# Summary of Studies Supporting USDA Product Licensure

| | |
|---|---|
| Establishment Name | Ceva Animal Health, LLC |
| USDA Vet Biologics Establishment Number | 368 |
| Product Code | 1431.50 |
| True Name | Coccidiosis Vaccine, Live Oocysts |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Immucox 5 - Biomune - Biomune Company<br>Immucox 5 - No distributor specified |
| Date of Compilation Summary | July 28, 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** | *Eimeria acervulina* |
| **Study Purpose** | Pivotal efficacy against *Eimeria acervulina* |
| **Product Administration** | One dose administered to chickens by the gel droplet application (oral route) |
| **Study Animals** | 53 chickens in the vaccinate group, 54 chickens in the positive control group and 20 chickens in the negative control group received a placebo vaccine. All chickens vaccinated at day-of-age. |
| **Challenge Description** | Homologous *Eimeria acervulina* administered at 30 days post vaccination to the vaccinate and positive control groups. |
| **Interval observed after challenge** | Chickens were observed daily for 5 days post challenge. Target tissues of duodenum, jejunum, ileum, ceca and large intestine were examined at 5 days post challenge. |
| **Results** | A chicken was considered affected by challenge if the lesion score was 2-4 (positive) in the intestine and unaffected if the lesion score was 0-1 (negative).<br><br>2/53 vaccinates and 48/54 positive controls and 0/20 negative controls were considered affected.<br><br>Raw data shown on the following page. |
| **USDA Approval Date** | January 27, 2016 |

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

**Table 1. Vaccinate Group**

| Tag No. | Lesion Score | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Ceca | Large Intestine |
| 307 | 2 | 0 | 0 | 0 | 0 |
| 337 | 3 | 3 | 0 | 1 | 0 |

**Table 2. Positive Control Group**

| Tag No. | Lesion Score | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Ceca | Large Intestine |
| 281 | 4 | 3 | 0 | 0 | 0 |
| 287 | 4 | 2 | 0 | 0 | 0 |
| 289 | 3 | 1 | 0 | 0 | 0 |
| 293 | 3 | 2 | 0 | 2 | 0 |
| 294 | 2 | 2 | 0 | 0 | 0 |
| 296 | 3 | 2 | 0 | 1 | 0 |
| 297 | 4 | 2 | 0 | 1 | 0 |
| 300 | 3 | 2 | 0 | 0 | 0 |
| 301 | 2 | 0 | 0 | 1 | 0 |
| 303 | 3 | 2 | 0 | 1 | 0 |
| 304 | 3 | 2 | 0 | 2 | 0 |
| 306 | 3 | 2 | 0 | 0 | 0 |
| 309 | 2 | 0 | 0 | 1 | 0 |
| 311 | 4 | 2 | 0 | 0 | 0 |
| 312 | 2 | 1 | 0 | 0 | 0 |
| 314 | 4 | 3 | 0 | 0 | 0 |
| 320 | 3 | 3 | 0 | 0 | 0 |
| 322 | 4 | 3 | 0 | 1 | 0 |
| 324 | 3 | 1 | 0 | 1 | 0 |
| 326 | 3 | 2 | 0 | 0 | 0 |
| 327 | 3 | 1 | 0 | 0 | 0 |
| 328 | 3 | 2 | 0 | 0 | 0 |
| 334 | 3 | 2 | 0 | 0 | 0 |
| 336 | 3 | 2 | 0 | 0 | 0 |
| 338 | 3 | 2 | 0 | 2 | 0 |
| 342 | 3 | 1 | 0 | 1 | 0 |
| 344 | 3 | 2 | 0 | 1 | 0 |
| 346 | 3 | 1 | 0 | 1 | 0 |
| 350 | 3 | 1 | 0 | 1 | 0 |
| 353 | 2 | 1 | 0 | 0 | 0 |
| 358 | 3 | 3 | 0 | 0 | 0 |
| 359 | 3 | 2 | 0 | 1 | 0 |
| 363 | 4 | 1 | 0 | 1 | 0 |
| 365 | 3 | 2 | 0 | 0 | 0 |
| 367 | 4 | 2 | 0 | 0 | 0 |
| 373 | 3 | 2 | 0 | 0 | 0 |
| 375 | 4 | 1 | 0 | 0 | 0 |
| 380 | 3 | 2 | 0 | 0 | 0 |
| 383 | 3 | 2 | 0 | 0 | 0 |
| 385 | 3 | 2 | 0 | 0 | 0 |
| 390 | 4 | 2 | 0 | 0 | 0 |
| 392 | 2 | 1 | 0 | 1 | 0 |
| 394 | 4 | 2 | 0 | 0 | 0 |
| 400 | 3 | 1 | 0 | 1 | 0 |
| 402 | 3 | 2 | 0 | 1 | 0 |
| 403 | 4 | 3 | 0 | 0 | 0 |
| 408 | 3 | 1 | 0 | 0 | 0 |
| 410 | 4 | 3 | 0 | 1 | 0 |

Key:
0 No gross lesions
+1 Scattered, white plaque-like lesions containing developing oocysts are confined to the duodenum. These lesions are elongated with the longer axis transversely oriented on the intestinal walls like the rungs of a ladder. They may be seen from either the serosal or mucosal intestinal surfaces. They may range up to a maximum of 5 lesions per square centimeter.

+2 Lesions are much closer together, but not coalescent; Lesions may extend as far posterior as 20 cm below the duodenum in 3-week-old birds. The intestinal walls show no thickening. Digestive tract contents are normal.
+3 Lesions are numerous enough to cause coalescence with reduction in lesion size and give the intestine a coated appearance. The intestinal wall is thickened and the contents are watery. Lesions may extend as far posterior as the yolk sac diverticulum.
+4 The mucosal wall is greyish with colonies completely coalescent. Congestion may be confined to small petechiae or, in extremely heavy infections, the entire mucosa may be bright red in color. The intestinal wall is very much thickened, and the intestine is filled with a creamy exudate which may bear large numbers of oocysts. Birds dying of coccidiosis are scored as +4.

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | *Eimeria acervulina* |
| **Study Purpose** | Demonstrate efficacy against *Eimeria acervulina* |
| **Product Administration** | One dose administered to day-of-age chickens by the gel droplet application via the oral route |
| **Study Animals** | 50 SPF chickens in the vaccinate group<br>50 SPF chickens in the positive control group<br>20 SPF chickens in the negative control group |
| **Challenge Description** | Homologous *Eimeria acervulina* administered at 27 days post vaccination to the vaccinate and positive control groups. Twenty control chickens remained unchallenged. |
| **Interval Observed After Challenge** | Chickens were observed daily for 5 days post challenge. Tissues of the small intestine (duodenum, jejunum, ileum), ceca and large intestine were examined at day 5 post challenge |
| **Results** | A chicken was considered affected by challenge if the lesion score was 2-4 (positive) in the duodenum, jejunum, or ileum and unaffected if the lesion score was 0-1 (negative).<br><br>5/49 vaccinates, 48/49 positive controls and 0/10 negative controls were considered affected.<br><br>Raw data shown on the following page. |
| **USDA Approval Date** | July 7, 2021 |

