



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1C91.R1
True Name	Infectious Laryngotracheitis-Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Innovax-ND-ILT - No distributor specified
Date of Compilation Summary	June 20, 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.

Study Type	Efficacy
Pertaining to	Infectious Laryngotracheitis Virus
Study Purpose	Evaluate the efficacy against Infectious Laryngotracheitis (ILT)
Product Administration	One dose administered <i>in ovo</i> at 18 days of embryonation
Study Animals	Group 1: 35 embryos, low dose study vaccine Group 2: 35 embryos, low dose study vaccine Group 3: 35 embryos, high dose study vaccine Group 4a: 15 embryos, diluent inoculated challenged controls Group 4b: 15 embryos, diluent inoculated nonchallenged controls
Challenge Description	Challenged with ILT virus four weeks postvaccination
Interval observed after challenge	Observed for clinical signs for 10 days postchallenge. Tissues evaluated for gross lesions 10 days postchallenge.
Results	Birds affected with Infectious Laryngotracheitis Disease: Group 1: 5/35 Group 2: 5/34 Group 3: 2/35 Group 4a: 13/14 Group 4b: 0/15 Requirements per 9 CFR 113.328(c)(5) were met. Raw data attached
USDA Approval Date	May 21, 2015

Treatment Group	Wing Tag No.	Isolation Unit No.	End of Study Status	Clinical Observations	Necropsy Result	Result
1	507	12	Alive	N	0	0
1	509	14	Alive	N	0	0
1	514	14	Dead	L,G,D	1	1
1	515	13	Alive	N	0	0
1	521	12	Alive	N	0	0
1	523	12	Alive	N	0	0
1	525	14	Dead	G,EB	1	1
1	528	13	Alive	N	0	0
1	530	13	Alive	N	0	0
1	531	14	Alive	N	0	0
1	544	12	Alive	N	0	0
1	561	12	Alive	N	0	0
1	562	12	Alive	N	0	0
1	568	12	Alive	N	0	0
1	570	13	Alive	N	0	0
1	572	13	Alive	N	0	0
1	574	14	Dead	D,L,G	1	1
1	579	14	Alive	N	0	0
1	580	12	Alive	N	0	0
1	583	13	Alive	N	0	0
1	596	13	Dead	L,G	1	1
1	597	12	Dead	G	1	1
1	602	13	Alive	N	0	0
1	606	14	Alive	N	0	0
1	609	14	Alive	N	0	0
1	613	12	Alive	N	0	0
1	619	14	Alive	N	0	0
1	621	13	Alive	N	0	0
1	627	14	Alive	N	0	0
1	628	13	Alive	N	0	0
1	629	12	Alive	N	0	0
1	630	13	Alive	N	0	0
1	632	14	Alive	N	0	0
1	633	12	Alive	N	0	0
1	635	13	Alive	N	0	0

Scoring: "0" indicates no signs of Infectious Laryngotracheitis

"1" indicates signs of Infectious Laryngotracheitis

C = Cough, 2 or more days; D = Severe depression, 2 or more days; E = Euthanized; EB = Expectorations with blood; G = Gasping, 2 or more days. If gasping occurs with severe depression or labored breathing during the observation period, bird is scored as positive for ILT; L = Labored breathing, 2 or more days; M = Mortality; N = No signs of Infectious Laryngotracheitis; O = Acute, ocular discharge/swelling

Treatment Group	Wing Tag No.	Isolation Unit No.	End of Study Status	Clinical Observations	Necropsy Result	Result
2	501	8	Alive	N	0	0
2	503	7	Alive	N	0	0
2	504	6	Alive	N	0	0
2	505	7	Alive	N	0	0
2	506	8	Alive	N	0	0
2	510	8	Alive	N	0	0
2	512	7	Alive	N	0	0
2	516	7	Alive	N	0	0
2	517	8	Alive	N	0	0
2	518	6	Alive	N	0	0
2	526	8	Alive	N	0	0
2	532	8	Dead	L,G,O	1	1
2	533	8	Alive	N	0	0
2	534	6	Alive	N	0	0
2	537	8	Dead	C,G,EB	1	1
2	542	8	Alive	N	0	0
2	545	7	Alive	N	0	0
2	546	7	Dead	L,G	1	1
2	551	6	Alive	C,L,G	0	1
2	554	6	Alive	N	0	0
2	558	8	Alive	N	0	0
2	559	6	Alive	N	0	0
2	563	7	Alive	N	0	0
2	569	7	Alive	N	0	0
2	573	7	Alive	N	0	0
2	584	6	Alive	N	0	0
2	587	7	Alive	N	0	0
2	588	6	Dead	G	1	1
2	589	6	Alive	N	0	0
2	590	6	Alive	N	0	0
2	595	6	Alive	N	0	0
2	599	8	Alive	N	0	0
2	608	7	Alive	N	0	0
2	610	7	Alive	N	0	0

Scoring: "0" indicates no signs of Infectious Laryngotracheitis

"1" indicates signs of Infectious Laryngotracheitis

C = Cough, 2 or more days; D = Severe depression, 2 or more days; E = Euthanized; EB = Expectoration with blood; G = Gasping, 2 or more days. If gasping occurs with severe depression or labored breathing during the observation period, bird is scored as positive for ILT; L = Labored breathing, 2 or more days; M = Mortality; N = No signs of Infectious Laryngotracheitis; O = Acute, ocular discharge/swelling

One bird (536) removed after vaccination and before challenge due to injury.

