



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Neotech, LLC
USDA Vet Biologics Establishment Number	472
Product Code	1301.20
True Name	Canine Distemper Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	NeoVac D - No distributor specified NeoVac FD - No distributor specified
Date of Compilation Summary	May 21, 2021

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	Canine Distemper Virus (CDV)
Study Purpose	To demonstrate efficacy against disease caused by CDV
Product Administration	Subcutaneous
Study Animals	Dogs
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	April 21, 2006

Study Type	Efficacy									
Pertaining to	Canine Distemper Virus (CDV)									
Study Purpose	To demonstrate efficacy against distemper disease									
Product Administration	2 subcutaneous doses administered 21 days apart									
Study Animals	Thirty-three 8 to 10 week old ferrets seronegative to CDV were randomly assigned to either group: vaccinates (n=24) or controls (n=9)									
Challenge Description	Ferrets were administered an intracerebral challenge of canine distemper virus 21 days after second vaccination									
Interval observed after challenge	Ferrets were observed twice a day for 21 days after challenge for clinical signs of distemper.									
Results	<p>The results of the study met the standards set forth in 9 CFR 113.302.</p> <p>Summary</p> <table border="1"> <thead> <tr> <th>Group</th> <th>Total</th> <th>Clinical Signs of CDV</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>24</td> <td>0</td> </tr> <tr> <td>Controls</td> <td>9</td> <td>9*</td> </tr> </tbody> </table> <p>* All 9 control ferrets succumbed to challenge</p> <p>Raw data: Data tables 1 through 6 are appended to the end of this summary.</p>	Group	Total	Clinical Signs of CDV	Vaccinates	24	0	Controls	9	9*
Group	Total	Clinical Signs of CDV								
Vaccinates	24	0								
Controls	9	9*								
USDA Approval Date	April 6, 2017									

Table #1: Daily Health Observations of ferrets (n=24) in the vaccinated group for days 1 to 7 post challenge.

Ferret ID	Treatment Group	D1	D2	D3	D4	D5	D6	D7
027	Vaccinate	N	N	N	N	N	N	N
029	Vaccinate	N	N	N	N	N	N	N
032	Vaccinate	N	N	N	N	N	N	N
033	Vaccinate	N	N	N	N	N	N	N
034	Vaccinate	N	N	N	N	N	N	N
696	Vaccinate	N	N	N	N	N	N	N
697	Vaccinate	N	N	N	N	N	N	N
700	Vaccinate	N	N	N	N	N	N	N
701	Vaccinate	N	N	N	N	N	N	N
702	Vaccinate	N	N	N	N	N	N	N
704	Vaccinate	N	N	N	N	N	N	N
705	Vaccinate	N	N	N	N	N	N	N
706	Vaccinate	N	N	N	N	N	N	N
709	Vaccinate	N	N	N	N	N	N	N
710	Vaccinate	N	N	N	N	N	N	N
715	Vaccinate	N	N	N	N	N	N	N
716	Vaccinate	N	N	N	N	N	N	N
972	Vaccinate	N	N	N	N	N	N	N
980	Vaccinate	N	N	N	N	N	N	N
981	Vaccinate	N	N	N	N	N	N	N
982	Vaccinate	N	N	N	N	N	N	N
986	Vaccinate	N	N	N	N	N	N	N
990	Vaccinate	N	N	N	N	N	N	N
995	Vaccinate	N	N	N	N	N	N	N

Abbreviation key:

N: none	L: lethargy	C: conjunctivitis
AP: apprehension	V: vomiting	P: prostration
ES: excessive salivation	S: seizures	
DI: diarrhea	D: death	
A: anorexia	F: fever	

Table #2: Daily Health Observations of ferrets (n=24) in the vaccinated group for days 8 to 14 post challenge.