**Table 1. Vaccinate Group**

| Bird Tag No. | Lesion Scores | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Ceca | Large Intestine |
| 2001 | 0 | 0 | 0 | 0 | 0 |
| 2005 | 0 | 0 | 0 | 0 | 0 |
| 2007 | 0 | 0 | 0 | 0 | 0 |
| 2008 | 0 | 0 | 0 | 0 | 0 |
| 2011 | 0 | 0 | 0 | 0 | 0 |
| 2012 | 0 | 0 | 0 | 0 | 0 |
| 2013 | 0 | 0 | 0 | 0 | 0 |
| 2015 | 0 | 0 | 0 | 0 | 0 |
| 2017 | 0 | 0 | 0 | 0 | 0 |
| 2018 | 0 | 0 | 0 | 0 | 0 |
| 2020 | 0 | 0 | 0 | 0 | 0 |
| 2021 | 0 | 0 | 0 | 0 | 0 |
| 2023 | 0 | 0 | 0 | 0 | 0 |
| 2028 | 0 | 0 | 0 | 0 | 0 |
| 2032 | 1 | 1 | 0 | 0 | 0 |
| 2035 | 0 | 0 | 0 | 0 | 0 |
| 2037 | 0 | 0 | 0 | 0 | 0 |
| 2038 | 0 | 0 | 0 | 0 | 0 |
| 2040 | 0 | 0 | 0 | 0 | 0 |
| 2047 | 0 | 0 | 0 | 0 | 0 |
| 2048 | 3 | 2 | 1 | 0 | 0 |
| 2050 | 0 | 0 | 0 | 0 | 0 |
| 2057 | 0 | 0 | 0 | 0 | 0 |
| 2061 | 2 | 2 | 0 | 0 | 0 |
| 2062 | 0 | 0 | 0 | 0 | 0 |
| 2067 | 0 | 0 | 0 | 0 | 0 |
| 2071 | 0 | 0 | 0 | 0 | 0 |
| 2072 | 0 | 0 | 0 | 0 | 0 |
| 2074 | 0 | 0 | 0 | 0 | 0 |
| 2075 | 3 | 3 | 2 | 0 | 0 |
| 2080 | 0 | 0 | 0 | 0 | 0 |
| 2081 | 0 | 0 | 0 | 0 | 0 |
| 2088 | 2 | 2 | 1 | 0 | 0 |
| 2091 | 0 | 0 | 0 | 0 | 0 |
| 2092 | 0 | 0 | 0 | 0 | 0 |
| 2093 | 0 | 0 | 0 | 0 | 0 |
| 2094 | 0 | 0 | 0 | 0 | 0 |

| | | | | | |
|---|---|---|---|---|---|
| 2096 | 2 | 2 | 1 | 0 | 0 |
| 2097 | 0 | 0 | 0 | 0 | 0 |
| 2099 | 0 | 0 | 0 | 0 | 0 |
| 2105 | 0 | 0 | 0 | 0 | 0 |
| 2106 | 0 | 0 | 0 | 0 | 0 |
| 2107 | 0 | 0 | 0 | 0 | 0 |
| 2110 | 0 | 0 | 0 | 0 | 0 |
| 2113 | 0 | 0 | 0 | 0 | 0 |
| 2116 | 0 | 0 | 0 | 0 | 0 |
| 2117 | 0 | 0 | 0 | 0 | 0 |
| 2119 | 0 | 0 | 0 | 0 | 0 |
| 2120 | 0 | 0 | 0 | 0 | 0 |

**Table 2. Positive Control Group**

| Bird Tag No. | Lesion Scores | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Ceca | Large Intestine |
| 2003 | 3 | 3 | 2 | 0 | 0 |
| 2004 | 4 | 3 | 2 | 0 | 0 |
| 2009 | 2 | 2 | 1 | 0 | 0 |
| 2010 | 3 | 3 | 2 | 0 | 0 |
| 2016 | 3 | 3 | 2 | 0 | 0 |
| 2019 | 3 | 3 | 0 | 0 | 0 |
| 2022 | 4 | 3 | 2 | 0 | 0 |
| 2024 | 3 | 3 | 2 | 0 | 0 |
| 2025 | 4 | 3 | 2 | 0 | 0 |
| 2029 | 3 | 2 | 2 | 2 | 0 |
| 2030 | 3 | 2 | 2 | 3 | 0 |
| 2033 | 3 | 3 | 2 | 0 | 0 |
| 2034 | 3 | 2 | 1 | 0 | 0 |
| 2039 | 3 | 2 | 2 | 0 | 0 |
| 2042 | 3 | 2 | 2 | 0 | 0 |
| 2043 | 4 | 3 | 2 | 0 | 0 |
| 2044 | 4 | 3 | 2 | 0 | 0 |
| 2045 | 3 | 2 | 1 | 0 | 0 |
| 2046 | 3 | 2 | 2 | 0 | 0 |
| 2049 | 4 | 3 | 2 | 0 | 0 |
| 2053 | 3 | 3 | 2 | 0 | 0 |
| 2054 | 4 | 3 | 2 | 0 | 0 |
| 2056 | 3 | 2 | 2 | 0 | 0 |
| 2058 | 4 | 3 | 2 | 0 | 0 |

| | | | | | |
|---|---|---|---|---|---|
| 2059 | 4 | 3 | 2 | 0 | 0 |
| 2060 | 4 | 3 | 2 | 0 | 0 |
| 2063 | 3 | 3 | 2 | 0 | 0 |
| 2065 | 4 | 3 | 2 | 0 | 0 |
| 2068 | 3 | 2 | 2 | 2 | 0 |
| 2069 | 4 | 3 | 2 | 0 | 0 |
| 2073 | 4 | 3 | 2 | 0 | 0 |
| 2076 | 3 | 2 | 2 | 0 | 0 |
| 2078 | 3 | 3 | 2 | 0 | 0 |
| 2082 | 4 | 3 | 2 | 0 | 0 |
| 2083 | 1 | 1 | 0 | 0 | 0 |
| 2084 | 4 | 3 | 3 | 0 | 0 |
| 2086 | 3 | 2 | 2 | 0 | 0 |
| 2087 | 4 | 3 | 2 | 0 | 0 |
| 2090 | 3 | 2 | 2 | 0 | 0 |
| 2095 | 3 | 3 | 2 | 0 | 0 |
| 2098 | 4 | 3 | 3 | 0 | 0 |
| 2101 | 3 | 2 | 1 | 0 | 0 |
| 2102 | 4 | 3 | 2 | 0 | 0 |
| 2104 | 3 | 3 | 2 | 0 | 0 |
| 2108 | 4 | 3 | 3 | 0 | 0 |
| 2109 | 3 | 3 | 2 | 1 | 0 |
| 2111 | 3 | 3 | 2 | 0 | 0 |
| 2112 | 3 | 3 | 2 | 0 | 0 |
| 2118 | 3 | 3 | 2 | 0 | 0 |

**Table 3. Negative Control Group**

| Bird Tag No. | Lesion Scores | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Ceca | Large Intestine |
| 2066 | 0 | 0 | 0 | 0 | 0 |
| 2070 | 0 | 0 | 0 | 0 | 0 |
| 2077 | 0 | 0 | 0 | 0 | 0 |
| 2079 | 0 | 0 | 0 | 0 | 0 |
| 2085 | 0 | 0 | 0 | 0 | 0 |
| 2089 | 0 | 0 | 0 | 0 | 0 |
| 2100 | 0 | 0 | 0 | 0 | 0 |
| 2103 | 0 | 0 | 0 | 0 | 0 |
| 2114 | 0 | 0 | 0 | 0 | 0 |
| 2115 | 0 | 0 | 0 | 0 | 0 |

Key:

0 No gross lesions.

+1 Scattered, white plaque-like lesions containing developing oocysts are confined to the duodenum. These lesions are elongated with the longer axis transversely oriented on the intestinal walls like the rungs of a ladder. They may be seen from either the serosal or mucosal intestinal surfaces. They may range up to a maximum of 5 lesions per square centimeter.