Treatment Group	Wing Tag No.	Isolation Unit No.	End of Study Status	Clinical Observations	Necropsy Result	Result
3	502	9	Alive	N	0	0
3	511	9	Alive	N	0	0
3	519	3	Alive	N	0	0
3	524	10	Alive	N	0	0
3	527	3	Alive	N	0	0
3	535	3	Alive	N	0	0
3	539	9	Alive	N	0	0
3	540	10	Alive	N	0	0
3	547	10	Alive	N	0	0
3	548	10	Alive	N	0	0
3	549	3	Alive	N	0	0
3	553	9	Alive	N	0	0
3	555	3	Alive	N	0	0
3	557	3	Alive	N	0	0
3	565	3	Dead	G, D	1	1
3	567	10	Alive	N	0	0
3	575	10	Alive	N	0	0
3	576	3	Alive	N	0	0
3	577	10	Alive	N	0	0
3	581	9	Alive	N	0	0
3	582	10	Alive	N	0	0
3	585	10	Alive	N	0	0
3	586	9	Alive	N	0	0
3	591	3	Alive	N	0	0
3	593	9	Alive	N	0	0
3	594	9	Alive	N	0	0
3	598	9	Alive	N	0	0
3	600	9	Alive	N	0	0
3	601	10	Dead	G	1	1
3	604	9	Alive	N	0	0
3	605	3	Alive	N	0	0
3	622	10	Alive	N	0	0
3	623	9	Alive	N	0	0
3	631	3	Alive	N	0	0
3	634	10	Alive	N	0	0

Scoring: "0" indicates no signs of Infectious Laryngotracheitis (07-Jan-14 through 16-Jan-14)

"1" indicates signs of Infectious Laryngotracheitis (07-Jan-14 through 16-Jan-14)

C = Cough, 2 or more days; D = Severe depression, 2 or more days; E = Euthanized; EB = Expectoration with blood; G = Gasping, 2 or more days. If gasping occurs with severe depression or labored breathing during the observation period, bird is scored as positive for ILT; L = Labored breathing, 2 or more days; M = Mortality; N = No signs of Infectious Laryngotracheitis; O = Acute, ocular discharge/swelling

Treatment Group	Wing Tag No.	Isolation Unit No.	End of Study Status	Clinical Observations	Necropsy Score	Result
4a	513	12	Dead	C,G	1	1
4a	522	6	Dead	L,G	1	1
4a	541	8	Alive	N	0	0
4a	543	3	Dead	L,C,G	1	1
4a	552	3	Dead	C,G	1	1
4a	556	9	Dead	D,L,G	1	1
4a	564	13	Dead	L,G	1	1
4a	566	7	Dead	L,G	1	1
4a	607	10	Dead	G,L	1	1
4a	614	8	Dead	G,M	1	1
4a	615	7	Dead	C,L,G	1	1
4a	616	14	Dead	G,D,L,M	1	1
4a	617	9	Dead	G	1	1
4a	624	6	Dead	L,G,M	1	1
4b	508	2	Alive	N	0	0
4b	520	2	Alive	N	0	0
4b	529	2	Alive	N	0	0
4b	538	2	Alive	N	0	0
4b	550	2	Alive	N	0	0
4b	560	2	Alive	N	0	0
4b	571	2	Alive	N	0	0
4b	578	2	Alive	N	0	0
4b	603	2	Alive	N	0	0
4b	611	2	Alive	N	0	0
4b	612	2	Alive	N	0	0
4b	618	2	Alive	N	0	0
4b	620	2	Alive	N	0	0
4b	625	2	Alive	N	0	0
4b	626	2	Alive	N	0	0

Scoring: "0" indicates no signs of Infectious Laryngotracheitis

"1" indicates signs of Infectious Laryngotracheitis

C = Cough, 2 or more days; D = Severe depression, 2 or more days; E = Euthanized; EB = Expectoration with blood; G = Gasping, 2 or more days. If gasping occurs with severe depression or labored breathing during the observation period, bird is scored as positive for ILT; L = Labored breathing, 2 or more days; M = Mortality; N = No signs of Infectious Laryngotracheitis; O = Acute, ocular discharge/swelling

One bird in Group 4a (592) removed after vaccination and before challenge due to injury.

