



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	1431.51
True Name	Coccidiosis Vaccine, Live Oocysts
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Immucox T - Biomune - Biomune Company Immucox T - No distributor specified
Date of Compilation Summary	March 10, 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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Eimeria adenoeides</i>
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Eimeria adenoeides</i> in turkeys
<b>Product Administration</b>	One dose administered to turkeys by the gel droplet application via the oral route
<b>Study Animals</b>	50 turkeys in the vaccinate group; and 49 turkeys in the positive control group and 20 turkeys in the negative control groups received a placebo vaccine. All turkeys were vaccinated at day of age.
<b>Challenge Description</b>	Homologous <i>Eimeria adenoeides</i> administered at 28 days post vaccination to the vaccinate group and positive control group. 20 control turkeys remained unchallenged.
<b>Interval Observed After Challenge</b>	Turkeys 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
<b>Results</b>	A turkey was considered affected by the challenge if the lesion score was 2-4 (positive) and unaffected in if the lesion score was 0-1 (negative).  1/50 vaccinates and 41/49 positive controls and 1/20 negative controls were considered affected.  Raw data shown on the following page.
<b>USDA Approval Date</b>	August 25, 2020

**Table 1. Vaccinate Group**

Bird Tag No.	Lesion Scores				
	Duodenum	Jejunum	Ileum	Ceca	Large Intestine
1301	0	0	0	0	0
1303	0	0	0	1	0
1305	0	0	0	0	0
1309	0	0	0	0	0
1310	0	0	0	0	0
1311	0	0	0	0	0
1314	0	0	0	0	0
1315	0	0	0	0	0
1316	0	0	0	0	0
1321	0	0	0	0	0
1326	0	0	0	0	0
1327	0	0	0	0	0
1331	0	0	0	0	0
1332	0	0	0	0	0
1333	0	0	0	0	0
1338	0	0	0	0	0
1341	0	0	0	1	0
1343	0	0	0	0	0
1344	0	0	0	0	0
1346	0	0	0	0	0
1351	0	0	0	0	0
1357	0	0	0	0	0
1359	0	0	0	0	0
1361	0	0	0	0	0
1372	0	0	0	0	0
1375	0	0	0	0	0
1376	0	0	0	0	0
1378	0	0	0	0	0
1381	0	0	0	0	0
1382	0	0	0	0	0
1385	0	0	0	0	0
1387	0	0	0	0	0
1388	0	0	0	0	0
1389	0	0	0	0	0
1397	0	0	0	0	0
1399	0	0	0	1	0
1404	0	0	0	0	0

1405	0	0	0	0	0
1408	0	0	0	0	0
1412	0	0	0	0	0
1414	0	0	0	0	0
1417	0	0	0	0	0
1419	0	0	0	0	0
1423	0	0	0	0	0
1424	0	0	0	0	0
1430	0	0	0	0	0
1431	0	0	0	0	0
1444	0	0	0	0	0
1446	0	0	0	2	0
1448	0	0	0	0	0

**Table 2. Positive Control Group**

Bird Tag No.	Lesion Scores				
	Duodenum	Jejunum	Ileum	Ceca	Large Intestine
1302	0	0	0	4	0
1306	0	0	0	4	0
1307	0	0	0	3	0
1313	0	0	0	4	0
1318	0	0	0	0	0
1320	0	0	0	3	0
1325	0	0	0	3	0
1328	0	0	0	4	0
1330	0	0	0	0	0
1339	0	0	0	4	0
1348	0	0	0	3	0
1349	0	0	0	0	0
1350	0	0	0	0	0
1354	0	0	0	4	0
1355	0	0	0	4	0
1362	0	0	0	4	0
1365	0	0	0	3	0
1366	0	0	0	4	0
1367	0	0	0	4	0
1368	0	0	0	3	0
1369	0	0	0	4	0
1373	0	0	0	0	0
1380	0	0	0	4	0

1384	0	0	0	4	0
1390	0	0	0	0	0
1391	0	0	0	4	0
1392	0	0	0	3	0
1393	0	0	0	4	0
1394	0	0	0	0	0
1395	0	0	0	0	0
1400	0	0	0	4	0
1402	0	0	0	4	0
1403	0	0	0	3	0
1406	0	0	0	3	0
1407	0	0	0	4	0
1413	0	0	0	3	0
1418	0	0	0	4	0
1425	0	1	0	4	0
1427	0	0	0	3	0
1428	0	0	0	4	0
1433	0	0	0	3	0
1434	0	0	0	4	0
1438	0	0	0	4	0
1441	0	0	0	4	0
1442	0	0	0	4	0
1443	0	0	0	4	0
1447	0	0	0	4	0
1449	0	0	0	4	0
1450	0	0	0	2	0