+2 Lesions are much closer together, but not coalescent; lesions may extend as far posterior as 20 cm below the duodenum in 3-week-old birds. The intestinal walls show no thickening. Digestive tract contents are normal.

+3 Lesions are numerous enough to cause coalescence with reduction in lesion size and give the intestine a coated appearance. The intestinal wall is thickened and the contents are watery. Lesions may extend as far posterior as the yolk sac diverticulum.

+4 The mucosal wall is greyish with colonies completely coalescent. Congestion may be confined to small petechiae or, in extremely heavy infections, the entire mucosa may be bright red in color (Morehouse and McGuire 1958). Individual lesions may be indistinguishable in the upper intestine. Typical ladder-like lesions appear in the middle part of the intestine. The intestinal wall is very much thickened, and the intestine is filled with a creamy exudate which may bear large numbers of oocysts. Birds dying of coccodiosis are scored a 4.

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | *Eimeria brunetti* |
| **Study Purpose** | Pivotal efficacy against *Eimeria brunetti* |
| **Product Administration** | One dose administered to chickens by the gel droplet application (oral route) |
| **Study Animals** | 54 chickens in the vaccinate group, 54 chickens in the positive control group and 20 chickens in the negative control group received a placebo vaccine. All chickens vaccinated at day-of-age. |
| **Challenge Description** | Homologous *Eimeria brunetti* administered at 30 days post vaccination to the vaccinate and positive control groups. |
| **Interval observed after challenge** | Chickens were observed daily for 6 days post challenge. Target tissues of duodenum, jejunum, ileum, ceca and large intestine were examined at 6 days post challenge. |
| **Results** | A chicken was considered affected by challenge if the lesion score was 2-4 (positive) in the intestine and unaffected if the lesion score was 0-1 (negative).<br><br>1/54 vaccinates and 46/54 positive controls and 0/20 negative controls were considered affected.<br><br>Raw data shown on the following page. |
| **USDA Approval Date** | January 27, 2016 |

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

**Table 1. Vaccinate Group**

| Tag No. | Lesion Score | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Ceca | Large Intestine |
| 6 | 0 | 1 | 1 | 1 | 2 |

**Table 2. Positive Control Group**

| Tag No. | Lesion Score | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Ceca | Large Intestine |
| 5 | 1 | 2 | 2 | 2 | 3 |
| 7 | 0 | 2 | 2 | 2 | 2 |
| 9 | 1 | 2 | 3 | 2 | 3 |
| 16 | 1 | 2 | 3 | 2 | 4 |
| 20 | 0 | 2 | 3 | 1 | 2 |
| 26 | 0 | 2 | 2 | 2 | 2 |
| 28 | 1 | 2 | 3 | 1 | 2 |
| 30 | 0 | 2 | 2 | 2 | 2 |
| 32 | 0 | 1 | 3 | 1 | 2 |
| 33 | 0 | 2 | 2 | 2 | 3 |
| 36 | 0 | 2 | 2 | 1 | 2 |
| 46 | 0 | 2 | 3 | 2 | 3 |
| 47 | 0 | 2 | 3 | 2 | 3 |
| 48 | 0 | 2 | 2 | 1 | 2 |
| 51 | 0 | 1 | 3 | 2 | 2 |
| 53 | 0 | 1 | 2 | 1 | 2 |
| 57 | 1 | 3 | 3 | 2 | 3 |
| 58 | 0 | 1 | 2 | 2 | 3 |
| 60 | 0 | 2 | 4 | 1 | 3 |
| 63 | 0 | 2 | 2 | 1 | 2 |
| 64 | 0 | 2 | 2 | 1 | 2 |
| 65 | 0 | 2 | 3 | 2 | 2 |
| 66 | 0 | 3 | 3 | 2 | 3 |
| 68 | 0 | 2 | 2 | 1 | 2 |
| 72 | 0 | 2 | 4 | 2 | 3 |
| 74 | 0 | 2 | 2 | 0 | 2 |
| 77 | 0 | 2 | 2 | 1 | 2 |
| 80 | 0 | 3 | 3 | 0 | 3 |
| 83 | 0 | 3 | 3 | 2 | 3 |
| 84 | 0 | 1 | 2 | 2 | 2 |
| 87 | 1 | 2 | 2 | 2 | 2 |
| 91 | 0 | 2 | 2 | 1 | 3 |
| 93 | 0 | 3 | 2 | 2 | 2 |
| 96 | 0 | 1 | 2 | 1 | 2 |
| 98 | 0 | 1 | 3 | 1 | 2 |
| 99 | 0 | 2 | 2 | 1 | 2 |
| 100 | 0 | 2 | 3 | 2 | 4 |
| 101 | 0 | 2 | 3 | 2 | 3 |
| 105 | 1 | 2 | 3 | 1 | 2 |
| 106 | 0 | 2 | 3 | 2 | 3 |
| 107 | 0 | 2 | 2 | 1 | 2 |
| 110 | 0 | 1 | 2 | 2 | 2 |
| 112 | 0 | 1 | 3 | 1 | 3 |
| 113 | 0 | 0 | 1 | 0 | 2 |
| 118 | 0 | 3 | 3 | 2 | 3 |
| 120 | 0 | 1 | 2 | 1 | 2 |

Key:
0 No gross lesions.
+1 No gross lesions. In the absence of distinct lesions, presence of parasites may go undetected unless scrapings from suspicious areas are examined microscopically.
+2 Intestinal wall may appear grey in color. The lower portion may be thickened and flecks of salmon-colored material sloughed from the intestine are present.

+3 Intestinal wall thickened and a blood-tinged catarrhal exudate present. Transverse red streaks may be present in the lower rectum and lesions occur in the cecal tonsils. Soft mucus plugs may be present in this latter area.
+4 Extensive coagulation necrosis of the mucosal surface of the lower intestine may be present. In some birds a dry necrotic membrane may line the intestine and caseous cores may plug the ceca. Lesions may extend into the middle or upper intestine. Dead birds are scored 4.