Study Type	Efficacy
Pertaining to	Infectious Laryngotracheitis Virus
Study Purpose	Evaluate the efficacy against Infectious Laryngotracheitis Virus (ILT)
Product Administration	One dose administered by the subcutaneous route
Study Animals	Day-old chicks divided into two groups: Group 3, 35 chicks, vaccine Group 5, 15 chicks, diluent inoculated
Challenge Description	Challenged with ILT virus four weeks postvaccination
Interval observed after challenge	Observed for clinical signs for 10 days postchallenge
Results	Summary of results: Vaccinates and controls were evaluated for clinical signs related to fowl laryngotracheitis per criteria in 9 CFR 113.328(c)(5). Birds positive for Infectious Laryngotracheitis: Group 3: 0/34 Group 5: 12/15 Requirements per 9 CFR 113.328(c)(5) were met Raw data attached
USDA Approval Date	May 21, 2015

Group 3: Post-Challenge Bird Observation Record, vaccinate

Treatment Group	Wing Tag No.	Isolation Unit No.	Clinical Observations	Result at End of Study
3	112	3	N	0
3	116	7	N	0
3	118	3	N	0
3	119	7	N	0
3	120	3	N	0
3	121	10	N	0
3	127	3	N	0
3	133	10	N	0
3	144	7	N	0
3	145	7	N	0
3	150	3	N	0
3	151	7	N	0
3	155	3	N	0
3	162	10	N	0
3	173	7	N	0
3	176	7	N	0
3	181	10	N	0
3	194	10	N	0
3	202	7	N	0
3	204	3	N	0
3	213	7	N	0
3	226	10	N	0
3	228	10	N	0
3	240	10	N	0
3	244	3	N	0
3	253	10	N	0
3	254	10	N	0
3	256	7	N	0
3	263	7	N	0
3	277	7	N	0
3	281	3	N	0
3	282	10	N	0
3	284	3	N	0
3	285	10	N	0

Result: "0" indicates no signs of Infectious Laryngotracheitis

"1" indicates signs of Infectious Laryngotracheitis

N = No signs of Infectious Laryngotracheitis

Group 5: Post-Challenge Bird Observation Record, diluent

Treatment Group	Wing Tag No.	Isolation Unit No.	Clinical Observations	Result at End of Study
5	108	3	L,E	1
5	109	1	N	0
5	110	3	N	0
5	124	7	G,E	1
5	139	2	G,L,E	1
5	140	1	G,EB,E	1
5	174	10	G,M	1
5	184	9	L,G,E	1
5	193	2	M	1
5	201	9	L,G,E	1
5	218	1	N	0
5	241	2	G,E	1
5	242	10	G,E	1
5	250	3	EB,O,E	1
5	252	7	G,E	1

Result: "0" indicates no signs of Infectious Laryngotracheitis

"1" indicates signs of Infectious Laryngotracheitis

D = Severe depression, 2 or more days

E = Euthanized

EB = Expectoration with blood

G = Gasping, 2 or more days. If gasping occurs with severe depression or labored breathing during the observation period, bird is scored as positive for ILT.

L = Labored breathing, 2 or more days

M = Mortality

N = No signs of Infectious Laryngotracheitis

O = Acute, ocular discharge/swelling

Study Type	Efficacy
Pertaining to	Marek's Disease Virus
Study Purpose	Evaluate the efficacy against Marek's disease virus
Product Administration	One dose administered subcutaneously at 1 day of age
Study Animals	Group 7: 30 embryos, diluent treatment non-challenged controls Group 9: 34 one day-old chicks, study vaccine Group 11: 35 one day-old chicks, diluent inoculated challenged controls
Challenge Description	Challenged with Marek's disease virus at five days of age
Interval observed after challenge	Observed for clinical signs daily postchallenge. Tissues evaluated for gross lesions 7 weeks postchallenge.
Results	Birds positive for Marek's Disease: Group 7: 0/30 Group 9: 4/34 Group 11: 34/35 Requirements per 9 CFR 113.330(c) were met. Raw data attached on attached page
USDA Approval Date	May 22, 2015

Count	Wing Tag No.	Isolator	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
1	3	173	0	0	0	0	0	0	0	0	dead	Euthanized to compare with dead bird
2	5	172	0	0	0	0	0	0	0	0	alive	
3	7	172	0	0	0	0	0	0	0	0	alive	
4	8	172	0	0	0	0	0	0	0	0	alive	
5	9	173	0	0	0	0	0	0	0	0	alive	
6	15	173	0	0	0	0	0	0	0	0	alive	
7	17	173	0	0	0	0	0	0	0	0	alive	
8	23	172	0	0	0	0	0	0	0	0	alive	
9	28	172	0	0	0	0	0	0	0	0	alive	
10	32	173	0	0	0	0	0	0	0	0	alive	
11	36	172	0	0	0	0	0	0	0	0	alive	
12	44	173	0	0	0	0	0	0	0	0	alive	
13	56	173	0	0	0	0	0	0	0	0	alive	
14	64	173	0	0	0	0	0	0	0	0	alive	
15	73	172	0	0	0	0	0	0	0	0	alive	
16	85	172	0	0	0	0	0	0	0	0	alive	
17	87	173	0	0	0	0	0	0	0	0	alive	
18	89	172	0	0	0	0	0	0	0	0	alive	
19	99	172	0	0	0	0	0	0	0	0	alive	
20	217	172	0	0	0	0	0	0	0	0	alive	
21	225	172	0	0	0	0	0	0	0	0	alive	
22	227	173	0	0	0	0	0	0	0	0	alive	
23	237	173	0	0	0	0	0	0	0	0	alive	
24	258	173	0	0	0	0	0	0	0	0	alive	
25	261	172	0	0	0	0	0	0	0	0	alive	
26	273	173	0	0	0	0	0	0	0	0	alive	
27	277	173	0	0	0	0	0	0	0	0	alive	
28	878	172	0	0	0	0	0	0	0	0	alive	
29	890	172	0	0	0	0	0	0	0	0	alive	
30	891	173	0	0	0	0	0	0	0	0	alive	

