



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	1231.11
True Name	Bronchitis Vaccine, Mass Type, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	April 06, 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.

Study Type	Efficacy						
Pertaining to	Infectious Bronchitis Virus (IBV), Massachusetts Type						
Study Purpose	To demonstrate the effectiveness against Infectious Bronchitis Virus, Massachusetts Type infection						
Product Administration	One dose administered by the course spray route						
Study Animals	60 SPF chickens per treatment group vaccinated at day of age						
Challenge Description	Homologous IB Mass-41 challenge virus administered at 25 days post vaccination						
Interval observed after challenge	Daily observation for 5 days post challenge; tissues examined at 5 days post challenge						
Results	<p>A chicken was considered affected by the challenge (positive) if IBV was recovered from the target tissue.</p> <p>The study fulfilled 9 CFR 113.327(c)</p> <table border="1"> <thead> <tr> <th>Treatment</th> <th>Number unaffected/Total</th> </tr> </thead> <tbody> <tr> <td>Vaccinated, challenged</td> <td>54/60</td> </tr> <tr> <td>Placebo-vaccinated, challenged control</td> <td>0/60</td> </tr> </tbody> </table> <p>6/60 vaccinates and 60/60 controls were affected by the challenge with IBV Mass.</p> <p>Raw data are shown on the attached pages.</p>	Treatment	Number unaffected/Total	Vaccinated, challenged	54/60	Placebo-vaccinated, challenged control	0/60
Treatment	Number unaffected/Total						
Vaccinated, challenged	54/60						
Placebo-vaccinated, challenged control	0/60						
USDA Approval Date	March 13, 2013						

Control Group

Control ID	Virus Recovery	Control ID	Virus Recovery
1	Pos	61	Pos
2	Pos	62	Pos
3	Pos	63	Pos
4	Pos	64	Pos
5	Pos	65	Pos
6	Pos	66	Pos
7	Pos	67	Pos
8	Pos	68	Pos
9	Pos	69	Pos
10	Pos	70	Pos
11	Pos	71	Pos
12	Pos	72	Pos
13	Pos	73	Pos
14	Pos	74	Pos
15	Pos	75	Pos
16	Pos	76	Pos
17	Pos	77	Pos
18	Pos	78	Pos
19	Pos	79	Pos
20	Pos	80	Pos
21	Pos	81	Pos
22	Pos	82	Pos
23	Pos	83	Pos
24	Pos	84	Pos
25	Pos	85	Pos
26	Pos	86	Pos
27	Pos	87	Pos
28	Pos	88	Pos
29	Pos	89	Pos
30	Pos	90	Pos

Vaccinate Group

Vaccinate ID	Virus Recovery	Vaccinate ID	Virus Recovery
31	Neg	91	Neg
32	Neg	92	Neg
33	Neg	93	Neg
34	Neg	94	Neg
35	Neg	95	Neg
36	Neg	96	Neg
37	Neg	97	Neg
38	Pos	98	Neg
39	Neg	99	Pos
40	Neg	100	Pos
41	Neg	101	Pos
42	Neg	102	Neg
43	Neg	103	Neg
44	Neg	104	Neg
45	Neg	105	Neg
46	Neg	106	Neg
47	Neg	107	Neg
48	Pos	108	Neg
49	Neg	109	Neg
50	Neg	110	Neg
51	Neg	111	Pos
52	Neg	112	Neg
53	Neg	113	Neg
54	Neg	114	Neg
55	Neg	115	Neg
56	Neg	116	Neg
57	Neg	117	Neg
58	Neg	118	Neg
59	Neg	119	Neg
60	Neg	120	Neg

Study Type	Safety																																									
Pertaining to	All fractions																																									
Study Purpose	Field safety																																									
Product Administration	One dose, coarse spray administration																																									
Study Animals	Commercial chickens at day of age. 100,800 were vaccinated with product vaccine and 78,400 were kept as controls. There were three independent sites. Commercial chickens were observed for 14 days post vaccination.																																									
Challenge Description	NA																																									
Interval observed after challenge	Chickens were observed daily for 14 days after vaccination.																																									
Results	<table border="1"> <thead> <tr> <th>Location</th> <th>Treatment Group</th> <th>Total Placed</th> <th>14 Day Mortality</th> <th>% Mortality</th> </tr> </thead> <tbody> <tr> <td rowspan="4">1</td> <td rowspan="2">Vaccinate</td> <td>19,200</td> <td>232</td> <td>1.21%</td> </tr> <tr> <td>19,200</td> <td>283</td> <td>1.47%</td> </tr> <tr> <td rowspan="2">Control</td> <td>19,200</td> <td>245</td> <td>1.28%</td> </tr> <tr> <td>19,200</td> <td>331</td> <td>1.72%</td> </tr> <tr> <td rowspan="3">2</td> <td rowspan="2">Vaccinate</td> <td>21,500</td> <td>293</td> <td>1.36%</td> </tr> <tr> <td>21,500</td> <td>273</td> <td>1.27%</td> </tr> <tr> <td>Control</td> <td>22,600</td> <td>335</td> <td>1.48%</td> </tr> <tr> <td rowspan="2">3</td> <td>Vaccinate</td> <td>19,400</td> <td>175</td> <td>0.90%</td> </tr> <tr> <td>Control</td> <td>17,400</td> <td>202</td> <td>1.16%</td> </tr> </tbody> </table> <p>No adverse reactions attributable to the vaccine were recorded.</p>	Location	Treatment Group	Total Placed	14 Day Mortality	% Mortality	1	Vaccinate	19,200	232	1.21%	19,200	283	1.47%	Control	19,200	245	1.28%	19,200	331	1.72%	2	Vaccinate	21,500	293	1.36%	21,500	273	1.27%	Control	22,600	335	1.48%	3	Vaccinate	19,400	175	0.90%	Control	17,400	202	1.16%
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