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | *Eimeria brunetti* |
| **Study Purpose** | Demonstrate efficacy against *Eimeria brunetti* |
| **Product Administration** | One dose administered to day-of-age chickens by the gel droplet application via the oral route |
| **Study Animals** | 50 SPF chickens in the vaccinate group<br>50 SPF chickens in the positive control group<br>20 SPF chickens in the negative control group |
| **Challenge Description** | Homologous *Eimeria brunetti* administered at 27 days post vaccination to the vaccinate and positive control groups. The negative control group remained unchallenged. |
| **Interval Observed After Challenge** | Chickens were observed daily for 6 days post challenge. Tissues of the small intestine (duodenum, jejunum, ileum), ceca and large intestine were examined at day 6 post challenge |
| **Results** | A chicken was considered affected by challenge if the lesion score was 2-4 (positive) in either the ileum or large intestine and unaffected if the lesion score was 0-1 (negative).<br><br>7/50 vaccinates, 46/50 positive controls and 0/10 negative controls were considered affected.<br><br>Raw data shown on the following page. |
| **USDA Approval Date** | July 7, 2021 |

**Table 1. Vaccinate Group**

| Bird Tag No. | Lesion Scores | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Caeca | Large Intestine |
| 2122 | 0 | 0 | 3 | 0 | 1 |
| 2124 | 0 | 0 | 3 | 0 | 2 |
| 2126 | 0 | 0 | 0 | 0 | 0 |
| 2127 | 0 | 0 | 0 | 0 | 0 |
| 2131 | 0 | 0 | 0 | 0 | 0 |
| 2132 | 0 | 0 | 0 | 0 | 0 |
| 2133 | 0 | 0 | 0 | 0 | 0 |
| 2136 | 0 | 0 | 1 | 0 | 0 |
| 2138 | 0 | 0 | 0 | 0 | 0 |
| 2140 | 0 | 0 | 3 | 0 | 1 |
| 2142 | 0 | 0 | 0 | 0 | 0 |
| 2146 | 0 | 0 | 0 | 0 | 0 |
| 2148 | 0 | 0 | 0 | 0 | 0 |
| 2150 | 0 | 0 | 0 | 0 | 0 |
| 2153 | 0 | 0 | 0 | 0 | 0 |
| 2154 | 0 | 0 | 0 | 0 | 0 |
| 2155 | 0 | 0 | 0 | 0 | 0 |
| 2157 | 0 | 0 | 0 | 0 | 0 |
| 2159 | 0 | 0 | 3 | 0 | 2 |
| 2161 | 0 | 0 | 2 | 0 | 1 |
| 2165 | 0 | 0 | 1 | 0 | 0 |
| 2166 | 0 | 0 | 0 | 0 | 0 |
| 2171 | 0 | 0 | 0 | 0 | 0 |
| 2172 | 0 | 0 | 0 | 0 | 0 |
| 2173 | 0 | 0 | 0 | 0 | 0 |
| 2176 | 0 | 0 | 0 | 0 | 0 |
| 2177 | 0 | 0 | 0 | 0 | 0 |
| 2178 | 0 | 0 | 0 | 0 | 0 |
| 2182 | 0 | 0 | 2 | 0 | 0 |
| 2183 | 0 | 0 | 0 | 0 | 0 |
| 2184 | 0 | 0 | 0 | 0 | 0 |
| 2188 | 0 | 0 | 0 | 0 | 0 |
| 2192 | 0 | 0 | 0 | 0 | 0 |
| 2198 | 0 | 0 | 0 | 0 | 0 |
| 2199 | 0 | 0 | 0 | 0 | 0 |
| 2201 | 0 | 0 | 0 | 0 | 0 |
| 2202 | 0 | 0 | 0 | 0 | 0 |

| | | | | | |
|---|---|---|---|---|---|
| 2204 | 0 | 0 | 0 | 0 | 0 |
| 2206 | 0 | 0 | 0 | 0 | 0 |
| 2210 | 0 | 0 | 1 | 0 | 0 |
| 2213 | 0 | 0 | 2 | 0 | 1 |
| 2216 | 0 | 0 | 0 | 0 | 0 |
| 2220 | 0 | 0 | 0 | 0 | 0 |
| 2223 | 0 | 0 | 0 | 0 | 0 |
| 2224 | 0 | 0 | 0 | 0 | 0 |
| 2225 | 0 | 0 | 0 | 0 | 0 |
| 2228 | 0 | 0 | 0 | 0 | 0 |
| 2233 | 0 | 0 | 0 | 0 | 0 |
| 2236 | 0 | 0 | 0 | 0 | 0 |
| 2238 | 0 | 0 | 0 | 0 | 0 |

**Table 2. Positive Control Group**

| Bird Tag No. | Lesion Scores | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Caeca | Large Intestine |
| 2121 | 0 | 0 | 3 | 0 | 2 |
| 2123 | 0 | 0 | 2 | 0 | 0 |
| 2128 | 0 | 0 | 3 | 0 | 0 |
| 2129 | 0 | 0 | 2 | 0 | 0 |
| 2130 | 0 | 0 | 3 | 0 | 2 |
| 2134 | 0 | 0 | 3 | 0 | 1 |
| 2135 | 0 | 0 | 4 | 0 | 1 |
| 2137 | 0 | 0 | 2 | 0 | 1 |
| 2144 | 0 | 0 | 2 | 0 | 0 |
| 2145 | 0 | 0 | 3 | 0 | 2 |
| 2149 | 0 | 0 | 3 | 0 | 1 |
| 2151 | 0 | 0 | 3 | 0 | 1 |
| 2152 | 0 | 0 | 4 | 0 | 2 |
| 2156 | 0 | 0 | 1 | 0 | 0 |
| 2158 | 0 | 0 | 3 | 0 | 1 |
| 2162 | 0 | 0 | 2 | 0 | 0 |
| 2163 | 0 | 0 | 3 | 0 | 1 |
| 2164 | 0 | 0 | 4 | 0 | 2 |
| 2169 | 0 | 0 | 2 | 0 | 0 |
| 2174 | 0 | 0 | 4 | 0 | 3 |
| 2175 | 0 | 0 | 3 | 0 | 2 |
| 2180 | 0 | 0 | 2 | 0 | 0 |
| 2185 | 0 | 0 | 3 | 0 | 1 |

| | | | | | |
|---|---|---|---|---|---|
| 2186 | 0 | 0 | 3 | 0 | 1 |
| 2189 | 0 | 0 | 4 | 0 | 2 |
| 2190 | 0 | 0 | 3 | 0 | 1 |
| 2193 | 0 | 0 | 3 | 2 | 2 |
| 2195 | 0 | 0 | 3 | 0 | 1 |
| 2196 | 0 | 0 | 1 | 0 | 0 |
| 2200 | 0 | 0 | 3 | 2 | 2 |
| 2203 | 0 | 0 | 4 | 0 | 3 |
| 2205 | 0 | 0 | 2 | 0 | 1 |
| 2207 | 0 | 0 | 2 | 0 | 1 |
| 2208 | 0 | 0 | 3 | 0 | 2 |
| 2209 | 0 | 0 | 1 | 0 | 0 |
| 2211 | 0 | 0 | 3 | 0 | 2 |
| 2214 | 0 | 0 | 4 | 0 | 2 |
| 2215 | 0 | 2 | 3 | 0 | 0 |
| 2217 | 0 | 0 | 2 | 0 | 0 |
| 2218 | 0 | 0 | 3 | 0 | 2 |
| 2221 | 0 | 0 | 3 | 0 | 2 |
| 2222 | 0 | 0 | 3 | 0 | 0 |
| 2226 | 0 | 0 | 3 | 0 | 1 |
| 2229 | 0 | 0 | 2 | 0 | 0 |
| 2230 | 0 | 0 | 1 | 0 | 0 |
| 2232 | 0 | 0 | 3 | 0 | 0 |
| 2234 | 0 | 0 | 4 | 0 | 2 |
| 2237 | 0 | 0 | 2 | 0 | 1 |
| 2239 | 0 | 0 | 3 | 0 | 1 |
| 2240 | 0 | 0 | 2 | 0 | 0 |