Group 7

Scoring: "0" indicates no lesions of Marek's disease; "1" indicates lesions of Marek's disease were observed.

Count	Wing Tag No.	Isolator	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
1	283	194	0	0	1	0	0	1	0	1	dead	Emaciated, hemorrhages thymus & spine tumor, red leg
2	286	194	0	0	0	0	0	0	1	1	dead	Nerves enlarged & yellow
3	290	194	0	0	0	0	0	0	0	0	alive	
4	291	194	0	0	0	0	0	0	0	0	alive	
5	294	194	0	0	0	0	0	0	0	0	alive	
6	302	194	0	0	0	0	0	0	0	0	alive	
7	312	194	0	0	0	0	0	0	0	0	alive	
8	317	194	0	0	0	0	0	0	0	0	alive	
9	318	194	0	0	0	0	0	0	0	0	alive	
10	319	194	0	0	0	0	0	0	0	0	alive	
11	328	194	1	0	0	1	0	0	0	1	alive	
12	343	194	0	0	0	0	0	0	0	0	alive	
13	344	194	0	0	0	0	0	0	0	0	alive	
14	345	194	0	0	0	0	0	0	0	0	alive	
15	347	194	0	0	0	0	0	0	0	0	alive	
16	352	194	0	0	0	0	0	0	0	0	alive	
17	353	194	0	0	0	0	0	0	0	0	alive	
18	355	208	0	0	0	1	0	0	0	1	alive	
19	361	208	0	0	0	0	0	0	0	0	alive	
20	362	208	0	0	0	0	0	0	0	0	alive	
21	365	208	0	0	0	0	0	0	0	No score	dead	Injury; Removed from study
22	366	208	0	0	0	0	0	0	0	0	alive	
23	377	208	0	0	0	0	0	0	0	0	alive	
24	387	208	0	0	0	0	0	0	0	0	alive	
25	389	208	0	0	0	0	0	0	0	0	alive	
26	392	208	0	0	0	0	0	0	0	0	alive	
27	397	208	0	0	0	0	0	0	0	0	alive	
28	406	208	0	0	0	0	0	0	0	0	alive	
29	415	208	0	0	0	0	0	0	0	0	alive	
30	431	208	0	0	0	0	0	0	0	0	alive	
31	444	208	0	0	0	0	0	0	0	0	alive	
32	449	208	0	0	0	0	0	0	0	0	alive	
33	450	208	0	0	0	0	0	0	0	0	alive	
34	451	208	0	0	0	0	0	0	0	0	alive	
35	452	208	0	0	0	0	0	0	0	0	alive	

Group 9

Scoring: "0" indicates no lesions of Marek's disease; "1" indicates lesions of Marek's disease were observed.

Count	Wing Tag No.	Isolator	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
1	288	221	1	0	0	0	0	1	0	1	alive	
2	298	221	0	0	1	0	0	1	1	1	dead	
3	299	221	1	1	1	0	1	1	0	1	alive	Emaciated
4	300	221	1	0	1	0	1	1	0	1	dead	Emaciated, red legs
5	303	221	1	1	1	1	1	0	0	1	alive	
6	311	221	1	1	1	0	1	1	0	1	dead	Emaciated, black comb
7	321	221	1	0	1	1	0	1	0	1	alive	Emaciated
8	326	221	0	0	0	0	0	0	0	0	alive	
9	327	221	0	1	0	0	0	1	0	1	dead	Severe petechia
10	337	23	0	0	1	0	1	0	0	1	alive	Clinical signs
11	348	23	0	1	1	0	0	0	0	1	dead	Bloody heart, petechial hemorrhages
12	357	23	1	1	1	0	1	0	1	1	dead	emaciated
13	358	23	1	1	1	0	1	1	0	1	alive	Clinical signs
14	360	23	0	0	1	0	1	1	1	1	dead	
15	364	23	1	1	1	0	1	0	0	1	dead	
16	369	23	1	0	1	0	0	0	0	1	alive	
17	372	23	0	0	1	0	1	1	0	1	dead	Bloody heart, Petechia
18	376	194	1	1	1	0	1	0	0	1	alive	Intestinal tumor
19	381	194	1	1	1	1	1	1	0	1	dead	Emaciated, red hocks
20	382	194	0	1	1	0	0	1	1	1	dead	Nerves-Normal
21	383	194	0	1	1	0	1	1	0	1	dead	Thymus tumor, some petechia
22	384	194	1	1	1	0	1	0	0	1	dead	Emaciated, red legs, black comb
23	403	194	0	0	0	0	1	0	1	1	dead	Hemorrhage, petechia
24	411	194	0	0	1	0	0	0	0	1	dead	Hemorrhage, petechia
25	412	194	1	1	1	No score	1	1	0	1	alive	Clinical signs
26	416	194	1	1	1	1	1	1	1	1	dead	Emaciated
27	422	208	1	0	1	0	1	1	0	1	alive	
28	423	208	0	0	1	0	0	1	0	1	dead	Few petechia
29	430	208	1	1	1	1	1	1	0	1	dead	Thymus tumor, red hocks
30	435	208	1	1	1	1	1	0	0	1	dead	Emaciated
31	442	208	1	0	1	0	0	1	0	1	dead	Severe petechia
32	443	208	1	1	1	0	1	0	0	1	dead	Emaciated, hemorrhagic thymus
33	445	208	1	1	1	0	1	1	1	1	dead	Red legs, swollen comb
34	446	208	1	0	1	1	0	0	0	1	alive	Clinical signs
35	447	208	0	1	1	0	1	1	0	1	dead	Emaciated, red legs