Ferret ID	Treatment Group	D8	D9	D10	D11	D12	D13	D14
027	Vaccinate	N	N	N	N	N	N	N
029	Vaccinate	N	N	N	N	N	N	N
032	Vaccinate	N	N	N	N	N	N	N
033	Vaccinate	N	N	N	N	N	N	N
034	Vaccinate	N	N	N	N	N	N	N
696	Vaccinate	N	N	N	N	N	N	N
697	Vaccinate	N	N	N	N	N	N	N
700	Vaccinate	N	N	N	N	N	N	N
701	Vaccinate	N	N	N	N	N	N	N
702	Vaccinate	N	N	N	N	N	N	N
704	Vaccinate	N	N	N	N	N	N	N
705	Vaccinate	N	N	N	N	N	N	N
706	Vaccinate	N	N	N	N	N	N	N
709	Vaccinate	N	N	N	N	N	N	N
710	Vaccinate	N	N	N	N	N	N	N
715	Vaccinate	N	N	N	N	N	N	N
716	Vaccinate	N	N	N	N	N	N	N
972	Vaccinate	N	N	N	N	N	N	N
980	Vaccinate	N	N	N	N	N	N	N
981	Vaccinate	N	N	N	N	N	N	N
982	Vaccinate	N	N	N	N	N	N	N
986	Vaccinate	N	N	N	N	N	N	N
990	Vaccinate	N	N	N	N	N	N	N
995	Vaccinate	N	N	N	N	N	N	N

Abbreviation key:

N: none	L: lethargy	C: conjunctivitis
AP: apprehension	V: vomiting	P: prostration
ES: excessive salivation	S: seizures	
DI: diarrhea	D: death	
A: anorexia	F: fever	

Table #3: Daily Health Observations of ferrets (n=24) in the vaccinated group for days 15 to 21 post challenge.

Ferret ID	Treatment Group	D15	D16	D17	D18	D19	D20	D21
027	Vaccinate	N	N	N	N	N	N	N
029	Vaccinate	N	N	N	N	N	N	N
032	Vaccinate	N	N	N	N	N	N	N
033	Vaccinate	N	N	N	N	N	N	N
034	Vaccinate	N	N	N	N	N	N	N
696	Vaccinate	N	N	N	N	N	N	N
697	Vaccinate	N	N	N	N	N	N	N
700	Vaccinate	N	N	N	N	N	N	N
701	Vaccinate	N	N	N	N	N	N	N
702	Vaccinate	N	N	N	N	N	N	N
704	Vaccinate	N	N	N	N	N	N	N
705	Vaccinate	N	N	N	N	N	N	N
706	Vaccinate	N	N	N	N	N	N	N
709	Vaccinate	N	N	N	N	N	N	N
710	Vaccinate	N	N	N	N	N	N	N
715	Vaccinate	N	N	N	N	N	N	N
716	Vaccinate	N	N	N	N	N	N	N
972	Vaccinate	N	N	N	N	N	N	N
980	Vaccinate	N	N	N	N	N	N	N
981	Vaccinate	N	N	N	N	N	N	N
982	Vaccinate	N	N	N	N	N	N	N
986	Vaccinate	N	N	N	N	N	N	N
990	Vaccinate	N	N	N	N	N	N	N
995	Vaccinate	N	N	N	N	N	N	N

Abbreviation key:

N: none	L: lethargy	C: conjunctivitis
AP: apprehension	V: vomiting	P: prostration
ES: excessive salivation	S: seizures	
DI: diarrhea	D: death	
A: anorexia	F: fever	

Table #4: Daily Health Observations of ferrets in the unvaccinated control group (n=9) for days 1 to 7 post challenge.

Ferret ID	Treatment Group	D1	D2	D3	D4	D5	D6	D7
018	Control	N	N	N	N	N	N	N
021	Control	N	N	N	N	N	N	N
983	Control	N	N	N	N	N	N	N
984	Control	N	N	N	N	N	N	N
694	Control	N	N	N	N	N	N	N
695	Control	N	N	N	N	N	N	N
698	Control	N	N	N	N	N	N	N
699	Control	N	N	N	N	N	N	N
711	Control	N	N	N	N	N	N	N

Abbreviation key:

N: none	L: lethargy	C: conjunctivitis
AP: apprehension	V: vomiting	P: prostration
ES: excessive salivation	S: seizures	
DI: diarrhea	D: death	
A: anorexia	F: fever	

Table #5: Daily Health Observations of ferrets in the unvaccinated control group (n=9) for days 8 to 14 post challenge.