**Table 3. Negative Control Group**

| Bird Tag No. | Lesion Scores | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Caeca | Large Intestine |
| 2181 | 0 | 0 | 0 | 0 | 0 |
| 2187 | 0 | 0 | 0 | 0 | 0 |
| 2191 | 0 | 0 | 0 | 0 | 0 |
| 2194 | 0 | 0 | 0 | 0 | 0 |
| 2197 | 0 | 0 | 0 | 0 | 0 |
| 2212 | 0 | 0 | 0 | 0 | 0 |
| 2219 | 0 | 0 | 0 | 0 | 0 |
| 2227 | 0 | 0 | 0 | 0 | 0 |
| 2231 | 0 | 0 | 0 | 0 | 0 |

| | | | | | |
|---|---|---|---|---|---|
| 2235 | 0 | 0 | 0 | 0 | 0 |

Key:

0 No gross lesions.

+1 No gross lesions. In the absence of distinct lesions, presence of parasites may go undetected unless scrapings from suspicious areas are examined microscopically.

+2 Intestinal wall may appear grey in color. The lower portion may be thickened and flecks of salmon-colored material sloughed from the intestine are present.

+3 Intestinal wall thickened and a blood-tinged catarrhal exudate present. Transverse red streaks may be present in the lower rectum and lesions occur in the cecal tonsils. Soft mucus plugs may be present in this latter area.

+4 Extensive coagulation necrosis of the mucosal surface of the lower intestine may be present. In some birds a dry necrotic membrane may line the intestine and caseous cores may plug the ceca. Lesions may extend into the middle or upper intestine. Dead birds are scored 4.

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | *Eimeria maxima* |
| **Study Purpose** | Pivotal efficacy against *Eimeria maxima* |
| **Product Administration** | One dose administered to chickens by the gel droplet application (oral route) |
| **Study Animals** | 54 chickens in the vaccinate group, 55 chickens in the positive control group and 20 chickens in the negative control group received a placebo vaccine. All chickens vaccinated at day-of-age. |
| **Challenge Description** | Homologous *Eimeria maxima* administered at 30 days post vaccination to the vaccinate and positive control groups. |
| **Interval observed after challenge** | Chickens were observed daily for 6 days post challenge. Target tissues of duodenum, jejunum, ileum, ceca and large intestine were examined at 6 days post challenge. |
| **Results** | A chicken was considered affected by challenge if the lesion score was 2-4 (positive) in the intestine and unaffected if the lesion score was 0-1 (negative).<br><br>0/54 vaccinates and 50/55 controls and 0/20 negative controls were considered affected.<br><br>Raw data shown on the following page. |
| **USDA Approval Date** | January 28, 2016 |

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

**Table 1. Positive Control Group**

| Tag No. | Lesion Score | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Ceca | Large Intestine |
| 424 | 2 | 4 | 3 | 0 | 0 |
| 425 | 2 | 3 | 1 | 0 | 0 |
| 428 | 3 | 4 | 2 | 0 | 0 |
| 437 | 2 | 2 | 1 | 1 | 0 |
| 440 | 1 | 3 | 1 | 0 | 0 |
| 441 | 2 | 4 | 3 | 0 | 0 |
| 442 | 2 | 3 | 1 | 0 | 0 |
| 445 | 2 | 3 | 1 | 1 | 0 |
| 446 | 3 | 4 | 0 | 0 | 0 |
| 448 | 2 | 2 | 0 | 0 | 0 |
| 449 | 2 | 3 | 2 | 0 | 0 |
| 454 | 2 | 2 | 2 | 0 | 0 |
| 458 | 3 | 3 | 2 | 0 | 0 |
| 459 | 2 | 3 | 1 | 2 | 0 |
| 460 | 2 | 3 | 2 | 1 | 0 |
| 464 | 2 | 3 | 1 | 0 | 0 |
| 468 | 2 | 3 | 2 | 1 | 0 |
| 472 | 3 | 3 | 1 | 0 | 0 |
| 474 | 2 | 4 | 2 | 1 | 1 |
| 477 | 2 | 4 | 2 | 0 | 0 |
| 479 | 1 | 3 | 1 | 0 | 0 |
| 481 | 1 | 3 | 1 | 2 | 0 |
| 488 | 3 | 4 | 2 | 1 | 0 |
| 492 | 1 | 3 | 2 | 0 | 0 |
| 493 | 2 | 3 | 2 | 1 | 0 |
| 494 | 1 | 2 | 1 | 2 | 0 |
| 496 | 1 | 3 | 2 | 0 | 0 |
| 500 | 2 | 4 | 2 | 2 | 0 |
| 501 | 0 | 2 | 2 | 0 | 0 |
| 503 | 4 | 4 | 0 | 0 | 0 |
| 505 | 2 | 3 | 2 | 0 | 0 |
| 508 | 2 | 3 | 1 | 0 | 0 |
| 509 | 1 | 3 | 1 | 0 | 0 |
| 511 | 2 | 3 | 1 | 2 | 1 |
| 513 | 2 | 3 | 2 | 0 | 0 |
| 514 | 2 | 3 | 2 | 0 | 0 |
| 519 | 2 | 3 | 1 | 0 | 0 |
| 523 | 1 | 2 | 1 | 1 | 1 |
| 524 | 1 | 3 | 1 | 0 | 0 |
| 525 | 0 | 3 | 0 | 0 | 0 |
| 530 | 3 | 4 | 2 | 1 | 0 |
| 533 | 3 | 4 | 3 | 0 | 0 |
| 537 | 2 | 3 | 1 | 1 | 0 |
| 540 | 3 | 4 | 2 | 2 | 0 |
| 541 | 2 | 3 | 1 | 2 | 0 |
| 544 | 1 | 4 | 1 | 0 | 0 |
| 545 | 3 | 4 | 3 | 1 | 0 |
| 547 | 3 | 4 | 2 | 0 | 0 |
| 550 | 2 | 3 | 1 | 1 | 0 |
| 553 | 2 | 3 | 0 | 0 | 0 |

Key:
0 No gross lesions.
+1 Small red petechiae may appear on the serosal side of the mid-intestine. There is no ballooning or thickening of the intestine, though small amounts of orange mucus may be present.
+2 Serosal surface may be speckled with numerous red petechiae; intestine may be filled with orange mucus; little or no ballooning of the intestine; thickening of the wall.
+3 Intestinal wall is ballooned and thickened. The mucosal surface is roughened; intestinal contents filled with pinpoint blood clots and mucus.
+4 The intestinal wall may be ballooned for most of its length; contains numerous blood clots and digested red blood cells giving a characteristic color and putrid odor; the wall is greatly thickened; dead birds are recorded with this score.