Group 11

Scoring: "0" indicates no lesions of Marek's disease; "1" indicates lesions of Marek's disease were observed.

Study Type	Efficacy
Pertaining to	Marek's Disease Virus (MDV)
Study Purpose	Evaluate the efficacy against MDV
Product Administration	One dose administered <i>in ovo</i>
Study Animals	Embryonated eggs. Eggs receiving the same treatment were hatched together. See below. Group 3: 30 eggs, low dose vaccine treatment Group 4: 35 eggs, high dose vaccine treatment Group 6: 35 eggs, diluent inoculated challenged controls Group 7: 25 eggs, diluent inoculated non-challenged controls
Challenge Description	Challenged with Marek's disease virus at 5 days of age.
Interval observed after challenge	Marek's disease challenged birds were observed daily and evaluated for gross lesions at 7 weeks of age.
Results	Summary of results Birds positive for MDV: Group 3: 6/30 Group 4: 1/35 Group 6: 31/35 Group 7: 0/25 Requirements for 9 CFR 113.330 were met Raw data attached
USDA Approval Date	May 22, 2015

Group 3

Count	Wing Tag No.	Isolator	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
1	203	167	0	0	0	0	0	0	0	0	alive	
2	211	167	0	0	0	0	0	0	0	0	alive	
3	212	167	0	0	0	0	0	0	0	0	alive	
4	217	167	0	0	0	0	0	0	0	0	alive	
5	250	167	0	0	1	1	0	0	0	1	alive	
6	301	167	0	0	0	0	0	0	0	0	alive	
7	302	167	0	0	0	0	0	0	0	0	alive	
8	318	167	0	0	0	0	0	0	0	0	alive	
9	330	167	0	0	0	1	0	0	0	1	alive	
10	379	167	0	0	0	0	0	0	0	0	alive	
11	415	167	0	0	0	0	0	0	0	0	alive	
12	423	167	0	0	0	1	1	0	0	1	alive	Kidney tumor
13	448	167	0	0	0	0	0	0	0	0	alive	
14	863	167	0	0	0	0	0	0	0	0	alive	
15	869	167	0	0	0	0	0	0	0	0	alive	
16	223	236	0	0	0	0	0	0	0	0	alive	
17	230	236	0	0	0	0	0	0	0	0	alive	
18	231	236	0	0	0	0	0	0	0	0	alive	
19	236	236	0	0	0	0	0	0	0	0	alive	
20	237	236	0	0	0	0	0	0	0	0	alive	
21	266	236	0	0	0	0	0	0	0	0	alive	
22	298	236	0	0	0	0	0	0	0	0	alive	
23	342	236	0	0	0	0	0	0	0	0	alive	
24	391	236	0	0	0	0	0	0	0	0	alive	
25	416	236	0	0	0	0	1	0	0	1	alive	
26	861	236	0	0	0	0	0	0	0	0	alive	
27	865	236	0	0	0	1	0	0	0	1	alive	Breast tumor
28	885	236	0	0	0	0	0	0	0	0	alive	
29	889	236	0	0	0	0	0	0	0	0	alive	
30	911	236	0	0	1	1	1	0	0	1	alive	Breast tumor

