Summary of Studies Supporting USDA Product Licensure

Establishment Name	Biomune Company
USDA Vet Biologics Establishment Number	368
Product Code	1231.1L
True Name	Bronchitis Vaccine, Georgia Type, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	CEVAC IBron LYO - No distributor specified
Date of Compilation Summary	September 01, 2017

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.

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Infectious Bronchitis Virus (IBV)</td></tr>
<tr><td>Study Purpose</td><td>Pivotal efficacy against IBV, Georgia 13 Type</td></tr>
<tr><td>Product Administration</td><td>One dose administered by the coarse spray route</td></tr>
<tr><td>Study Animals</td><td>30 chickens per treatment group vaccinated at day of age</td></tr>
<tr><td>Challenge Description</td><td>Heterologous IBV Georgia 13 Type administered at 28 days post vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Daily observation for 5 days post challenge; IBV evaluated in the target tissue day 5 post challenge</td></tr>
<tr><td>Results</td><td>A chicken was considered affected by the challenge (positive) if IBV was recovered from the target tissue.

The study fulfilled 9 CFR 113.327(c)

<table><tr><td>Treatment</td><td>Number protected/Total</td></tr><tr><td>Vaccinated, challenged</td><td>26/30</td></tr><tr><td>Placebo-vaccinated, challenged control</td><td>0/30</td></tr></table>
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Vaccinate ID	Virus Recovery	Control ID	Virus Recovery
1	Neg	1	Pos
2	Pos	2	Pos
3	Neg	3	Pos
4	Neg	4	Pos
5	Neg	5	Pos
6	Neg	6	Pos
7	Neg	7	Pos
8	Neg	8	Pos
9	Neg	9	Pos
10	Neg	10	Pos
11	Neg	11	Pos
12	Neg	12	Pos
13	Neg	13	Pos
14	Neg	14	Pos
15	Pos	15	Pos
16	Neg	16	Pos
17	Neg	17	Pos
18	Neg	18	Pos
19	Neg	19	Pos
20	Neg	20	Pos
21	Neg	21	Pos
22	Pos	22	Pos
23	Neg	23	Pos
24	Neg	24	Pos
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27	Neg	27	Pos
28	Neg	28	Pos
29	Neg	29	Pos
30	Pos	30	Pos

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<tr><td>Study Purpose</td><td>Pivotal efficacy against IBV, Georgia 08 Type infection</td></tr>
<tr><td>Product Administration</td><td>One dose administered by the coarse spray route</td></tr>
<tr><td>Study Animals</td><td>30 chickens per treatment group vaccinated at day of age</td></tr>
<tr><td>Challenge Description</td><td>Homologous IBV Georgia 08 administered at 26 days post vaccination</td></tr>
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10	Neg	10	Pos
11	Neg	11	Pos
12	Neg	12	Pos
13	Pos	13	Pos
14	Neg	14	Pos
15	Neg	15	Pos
16	Neg	16	Pos
17	Pos	17	Pos
18	Neg	18	Pos
19	Neg	19	Pos
20	Neg	20	Neg
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<tr><td>Product Administration</td><td>One dose administered by the gel spray route (gel droplet by oral administration)</td></tr>
<tr><td>Study Animals</td><td>30 chickens per treatment group vaccinated at day of age</td></tr>
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3	Neg	3	Pos
4	Neg	4	Pos
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15	Neg	15	Pos
16	Neg	16	Pos
17	Neg	17	Pos
18	Neg	18	Pos
19	Neg	19	Pos
20	Neg	20	Pos
21	Neg	21	Pos
22	Neg	22	Pos
23	Neg	23	Pos
24	Neg	24	Pos
25	Neg	25	Pos
26	Neg	26	Pos
27	Neg	27	Pos
28	Neg	28	Neg
29	Neg	29	Pos
30	Neg	30	Pos

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate safety under field conditions</td></tr>
<tr><td>Product Administration</td><td>Single dose, coarse spray administration</td></tr>
<tr><td>Study Animals</td><td>Commercial broilers at day of age. Three independent sites</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Commercial broilers were observed for 14 days post vaccination.</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Site</th><th>Treatment</th><th>Number of Chickens</th><th>Percent Mortality</th><th>Percent Condemnation</th></tr>
<tr><td rowspan="2">1</td><td>Vaccinate</td><td>19,000</td><td>4.0</td><td>Not available</td></tr>
<tr><td>Control</td><td>21,000</td><td>3.6</td><td>Not available</td></tr>
<tr><td rowspan="2">2</td><td>Vaccinate</td><td>40,000</td><td>1.9</td><td>Not available</td></tr>
<tr><td>Control</td><td>40,000</td><td>3.6</td><td>Not available</td></tr>
<tr><td rowspan="2">3</td><td>Vaccinate</td><td>23,800</td><td>0.8</td><td>Not available</td></tr>
<tr><td>Control</td><td>23,800</td><td>1.0</td><td>Not available</td></tr>
</table>
No adverse reactions observed
</td></tr>
<tr><td>USDA Approval Date</td><td>December 17, 2015</td></tr>
</table>

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety of product under typical use conditions.</td></tr>
<tr><td>Product Administration</td><td>One dose administered via the gel droplet application (oral route).</td></tr>
<tr><td>Study Animals</td><td>Broiler chickens at day-of-age.
44,000 were vaccinated with product vaccine and 44,000 were kept as controls. Animals were observed daily for mortality through 21 days after vaccination.</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Not applicable</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Location</th><th>Treatment</th><th>Total Placed</th><th>21 Day Mortality</th><th>% Mortality</th><th>% Condemnation</th></tr>
<tr><td>1</td><td>Product Vaccine</td><td>23,000</td><td>337</td><td>1.47%</td><td>0.20%</td></tr>
<tr><td>1</td><td>Control</td><td>23,000</td><td>334</td><td>1.45%</td><td>0.31%</td></tr>
<tr><td>2</td><td>Product Vaccine</td><td>21,000</td><td>531</td><td>2.53%</td><td>0.60%</td></tr>
<tr><td>2</td><td>Control</td><td>21,000</td><td>491</td><td>2.29%</td><td>0.19%</td></tr>
</table>

No adverse reactions attributable to the vaccine were recorded.
</td></tr>
<tr><td>USDA Approval Date</td><td>July 11, 2017</td></tr>
</table>