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | *Eimeria maxima* |
| **Study Purpose** | Demonstrate efficacy against *Eimeria maxima* |
| **Product Administration** | One dose administered to day-of-age chickens by the gel droplet application via the oral route |
| **Study Animals** | 50 SPF chickens in the vaccinate group<br>50 SPF chickens in the positive control group<br>20 SPF chickens in the negative control group |
| **Challenge Description** | Homologous *Eimeria maxima* administered at 27 days post vaccination to the vaccinate and positive control groups. Twenty negative control chickens remained unchallenged. |
| **Interval Observed After Challenge** | Chickens were observed daily for 6 days post challenge. Tissues of the small intestine (duodenum, jejunum, ileum), ceca and large intestine were examined at day 6 post challenge. |
| **Results** | A chicken was considered affected by challenge if the lesion score was 2-4 (positive) in either the duodenum, jejunum, or ileum and unaffected if the lesion score was 0-1 (negative).<br><br>8/50 vaccinates, 49/50 positive controls and 0/10 negative controls were considered affected.<br><br>Raw data shown on the following page. |
| **USDA Approval Date** | July 13, 2021 |

**Table 1. Vaccinate Group**

| Bird Tag No. | Lesion Scores | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Caeca | Large Intestine |
| 2242 | 0 | 0 | 0 | 0 | 0 |
| 2244 | 0 | 0 | 0 | 0 | 0 |
| 2246 | 0 | 0 | 0 | 0 | 0 |
| 2251 | 0 | 0 | 0 | 0 | 0 |
| 2253 | 0 | 1 | 0 | 0 | 0 |
| 2254 | 0 | 0 | 0 | 0 | 0 |
| 2257 | 0 | 1 | 0 | 0 | 0 |
| 2259 | 0 | 0 | 0 | 0 | 0 |
| 2260 | 2 | 2 | 1 | 0 | 0 |
| 2261 | 0 | 0 | 0 | 0 | 0 |
| 2263 | 0 | 0 | 0 | 0 | 0 |
| 2268 | 0 | 0 | 0 | 0 | 0 |
| 2269 | 0 | 1 | 0 | 0 | 0 |
| 2272 | 0 | 0 | 0 | 0 | 0 |
| 2273 | 0 | 0 | 0 | 0 | 0 |
| 2276 | 0 | 2 | 1 | 0 | 0 |
| 2279 | 2 | 4 | 3 | 2 | 0 |
| 2280 | 0 | 0 | 0 | 0 | 0 |
| 2282 | 0 | 0 | 0 | 0 | 0 |
| 2285 | 0 | 0 | 0 | 0 | 0 |
| 2286 | 0 | 0 | 0 | 0 | 0 |
| 2287 | 0 | 2 | 2 | 0 | 0 |
| 2288 | 0 | 0 | 0 | 0 | 0 |
| 2289 | 0 | 1 | 0 | 0 | 0 |
| 2296 | 0 | 2 | 0 | 0 | 0 |
| 2298 | 0 | 0 | 0 | 0 | 0 |
| 2299 | 0 | 0 | 0 | 0 | 0 |
| 2301 | 2 | 3 | 1 | 0 | 0 |
| 2302 | 0 | 0 | 0 | 0 | 0 |
| 2303 | 0 | 0 | 0 | 0 | 0 |
| 2309 | 0 | 0 | 0 | 0 | 0 |
| 2310 | 0 | 0 | 0 | 0 | 0 |
| 2313 | 0 | 0 | 0 | 0 | 0 |
| 2318 | 0 | 0 | 0 | 0 | 0 |
| 2320 | 0 | 0 | 0 | 0 | 0 |
| 2323 | 1 | 1 | 0 | 0 | 0 |
| 2324 | 0 | 0 | 0 | 0 | 0 |

| | | | | | |
|---|---|---|---|---|---|
| 2326 | 1 | 1 | 2 | 0 | 0 |
| 2327 | 0 | 0 | 0 | 0 | 0 |
| 2329 | 0 | 0 | 0 | 0 | 0 |
| 2333 | 0 | 0 | 0 | 0 | 0 |
| 2341 | 2 | 3 | 3 | 0 | 0 |
| 2342 | 0 | 0 | 0 | 0 | 0 |
| 2345 | 0 | 0 | 0 | 0 | 0 |
| 2350 | 0 | 1 | 1 | 0 | 0 |
| 2351 | 0 | 0 | 0 | 0 | 0 |
| 2355 | 0 | 0 | 0 | 0 | 0 |
| 2356 | 0 | 0 | 0 | 0 | 0 |
| 2357 | 0 | 0 | 0 | 0 | 0 |
| 2359 | 0 | 0 | 0 | 0 | 0 |

**Table 2. Positive Control Group**

| Bird Tag No. | Lesion Scores | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Caeca | Large Intestine |
| 2241 | 1 | 3 | 1 | 0 | 0 |
| 2243 | 0 | 2 | 1 | 0 | 0 |
| 2245 | 1 | 3 | 2 | 0 | 0 |
| 2247 | 2 | 4 | 3 | 0 | 0 |
| 2249 | 2 | 3 | 2 | 0 | 0 |
| 2250 | 2 | 4 | 3 | 0 | 0 |
| 2252 | 2 | 2 | 1 | 0 | 0 |
| 2255 | 1 | 2 | 1 | 0 | 0 |
| 2256 | 2 | 3 | 2 | 0 | 1 |
| 2262 | 2 | 3 | 3 | 0 | 0 |
| 2264 | 2 | 3 | 2 | 0 | 0 |
| 2265 | 2 | 3 | 2 | 0 | 1 |
| 2270 | 2 | 3 | 3 | 0 | 0 |
| 2271 | 1 | 3 | 2 | 0 | 0 |
| 2274 | 1 | 3 | 2 | 0 | 0 |
| 2277 | 1 | 3 | 2 | 0 | 0 |
| 2278 | 1 | 3 | 2 | 0 | 0 |
| 2281 | 2 | 3 | 2 | 0 | 2 |
| 2284 | 2 | 4 | 3 | 0 | 0 |
| 2294 | 2 | 3 | 2 | 0 | 1 |
| 2295 | 2 | 3 | 2 | 0 | 0 |
| 2297 | 2 | 4 | 3 | 0 | 0 |
| 2300 | 0 | 1 | 1 | 0 | 0 |