Prov. is proventriculus

Scoring: "0" indicates no lesions of Marek's disease

"1" indicates lesions of Marek's disease were observed

Group 4

Count	Wing Tag No.	Isolator	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
1	216	186	0	0	0	0	0	0	0	0	alive	
2	256	186	0	0	0	0	0	0	0	0	alive	
3	265	186	0	0	0	0	0	0	0	0	alive	
4	273	186	0	0	0	0	0	0	0	0	alive	
5	328	186	0	0	0	0	0	0	0	0	alive	
6	340	186	0	0	0	0	0	0	0	0	alive	
7	362	186	0	0	0	0	0	0	0	0	alive	
8	372	186	0	0	0	0	0	0	0	0	alive	
9	469	186	0	0	0	0	0	0	0	0	alive	
10	492	186	0	0	0	0	0	0	0	0	alive	
11	828	186	0	0	0	0	0	0	0	0	alive	
12	867	186	0	0	0	0	0	0	0	0	alive	
13	875	186	0	0	0	0	0	0	0	0	alive	
14	878	186	0	0	0	0	0	0	0	0	alive	
15	882	186	0	0	0	0	0	0	0	0	alive	
16	891	186	0	0	0	0	0	0	0	0	alive	
17	896	186	0	0	0	0	0	0	0	0	alive	
18	907	186	0	0	0	0	0	0	0	0	alive	
19	248	235	0	0	0	0	0	0	0	0	alive	
20	312	235	0	0	0	0	0	0	0	N/A	alive	Emaciated
21	331	235	0	0	0	0	0	0	0	0	alive	
22	338	235	0	0	0	0	0	0	0	0	alive	
23	381	235	0	0	0	0	0	0	0	0	alive	
24	387	235	0	1	1	1	1	0	0	1	dead	
25	389	235	0	0	0	0	0	0	0	0	alive	
26	424	235	0	0	0	0	0	0	0	0	alive	
27	441	235	0	0	0	0	0	0	0	0	alive	
28	459	235	0	0	0	0	0	0	0	0	alive	
29	489	235	0	0	0	0	0	0	0	0	alive	
30	495	235	0	0	0	0	0	0	0	0	alive	
31	822	235	0	0	0	0	0	0	0	0	alive	
32	840	235	0	0	0	0	0	0	0	0	alive	
33	854	235	0	0	0	0	0	0	0	0	alive	
34	857	235	0	0	0	0	0	0	0	0	alive	
35	862	235	0	0	0	0	0	0	0	0	alive	

Prov. is proventriculus

N/A is not available

Scoring: "0" indicates no lesions of Marek's disease

"1" indicates lesions of Marek's disease were observed

Group 6

Count	Wing Tag No.	Isolator	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
1	206	167	0	0	0	0	0	0	0	0	alive	
2	309	167	1	1	1	0	1	1	0	1	dead	
3	350	167	0	0	0	0	1	1	0	1	alive	Emaciated
4	368	167	1	1	1	0	0	1	0	1	dead	
5	400	167	1	0	1	0	1	1	1	1	dead	
6	408	167	0	0	0	0	0	0	0	0	alive	
7	436	167	1	1	1	0	1	1	0	1	dead	
8	498	167	1	0	1	1	1	0	0	1	alive	
9	901	167	1	1	1	1	1	1	0	1	alive	
10	225	186	1	0	0	0	1	0	0	1	alive	
11	285	186	1	0	1	0	1	0	0	1	alive	
12	315	186	0	0	0	0	0	0	0	1	dead	Severe petechiae
13	321	186	1	0	1	0	1	1	0	1	dead	
14	353	186	0	0	1	0	1	1	0	1	dead	
15	429	186	0	1	1	0	1	1	0	1	alive	Emaciated
16	475	186	0	0	0	0	0	0	0	1	dead	Severe petechiae
17	838	186	1	0	1	0	1	0	0	1	dead	Emaciated, dehydrated, red legs
18	287	235	1	1	1	0	1	1	0	1	alive	
19	305	235	1	0	0	1	1	0	0	1	alive	
20	324	235	1	0	0	1	1	1	0	1	alive	
21	346	235	1	1	1	0	0	1	0	1	dead	Emaciated
22	373	235	1	1	0	0	0	0	0	1	alive	
23	388	235	1	1	1	0	0	0	0	1	alive	Emaciated, black comb
24	477	235	1	1	1	0	1	1	0	1	dead	Breast tumor
25	482	235	0	0	0	0	0	0	0	0	alive	
26	905	235	1	1	1	0	0	1	0	1	alive	
27	257	236	1	0	0	0	1	1	0	1	dead	
28	284	236	0	1	1	0	1	1	0	1	dead	Severe hemorrhage
29	288	236	1	1	1	0	1	1	0	1	dead	
30	317	236	1	1	1	0	1	0	0	1	dead	
31	500	236	0	1	1	0	1	0	0	1	dead	Red breast & legs
32	860	236	0	1	1	1	1	1	0	1	dead	
33	877	236	1	0	1	0	1	0	0	1	alive	
34	886	236	0	0	0	0	0	0	0	0	alive	
35	906	236	1	1	1	0	1	1	0	1	dead	Red skin, black comb

