression	Paralysis	Respiratory
1	101				
1	112				
1	116				
1	123				
1	124				
1	128				
1	145				
1	158				
1	160				
1	167				
1	170				

1	178				
1	197				
1	207	X			
1	211				
1	221				
1	237				
1	241				
1	254				
1	273				
1	276				
1	284				
1	286				
1	292				
1	314				
1	323				
1	329				
1	332				
1	334				
1	336				
2	113	X			
2	139			X	
2	143				X
2	148			X	X
2	150			X	
2	152			X	X
2	153				X
2	155			X	
2	157			X	X
2	166			X	
2	172			X	
2	182			X	
2	190			X	X
2	191			X	X
2	195			X	
2	201	X			
2	217			X	
2	222	X			



2	225			X	
2	228			X	X
2	234				X
2	260			X	X
2	263			X	
2	266			X	X
2	269			X	
2	270			X	X
2	275			X	X
2	281				X
2	312			X	X
3	106				
3	117				
3	121				
3	133				
3	136				
3	140				
3	141				
3	149				
3	151				
3	154				
3	156				
3	163				
3	175				
3	176				
3	188				
3	194				
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3	202				
3	208				
3	243				
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3	291				
3	297				
3	302				
3	305				
3	313				

3	321				
3	327				
3	330				
3	331				

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Newcastle disease Virus
<b>Study Purpose</b>	Demonstrate efficacy against Newcastle disease
<b>Product Administration</b>	One dose by subcutaneous route
<b>Study Animals</b>	Day-old chicks divided into 3 groups Group 1 vaccinated with product and challenged Group 2 placebo vaccinated and challenged (positive control) Group 3 placebo vaccinated non-challenged (negative control)
<b>Challenge Description</b>	USDA Newcastle Disease Virus strain Texas GB given at 28 days of age.
<b>Interval observed after challenge</b>	Birds were daily observed for 14 days post challenge.
<b>Results</b>	Vaccines and controls were evaluated in terms of Newcastle disease clinical signs per the criteria in 9 CFR 113.329(c).  Birds with clinical signs, including mortality: Group 1: 0/40 Group 2: 40/40 Group 3: 1/40  Requirements of 9 CFR 113.329(c) were met.  Raw data on attached page
<b>USDA Approval Date</b>	April 28, 2020

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

Group	Animal	Clinical Signs of NDV			
		Paralysis	Depression	Respiratory	Mortality
1	308				
1	313				
1	322				
1	325				
1	330				
1	331				
1	332				
1	338				
1	346				
1	351				
1	353				
1	354				
1	358				

1	362				
1	373				
1	375				
1	377				
1	382				
1	383				
1	385				
1	390				
1	400				
1	401				
1	406				
1	407				
1	415				
1	420				
1	428				
1	432				
1	447				
1	452				
1	456				
1	461				
1	468				
1	469				
1	470				
1	475				
1	480				
1	483				
1	490				
2	301	X	X	X	
2	305	X	X	X	
2	312	X	X	X	
2	314	X	X	X	
2	315	X	X	X	
2	316	X	X	X	
2	319	X	X	X	
2	329	X	X	X	
2	333	X	X	X	
2	334	X	X	X	
2	342	X	X	X	
2	344	X	X	X	
2	356	X	X	X	
2	360	X	X	X	
2	364	X	X	X	
2	368	X	X	X	
2	379	X	X	X	
2	380	X	X	X	

2	384	X	X	X	
2	387	X	X	X	
2	395				X
2	398				X
2	404	X	X	X	
2	405	X	X	X	
2	408				X
2	409	X	X	X	
2	412				X
2	416	X	X	X	
2	417	X	X	X	
2	421				X
2	424	X	X	X	
2	425	X	X	X	
2	426	X	X	X	
2	434	X	X	X	
2	464	X	X	X	
2	467				X
2	472	X	X	X	
2	481				X
2	485	X	X	X	
2	491	X	X	X	
3	304				
3	307				
3	309				
3	320				
3	321				
3	337				
3	341				
3	352				
3	355				
3	357				
3	366				
3	369				
3	371				
3	376				
3	388				
3	389				
3	396				
3	397				
3	402				
3	411				
3	422				
3	433				
3	437				

3	443				
3	444				
3	446				
3	448				
3	454				
3	455				
3	457				
3	460				
3	463				X
3	473				
3	477				
3	478				
3	479				
3	482				
3	484				
3	486				

<b>Study Type</b>	Safety																																																			
<b>Pertaining to</b>	ALL																																																			
<b>Study Purpose</b>	To demonstrate safety under field conditions.																																																			
<b>Product Administration</b>	One dose administered in ovo (IO) or subcutaneously (SC) at day-of-hatch.																																																			
<b>Study Animals</b>	Approximately 237,452 commercial broiler chickens Site A: Vaccinates: 34,300, Controls: 34,300 Site B: Vaccinates: 26,900, Controls: 26,900 Site C: Vaccinates: 58,058, Controls: 56,994																																																			
<b>Challenge Description</b>																																																				
<b>Interval observed after challenge</b>																																																				
<b>Results</b>	<table border="1"> <thead> <tr> <th>Description</th> <th>Site</th> <th>Route</th> <th>Percent Hatchability</th> <th>Total Placed</th> <th>Overall Mortality (%) 35 to 62 days-of-age</th> <th>Total Condemnation Rates (%)</th> </tr> </thead> <tbody> <tr> <td rowspan="3">Vaccinates</td> <td>A</td> <td>IO</td> <td>87.30</td> <td>34,300</td> <td>5.64</td> <td>0.167</td> </tr> <tr> <td>B</td> <td>IO</td> <td>86.13</td> <td>26,900</td> <td>4.09</td> <td>0.130</td> </tr> <tr> <td>C</td> <td>SC</td> <td>NA</td> <td>58,058</td> <td>5.16</td> <td>0.716</td> </tr> <tr> <td rowspan="3">Controls</td> <td>A</td> <td>IO</td> <td>83.55</td> <td>34,300</td> <td>5.08</td> <td>0.672</td> </tr> <tr> <td>B</td> <td>IO</td> <td>79.07</td> <td>26,900</td> <td>3.30</td> <td>0.168</td> </tr> <tr> <td>C</td> <td>SC</td> <td>NA</td> <td>56,994</td> <td>5.87</td> <td>0.791</td> </tr> </tbody> </table>							Description	Site	Route	Percent Hatchability	Total Placed	Overall Mortality (%) 35 to 62 days-of-age	Total Condemnation Rates (%)	Vaccinates	A	IO	87.30	34,300	5.64	0.167	B	IO	86.13	26,900	4.09	0.130	C	SC	NA	58,058	5.16	0.716	Controls	A	IO	83.55	34,300	5.08	0.672	B	IO	79.07	26,900	3.30	0.168	C	SC	NA	56,994	5.87	0.791
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