| | | | | | |
|---|---|---|---|---|---|
| 2304 | 1 | 3 | 3 | 0 | 0 |
| 2305 | 2 | 3 | 2 | 0 | 0 |
| 2307 | 1 | 3 | 3 | 0 | 0 |
| 2308 | 0 | 2 | 0 | 0 | 0 |
| 2311 | 2 | 3 | 2 | 0 | 0 |
| 2312 | 2 | 4 | 2 | 0 | 0 |
| 2314 | 0 | 3 | 3 | 0 | 0 |
| 2315 | 2 | 3 | 3 | 0 | 0 |
| 2316 | 2 | 3 | 1 | 0 | 0 |
| 2317 | 2 | 4 | 3 | 0 | 0 |
| 2319 | 2 | 3 | 2 | 0 | 0 |
| 2322 | 2 | 3 | 3 | 0 | 0 |
| 2328 | 1 | 3 | 1 | 0 | 0 |
| 2330 | 2 | 3 | 2 | 0 | 0 |
| 2332 | 1 | 3 | 2 | 0 | 0 |
| 2334 | 2 | 3 | 0 | 0 | 0 |
| 2335 | 2 | 3 | 2 | 0 | 0 |
| 2338 | 2 | 4 | 3 | 0 | 0 |
| 2343 | 1 | 2 | 2 | 0 | 0 |
| 2344 | 2 | 3 | 2 | 0 | 0 |
| 2346 | 2 | 3 | 2 | 0 | 0 |
| 2347 | 2 | 3 | 2 | 0 | 0 |
| 2348 | 2 | 3 | 1 | 0 | 0 |
| 2349 | 1 | 2 | 2 | 0 | 0 |
| 2354 | 1 | 4 | 3 | 0 | 0 |
| 2358 | 2 | 3 | 2 | 0 | 1 |
| 2360 | 0 | 3 | 1 | 0 | 0 |

**Table 3. Negative Control Group**

| Bird Tag No. | Lesion Scores | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Caeca | Large Intestine |
| 2306 | 0 | 0 | 0 | 0 | 0 |
| 2321 | 0 | 0 | 0 | 0 | 0 |
| 2325 | 0 | 0 | 0 | 0 | 0 |
| 2331 | 0 | 0 | 0 | 0 | 0 |
| 2336 | 0 | 0 | 0 | 0 | 0 |
| 2337 | 0 | 0 | 0 | 0 | 0 |
| 2339 | 0 | 0 | 0 | 0 | 0 |
| 2340 | 0 | 0 | 0 | 0 | 0 |
| 2352 | 0 | 0 | 0 | 0 | 0 |

| | | | | | |
|---|---|---|---|---|---|
| 2353 | 0 | 0 | 0 | 0 | 0 |

Key:

0 No gross lesions.

+1 Small red petechiae may appear on the serosal side of the mid-intestine. There is no ballooning or thickening of the intestine, though small amounts of orange mucus may be present.

+2 Serosal surface may be speckled with numerous red petechiae; intestine may be filled with orange mucus; little or no ballooning of the intestine; thickening of the wall.

+3 Intestinal wall is ballooned and thickened. The mucosal surface is roughened; intestinal contents filled with pinpoint blood clots and mucus.

+4 The intestinal wall may be ballooned for most of its length; contains numerous blood clots and digested red blood cells giving a characteristic color and putrid odor; the wall is greatly thickened; dead birds are recorded with this score.

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | *Eimeria necatrix* |
| **Study Purpose** | Pivotal efficacy against *Eimeria necatrix* |
| **Product Administration** | One dose administered to chickens by the gel droplet application (oral route) |
| **Study Animals** | 55 chickens in the vaccinate group, 55 chickens in the positive control group and 20 chickens in the negative control group received a placebo vaccine. All chickens vaccinated at day-of-age. |
| **Challenge Description** | Homologous *Eimeria necatrix* administered at 30 days post vaccination to the vaccinate and positive control groups. |
| **Interval observed after challenge** | Chickens were observed daily for 6 days post challenge. Target tissues of duodenum, jejunum, ileum, ceca and large intestine were examined at 6 days post challenge. |
| **Results** | A chicken was considered affected by challenge if the lesion score was 2-4 (positive) in the intestine and unaffected if the lesion score was 0-1 (negative).<br><br>0/55 vaccinates and 54/55 controls and 0/20 negative controls were considered affected.<br><br>Raw data shown on the following page. |
| **USDA Approval Date** | January 28, 2016 |

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

**Table 1. Positive Control Group**

| Tag No. | Lesion Score | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Ceca | Large Intestine |
| 581 | 1 | 3 | 0 | 0 | 0 |
| 582 | 2 | 3 | 1 | 1 | 0 |
| 586 | 1 | 3 | 1 | 1 | 0 |
| 587 | 1 | 3 | 0 | 3 | 0 |
| 590 | 1 | 2 | 1 | 0 | 0 |
| 595 | 2 | 3 | 1 | 3 | 0 |
| 596 | 2 | 3 | 0 | 0 | 0 |
| 602 | 1 | 3 | 1 | 0 | 0 |
| 607 | 1 | 3 | 1 | 1 | 0 |
| 608 | 2 | 3 | 2 | 2 | 0 |
| 612 | 1 | 4 | 2 | 1 | 0 |
| 613 | 2 | 3 | 0 | 1 | 0 |
| 615 | 2 | 4 | 1 | 1 | 0 |
| 616 | 1 | 4 | 1 | 1 | 0 |
| 617 | 2 | 4 | 2 | 1 | 1 |
| 619 | 2 | 4 | 2 | 1 | 0 |
| 623 | 1 | 3 | 2 | 1 | 0 |
| 624 | 2 | 4 | 2 | 0 | 0 |
| 625 | 2 | 4 | 1 | 1 | 0 |
| 626 | 1 | 3 | 0 | 1 | 0 |
| 631 | 1 | 3 | 1 | 0 | 0 |
| 633 | 1 | 2 | 0 | 0 | 0 |
| 635 | 2 | 2 | 0 | 0 | 0 |
| 639 | 1 | 4 | 2 | 1 | 2 |
| 641 | 1 | 3 | 2 | 1 | 0 |
| 643 | 1 | 3 | 0 | 0 | 0 |
| 644 | 1 | 3 | 1 | 1 | 0 |
| 646 | 1 | 3 | 1 | 1 | 0 |
| 647 | 2 | 3 | 1 | 0 | 0 |
| 648 | 2 | 4 | 2 | 1 | 0 |
| 649 | 1 | 3 | 0 | 0 | 0 |
| 650 | 2 | 3 | 0 | 0 | 0 |
| 655 | 2 | 3 | 1 | 0 | 0 |
| 656 | 2 | 3 | 1 | 1 | 0 |
| 659 | 1 | 3 | 1 | 1 | 0 |
| 661 | 2 | 2 | 2 | 1 | 0 |
| 665 | 1 | 2 | 1 | 0 | 0 |
| 668 | 1 | 3 | 2 | 1 | 0 |
| 669 | 1 | 3 | 1 | 0 | 0 |
| 672 | 2 | 4 | 2 | 1 | 0 |
| 674 | 2 | 4 | 2 | 0 | 0 |
| 676 | 1 | 2 | 1 | 0 | 0 |
| 679 | 2 | 3 | 1 | 0 | 0 |
| 681 | 1 | 3 | 0 | 1 | 0 |
| 683 | 1 | 3 | 2 | 1 | 0 |
| 686 | 2 | 2 | 1 | 0 | 0 |
| 687 | 1 | 3 | 1 | 1 | 1 |
| 697 | 1 | 3 | 1 | 1 | 1 |
| 698 | 1 | 3 | 1 | 1 | 0 |
| 701 | 1 | 4 | 2 | 0 | 1 |
| 702 | 2 | 3 | 1 | 1 | 0 |
| 703 | 2 | 3 | 1 | 0 | 0 |
| 704 | 2 | 3 | 1 | 0 | 1 |
| 707 | 2 | 2 | 1 | 0 | 0 |

Key:
0 No gross lesions.
+1 Small scattered petechiae and white spots easily seen from the serosal side; little if any damage apparent on the mucosal surface.
+2 Numerous petechiae on the serosal surface; slight ballooning confined to the midgut area may be present.