Prov. is proventriculus

Scoring: "0" indicates no lesions of Marek's disease

"1" indicates lesions of Marek's disease were observed

Group 7

Count	Wing Tag No.	Isolator	Heart	Liver	Spleen	Gonads	Kidneys	Prov	Paralysis	Result	End of Study Status	Comments
1	202	89	0	0	0	0	0	0	0	0	alive	
2	289	89	0	0	0	0	0	0	0	0	alive	
3	370	89	0	0	0	0	0	0	0	0	alive	
4	384	89	0	0	0	0	0	0	0	0	alive	
5	445	89	0	0	0	0	0	0	0	0	alive	
6	453	89	0	0	0	0	0	0	0	0	alive	
7	490	89	0	0	0	0	0	0	0	0	alive	
8	842	89	0	0	0	0	0	0	0	0	alive	
9	866	89	0	0	0	0	0	0	0	0	alive	
10	872	89	0	0	0	0	0	0	0	0	alive	
11	876	89	0	0	0	0	0	0	0	0	alive	
12	894	89	0	0	0	0	0	0	0	0	alive	
13	241	90	0	0	0	0	0	0	0	0	alive	
14	263	90	0	0	0	0	0	0	0	0	alive	
15	269	90	0	0	0	0	0	0	0	0	alive	
16	281	90	0	0	0	0	0	0	0	0	alive	
17	294	90	0	0	0	0	0	0	0	0	alive	
18	458	90	0	0	0	0	0	0	0	0	alive	
19	461	90	0	0	0	0	0	0	0	0	alive	
20	478	90	0	0	0	0	0	0	0	0	alive	
21	825	90	0	0	0	0	0	0	0	0	alive	
22	846	90	0	0	0	0	0	0	0	0	alive	
23	868	90	0	0	0	0	0	0	0	0	alive	
24	890	90	0	0	0	0	0	0	0	0	alive	
25	892	90	0	0	0	0	0	0	0	0	alive	

Prov. is proventriculus

Scoring: "0" indicates no lesions of Marek's disease

"1" indicates lesions of Marek's disease were observed

Study Type	Efficacy
Pertaining to	Newcastle Disease Virus
Study Purpose	Evaluate the efficacy against Newcastle Disease Virus (NDV)
Product Administration	One dose administered subcutaneously at 1 day of age
Study Animals	Day-old chicks divided into three groups Group 10: 30 chicks, low dose vaccine treatment Group 11: 30 chicks, high dose vaccine treatment Group 13: 12 chicks, diluent inoculated challenged controls
Challenge Description	Challenged with Newcastle virus at four weeks postvaccination
Interval observed after challenge	Observed for clinical signs for 14 days postchallenge
Results	Vaccinates and controls were evaluated for clinical signs related to Newcastle disease per criteria in 9 CFR 113.329(c)(3). Birds with clinical signs: Group 10: 0/30 Group 11: 1/30 Group 13: 12/12 Requirements per 9 CFR 113.329(c)(3) were met Raw data attached
USDA Approval Date	May 21, 2015

		Days Post-Challenge - Clinical Signs															
Group/ Treatment	Wing Tag No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Status	Final Result
Group 10	455	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	457	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	461	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	469	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	476	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	482	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	490	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	497	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	514	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	549	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	550	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	551	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	577	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	592	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	608	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	630	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	648	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	649	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	654	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	661	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	684	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	702	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	710	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	722	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	736	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	741	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	745	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	798	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	806	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	809	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0

¹Scoring: "0" indicates no clinical signs of Newcastle Disease
"1" indicates clinical signs of Newcastle Disease
"D" indicates dead

		Days Post-Challenge - Clinical Signs															
Group/ Treatment	Wing Tag No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Status	Final Result
Group 11	471	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	472	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	483	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	485	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	500	0	0	0	0	0	0	0	1	D	D	D	D	D	D	dead	1
	529	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	531	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	534	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	545	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	559	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	572	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	610	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	619	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	631	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	637	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	644	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	652	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	680	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	686	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	708	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	724	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	725	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	818	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	740	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	749	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	750	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	760	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	766	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	800	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
	814	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0

¹Scoring: "0" indicates no clinical signs of Newcastle Disease

"1" indicates clinical signs of Newcastle Disease

"D" indicates dead

		Days Post-Challenge - Clinical Signs															
Group/ Treatment	Wing Tag No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Status	Final Result
13 Sterile Diluent	467	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
	590	0	1	D	D	D	D	D	D	D	D	D	D	D	D	dead	1
	609	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
	634	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
	643	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
	784	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
	787	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
	792	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
	811	0	1	D	D	D	D	D	D	D	D	D	D	D	D	dead	1
	820	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
	821	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
	980	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1

¹Scoring: "0" indicates no clinical signs of Newcastle Disease
"1" indicates clinical signs of Newcastle Disease
"D" indicates dead