Ferret ID	Treatment Group	D8	D9	D10	D11	D12	D13	D14
018	Control	N	N	S	S	A,L,V,S	C,A,L,V,S	A,L,S,D
021	Control	N	N	F	N	V,S	C,A,L,V,S	A,L,S,D
983	Control	N	N	N	N	N	N	AP
984	Control	N	V	A	A	A,L,V	ES,A,L,P,S	D
694	Control	D,V	ES,V	A,L,V	AP,ES,L,V,P	D	D	D
695	Control	N	N	AP,A,L,S	ES,A,L,V,P,S,D	D	D	D
698	Control	N	N	N	N	N	A	A,L,S
699	Control	N	N	A	A,L,S	ES,A,L,V,P,S	A,L,P,S	A,L,P,S,D
711	Control	N	N	N	A	AP,A,L	A,L,S	A,L,P,S,D

Abbreviation key:

N: none	L: lethargy	C: conjunctivitis
AP: apprehension	V: vomiting	P: prostration
ES: excessive salivation	S: seizures	
DI: diarrhea	D: death	
A: anorexia	F: fever	

Table #6: Daily Health Observations of ferrets in the unvaccinated control group (n=9) for days 15 to 21 post challenge.

Ferret ID	Treatment Group	D15	D16	D17	D18	D19	D20	D21
018	Control	D	D	D	D	D	D	D
021	Control	D	D	D	D	D	D	D
983	Control	AP	A	AP,ES,A, L,V,S	C,L,D, V,P,S	D	D	D
984	Control	D	D	D	D	D	D	D
694	Control	D	D	D	D	D	D	D
695	Control	D	D	D	D	D	D	D
698	Control	ES,A, L,P,S	D	D	D	D	D	D
699	Control	D	D	D	D	D	D	D
711	Control	D	D	D	D	D	D	D

Abbreviation key:

N: none	L: lethargy	C: conjunctivitis
AP: apprehension	V: vomiting	P: prostration
ES: excessive salivation	S: seizures	
DI: diarrhea	D: death	
A: anorexia	F: fever	