+3 Extensive hemorrhage into the lumen of the intestine; serosal surface is covered with red petechiae and/or white plaques. The serosal surface is rough and thickened with many pinpoint hemorrhages. Normal intestinal contents are lacking; ballooning extends over lower half of small intestine.
+4 Extensive hemorrhage giving the intestine a dark color; intestinal contents consist of read or brown mucus. Ballooning may extend throughout much of the length of the intestine. Dead birds are scored as 4.

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | *Eimeria tenella* |
| **Study Purpose** | Pivotal efficacy against *Eimeria tenella* |
| **Product Administration** | One dose administered to chickens by the gel droplet application (oral route) |
| **Study Animals** | 55 chickens in the vaccinate group, 55 chickens in the positive control group and 20 chickens in the negative control group received a placebo vaccine. All chickens vaccinated at day-of-age. |
| **Challenge Description** | Homologous *Eimeria tenella* administered at 30 days post vaccination to the vaccinate and positive control groups. |
| **Interval observed after challenge** | Chickens were observed daily for 5 days post challenge. Target tissues of duodenum, jejunum, ileum, ceca and large intestine were examined at 5 days post challenge. |
| **Results** | A chicken was considered affected by challenge if the lesion score was 2-4 (positive) in the intestine and unaffected if the lesion score was 0-1 (negative).<br><br>3/55 vaccinates and 47/55 positive controls and 0/20 negative controls were considered affected.<br><br>Raw data shown on the following page. |
| **USDA Approval Date** | January 28, 2016 |

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

**Table 1. Vaccinate Group**

| Tag No. | Lesion Score | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Ceca | Large Intestine |
| 769 | 0 | 0 | 0 | 2 | 0 |
| 804 | 1 | 0 | 0 | 2 | 0 |
| 812 | 0 | 0 | 0 | 2 | 0 |

**Table 2. Positive Control Group**

| Tag No. | Lesion Score | | | | |
|---|---|---|---|---|---|
| | Duodenum | Jejunum | Ileum | Ceca | Large Intestine |
| 723 | 1 | 0 | 0 | 4 | 0 |
| 729 | 1 | 1 | 0 | 4 | 0 |
| 730 | 1 | 0 | 0 | 3 | 0 |
| 731 | 1 | 0 | 0 | 3 | 0 |
| 733 | 1 | 0 | 0 | 3 | 0 |
| 737 | 1 | 0 | 0 | 3 | 0 |
| 739 | 2 | 0 | 0 | 2 | 0 |
| 741 | 0 | 0 | 0 | 3 | 0 |
| 742 | 1 | 0 | 0 | 3 | 0 |
| 743 | 0 | 0 | 0 | 3 | 0 |
| 745 | 0 | 0 | 0 | 2 | 0 |
| 748 | 1 | 0 | 0 | 3 | 0 |
| 749 | 2 | 0 | 0 | 3 | 0 |
| 752 | 1 | 0 | 0 | 3 | 0 |
| 754 | 1 | 0 | 0 | 2 | 0 |
| 755 | 1 | 0 | 0 | 3 | 0 |
| 759 | 0 | 0 | 0 | 2 | 0 |
| 762 | 1 | 0 | 0 | 3 | 1 |
| 763 | 0 | 0 | 0 | 3 | 1 |
| 764 | 1 | 0 | 0 | 3 | 0 |
| 766 | 1 | 0 | 0 | 3 | 0 |
| 767 | 1 | 0 | 0 | 3 | 0 |
| 768 | 2 | 0 | 0 | 2 | 0 |
| 773 | 1 | 0 | 0 | 2 | 0 |
| 774 | 1 | 0 | 0 | 3 | 0 |
| 775 | 1 | 0 | 0 | 3 | 0 |
| 777 | 1 | 0 | 0 | 3 | 0 |
| 778 | 1 | 2 | 0 | 3 | 0 |
| 779 | 2 | 0 | 0 | 3 | 0 |
| 781 | 0 | 0 | 0 | 2 | 0 |
| 784 | 0 | 0 | 0 | 2 | 0 |
| 785 | 1 | 0 | 0 | 3 | 0 |
| 795 | 2 | 0 | 0 | 3 | 0 |
| 796 | 0 | 0 | 0 | 3 | 0 |
| 805 | 1 | 0 | 0 | 2 | 0 |
| 807 | 2 | 0 | 0 | 3 | 0 |
| 813 | 1 | 0 | 0 | 3 | 0 |
| 815 | 2 | 0 | 0 | 3 | 0 |
| 816 | 1 | 0 | 0 | 3 | 0 |
| 826 | 1 | 0 | 0 | 3 | 0 |
| 836 | 0 | 0 | 0 | 3 | 0 |
| 838 | 0 | 0 | 0 | 3 | 0 |
| 843 | 1 | 0 | 0 | 4 | 0 |
| 844 | 1 | 0 | 0 | 3 | 0 |
| 845 | 1 | 0 | 0 | 3 | 0 |
| 848 | 1 | 0 | 0 | 3 | 0 |
| 849 | 1 | 0 | 0 | 2 | 0 |

Key:
0 No gross lesions.
+l Very few scattered petechiae on the cecal wall; no thickening of the cecal walls; normal cecal contents present.
+2 Lesions more numerous with noticeable blood in the cecal contents; cecal wall is somewhat thickened; normal cecal contents present.
+3 Large amounts of blood or cecal cores present; cecal walls greatly thickened; little, if any, fecal contents in the ceca.
+4 Cecal wall greatly distended with blood or large caseous cores; fecal debris lacking or included in cores. Dead birds are scored as +4.

<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, gel droplet administration</td></tr>
<tr><td>Study Animals</td><td>Commercial Layer and Broiler Breeder chickens at day of age (vaccinate) at four independent sites</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Chickens were observed daily for 21 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></tr>
<tr><td rowspan="2">1</td><td>Vaccinate</td><td>41,300</td><td>0.73</td></tr>
<tr><td>control</td><td>41,500</td><td>0.71</td></tr>
<tr><td rowspan="2">2</td><td>Vaccinate</td><td>30,000</td><td>4.04</td></tr>
<tr><td>control</td><td>26,000</td><td>3.7</td></tr>
<tr><td rowspan="2">3</td><td>Vaccinate</td><td>22,300</td><td>1.39</td></tr>
<tr><td>control</td><td>22,300</td><td>0.87</td></tr>
<tr><td rowspan="2">4</td><td>Vaccinate</td><td>20,000</td><td>1.77</td></tr>
<tr><td>control</td><td>20,372</td><td>0.83</td></tr>
</table>
No adverse events attributable to the vaccine were observed.<br>Birds in the control group were vaccinated according to standard practice of the poultry producer.
</td></tr>
<tr><td>USDA Approval Date</td><td>December 19, 2018</td></tr>
</table>