Study Type	Efficacy
Pertaining to	Newcastle Disease Virus (NDV)
Study Purpose	Evaluate the efficacy against NDV
Product Administration	One dose administered <i>in ovo</i> to 18-day-old embryonated chicken eggs
Study Animals	Embryonated eggs. Eggs receiving the same treatment were hatched together. See below. Group 10: 21 eggs, vaccine treatment Group 13: 12 eggs, diluent inoculated challenged controls
Challenge Description	Challenged with Newcastle virus at four weeks of age.
Interval observed after challenge	Newcastle challenged birds were observed daily and evaluated for gross lesions 14 days post challenge.
Results	Summary of results Birds positive for NDV: Group 10: 1/21 Group 13: 12/12 Requirements for 113.329 were met Raw data attached
USDA Approval Date	May 22, 2015

Group 10

		Days Post-Challenge - Clinical Signs ¹															
Count	Wing Tag No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Status	Final Result
1	229	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
2	259	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
3	300	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
4	306	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
5	313	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
6	325	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
7	333	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
8	348	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
9	352	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
10	377	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
11	395	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
12	411	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
13	427	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
14	479	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
15	484	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
16	493	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
17	497	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
18	852	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
19	874	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0
20	888	0	0	0	1	D	D	D	D	D	D	D	D	D	D	dead	1
21	898	0	0	0	0	0	0	0	0	0	0	0	0	0	0	alive	0

¹Scoring: "0" indicates no clinical signs of Newcastle Disease
 "1" indicates clinical signs of Newcastle Disease
 "D" indicates dead

Group 13

		Days Post-Challenge - Clinical Signs ¹															
Count	Wing Tag No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Status	Result
1	226	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
2	234	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
3	238	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
4	303	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
5	327	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
6	332	0	0	0	1	D	D	D	D	D	D	D	D	D	D	dead	1
7	344	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
8	351	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
9	438	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
10	486	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
11	491	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1
12	856	0	0	1	D	D	D	D	D	D	D	D	D	D	D	dead	1

¹Scoring: "0" indicates no clinical signs of Newcastle Disease
 "1" indicates clinical signs of Newcastle Disease
 "D" indicates dead

Study Type	Safety																																																																															
Pertaining to	ALL																																																																															
Study Purpose	To demonstrate safety of product under typical field conditions																																																																															
Product Administration	One dose was administered <i>in ovo</i> to 18-19 day old chicken embryos at Site 1 and Site 2. One dose was administered subcutaneously to day-old chickens at Site 3 and Site 4. At each site, one group received the test vaccine and one group received vaccinations according to site standard practices.																																																																															
Study Animals	A total of 93, 400 test chicks in 3 states; 47, 100 embryos and 46,300 day-old chicks.																																																																															
Challenge Description	NA																																																																															
Interval observed after vaccination	Chicks were observed for daily mortality 21 days after vaccination.																																																																															
Results	<table><tr><th>Site Identifier</th><th>Route of Administration</th><th>Treatment Group</th><th>Total Placed</th><th>21 Day Mortality</th><th>% Mortality</th><th>% Hatchability</th><th>Condemnation Rates</th></tr><tr><td>01</td><td>In Ovo</td><td>Test Group</td><td>25500</td><td>295</td><td>1.2</td><td>89.95%</td><td>0.08%</td></tr><tr><td>01</td><td>In Ovo</td><td>Control Group</td><td>25500</td><td>402</td><td>1.6</td><td>91.27%</td><td>0.04%</td></tr><tr><td>02</td><td>In Ovo</td><td>Test Group</td><td>21600</td><td>231</td><td>1.1</td><td>81.09%</td><td>0.09%</td></tr><tr><td>02</td><td>In Ovo</td><td>Control Group</td><td>21600</td><td>222</td><td>1.0</td><td>82.12%</td><td>0.51%</td></tr><tr><td>03</td><td>Subcutaneous</td><td>Test Group</td><td>23500</td><td>277</td><td>1.2</td><td>NA</td><td>0.15%</td></tr><tr><td>03</td><td>Subcutaneous</td><td>Control Group</td><td>23500</td><td>415</td><td>1.8</td><td>NA</td><td>0.19%</td></tr><tr><td>04</td><td>Subcutaneous</td><td>Test Group</td><td>22800</td><td>456</td><td>2.0</td><td>NA</td><td>0.09%</td></tr><tr><td>04</td><td>Subcutaneous</td><td>Control Group</td><td>22800</td><td>386</td><td>1.7</td><td>NA</td><td>0.12%</td></tr></table>								Site Identifier	Route of Administration	Treatment Group	Total Placed	21 Day Mortality	% Mortality	% Hatchability	Condemnation Rates	01	In Ovo	Test Group	25500	295	1.2	89.95%	0.08%	01	In Ovo	Control Group	25500	402	1.6	91.27%	0.04%	02	In Ovo	Test Group	21600	231	1.1	81.09%	0.09%	02	In Ovo	Control Group	21600	222	1.0	82.12%	0.51%	03	Subcutaneous	Test Group	23500	277	1.2	NA	0.15%	03	Subcutaneous	Control Group	23500	415	1.8	NA	0.19%	04	Subcutaneous	Test Group	22800	456	2.0	NA	0.09%	04	Subcutaneous	Control Group	22800	386	1.7	NA	0.12%
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USDA Approval Date	January 8, 2019																																																																															