Study Type	Safety																																																																																	
Pertaining to	Canine Distemper Virus (CDV)																																																																																	
Study Purpose	To demonstrate safety under conditions of normal use in ferrets																																																																																	
Product Administration	Subcutaneous doses of vaccine were administered 14 days apart.																																																																																	
Study Animals	Three separate regimens were evaluated for safety. The first regimen consisted of vaccinating 200, 6-13 week old ferrets twice, 14 days apart. The second regimen consisted of vaccinating 199, 6-13 week old ferrets three times at a 14 day interval. The third regimen consisted of vaccinating 101 adults, between the ages of 1-2 years of age twice, 14 days apart.																																																																																	
Challenge Description	N/A																																																																																	
Interval observed after challenge	Ferrets were monitored immediately after each vaccination and then daily for 14 days for adverse events.																																																																																	
Results	<p>Frequency of Post Vaccination Adverse Events</p> <table border="1"> <thead> <tr> <th>Adverse Event</th> <th>Adverse Events Per Vaccination</th> <th>Percentage of Adverse Event</th> </tr> </thead> <tbody> <tr><td>Anaphylaxis</td><td>0/1196</td><td>0%</td></tr> <tr><td>Lymphadenopathy</td><td>0/1196</td><td>0%</td></tr> <tr><td>Aggression</td><td>0/1196</td><td>0%</td></tr> <tr><td>Hyperactivity</td><td>0/1196</td><td>0%</td></tr> <tr><td>Vocalization</td><td>0/1196</td><td>0%</td></tr> <tr><td>Hypersalivation</td><td>0/1196</td><td>0%</td></tr> <tr><td>Abdominal pain</td><td>0/1196</td><td>0%</td></tr> <tr><td>Diarrhea*</td><td>1/1196</td><td>0.08%</td></tr> <tr><td>Vomiting*</td><td>15/1196</td><td>1.25%</td></tr> <tr><td>Ocular discharge</td><td>0/1196</td><td>0%</td></tr> <tr><td>Conjunctivitis</td><td>0/1196</td><td>0%</td></tr> <tr><td>Corneal edema</td><td>0/1196</td><td>0%</td></tr> <tr><td>Angioedema</td><td>0/1196</td><td>0%</td></tr> <tr><td>Urticaria</td><td>0/1196</td><td>0%</td></tr> <tr><td>Site abscess</td><td>0/1196</td><td>0%</td></tr> <tr><td>Site alopecia</td><td>0/1196</td><td>0%</td></tr> <tr><td>Site erythema</td><td>0/1196</td><td>0%</td></tr> <tr><td>Site stinging</td><td>0/1196</td><td>0%</td></tr> <tr><td>Site granuloma</td><td>0/1196</td><td>0%</td></tr> <tr><td>Anorexia</td><td>0/1196</td><td>0%</td></tr> <tr><td>Not drinking</td><td>0/1196</td><td>0%</td></tr> <tr><td>Lethargy*</td><td>5/1196</td><td>0.41%</td></tr> <tr><td>Depression</td><td>0/1196</td><td>0%</td></tr> <tr><td>Fever</td><td>0/1196</td><td>0%</td></tr> <tr><td>Distemper signs</td><td>0/1196</td><td>0%</td></tr> <tr><td>Death**</td><td>2/1196</td><td>0.17%</td></tr> </tbody> </table>	Adverse Event	Adverse Events Per Vaccination	Percentage of Adverse Event	Anaphylaxis	0/1196	0%	Lymphadenopathy	0/1196	0%	Aggression	0/1196	0%	Hyperactivity	0/1196	0%	Vocalization	0/1196	0%	Hypersalivation	0/1196	0%	Abdominal pain	0/1196	0%	Diarrhea*	1/1196	0.08%	Vomiting*	15/1196	1.25%	Ocular discharge	0/1196	0%	Conjunctivitis	0/1196	0%	Corneal edema	0/1196	0%	Angioedema	0/1196	0%	Urticaria	0/1196	0%	Site abscess	0/1196	0%	Site alopecia	0/1196	0%	Site erythema	0/1196	0%	Site stinging	0/1196	0%	Site granuloma	0/1196	0%	Anorexia	0/1196	0%	Not drinking	0/1196	0%	Lethargy*	5/1196	0.41%	Depression	0/1196	0%	Fever	0/1196	0%	Distemper signs	0/1196	0%	Death**	2/1196	0.17%
Adverse Event	Adverse Events Per Vaccination	Percentage of Adverse Event																																																																																
Anaphylaxis	0/1196	0%																																																																																
Lymphadenopathy	0/1196	0%																																																																																
Aggression	0/1196	0%																																																																																
Hyperactivity	0/1196	0%																																																																																
Vocalization	0/1196	0%																																																																																
Hypersalivation	0/1196	0%																																																																																
Abdominal pain	0/1196	0%																																																																																
Diarrhea*	1/1196	0.08%																																																																																
Vomiting*	15/1196	1.25%																																																																																
Ocular discharge	0/1196	0%																																																																																
Conjunctivitis	0/1196	0%																																																																																
Corneal edema	0/1196	0%																																																																																
Angioedema	0/1196	0%																																																																																
Urticaria	0/1196	0%																																																																																
Site abscess	0/1196	0%																																																																																
Site alopecia	0/1196	0%																																																																																
Site erythema	0/1196	0%																																																																																
Site stinging	0/1196	0%																																																																																
Site granuloma	0/1196	0%																																																																																
Anorexia	0/1196	0%																																																																																
Not drinking	0/1196	0%																																																																																
Lethargy*	5/1196	0.41%																																																																																
Depression	0/1196	0%																																																																																
Fever	0/1196	0%																																																																																
Distemper signs	0/1196	0%																																																																																
Death**	2/1196	0.17%																																																																																

	<p>*Adverse events were resolved within 8 hours without medical treatment.</p> <p>**Not attributable to vaccination were 2 deaths as affirmed by licensee. Deaths occurred 12 and 13 days after the first vaccination of young ferrets.</p>
USDA Approval Date	February 20, 2019

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under typical field conditions
Product Administration	Subcutaneous administration
Study Animals	Dogs
Challenge Description	N/A
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 20, 2007