**Table 3. Negative Control Group**

Bird Tag No.	Lesion Scores				
	Duodenum	Jejunum	Ileum	Ceca	Large Intestine
1308	0	0	0	0	0
1312	0	0	0	0	0
1323	0	0	0	0	0
1324	0	0	0	0	0
1329	0	0	0	0	0
1335	0	0	0	0	0
1337	0	0	0	0	0
1352	0	0	0	0	0
1356	0	0	0	0	0
1377	0	0	0	0	0

1396	0	0	0	0	0
1401	0	0	0	0	0
1410	0	0	0	2	0
1411	0	0	0	0	0
1420	0	0	0	0	0
1429	0	0	0	0	0
1432	0	0	0	0	0
1439	0	0	0	0	0
1440	0	0	0	0	0
1445	0	0	0	0	0

Key:

- 0 No gross lesions
- +1 Whitish cecal core and/or normal cecal contents. Mucosal wall have slight evidence of raised lesions at some isolated point in the cecal area.
- +2 Whitish cecal contents with or without solid cecal core. Evidence of raised lesions at one or more points in the cecal core area.
- +3 Well defined cecal core material, either solid or fragmented and raised lesions over a major area of the caeca.
- +4 More severe and extensive lesions than +3, over entire cecal area.

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Eimeria meleagriditis</i>
<b>Study Purpose</b>	Demonstrate effectiveness in turkeys against <i>Eimeria meleagriditis</i>
<b>Product Administration</b>	One dose administered to turkeys by the gel droplet application via the oral route
<b>Study Animals</b>	47 turkeys in the vaccinate group; and 45 turkeys in the positive control group and 20 turkeys in the negative control group received a placebo vaccine. All turkeys were vaccinated at day of age.
<b>Challenge Description</b>	Homologous <i>Eimeria meleagriditis</i> administered at 28 days post vaccination to the vaccinate group and positive control group. 20 control turkeys remained unchallenged.
<b>Interval Observed After Challenge</b>	All turkeys 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.
<b>Results</b>	A turkey was considered affected by the challenge if the lesion score was 2-4 (positive) and unaffected if the lesion score was 0-1 (negative).  0/47 vaccinates, 38/45 positive controls, and 0/20 negative controls were considered affected.  Raw data shown on the following page.
<b>USDA Approval Date</b>	May 26, 2020 and August 25, 2020

**Table 1. Vaccinate Group**

Bird Tag No.	Lesion Scores				
	Duodenum	Jejunum	Ileum	Ceca	Large Intestine
1454	0	0	0	0	0
1462	0	0	0	0	0
1464	0	0	0	0	0
1465	0	0	0	0	0
1466	0	0	0	0	0
1468	0	0	0	0	0
1469	0	0	0	0	0
1472	0	0	0	0	0
1473	0	0	0	0	0
1477	0	0	0	0	0
1479	0	0	0	0	0
1482	0	0	0	0	0
1485	0	0	0	0	0
1488	0	0	0	0	0
1489	0	0	0	0	0
1497	0	0	0	0	0
1502	0	0	0	0	0
1508	0	0	0	0	0
1509	0	0	0	0	0
1515	0	0	0	0	0
1517	0	0	0	0	0
1518	0	0	0	0	0
1520	0	0	0	0	0
1526	0	0	0	0	0
1527	0	0	0	0	0
1530	0	0	0	0	0
1531	0	0	0	0	0
1534	0	0	0	0	0
1540	0	0	0	0	0
1546	1	0	0	0	0
1547	0	0	0	0	0
1548	0	0	0	0	0
1550	0	0	0	0	0
1551	0	0	0	0	0
1553	0	0	0	0	0
1555	0	0	0	0	0
1561	0	0	0	0	0



1567	0	0	0	0	0
1570	0	0	0	0	0
1571	0	0	0	0	0
1574	0	0	0	0	0
1576	0	0	0	0	0
1578	0	0	0	0	0
1579	0	0	0	0	0
1583	0	0	0	0	0
1587	0	0	0	0	0
1589	0	0	0	0	0

**Table 2. Positive Control Group**

Bird Tag No.	Lesion Scores				
	Duodenum	Jejunum	Ileum	Ceca	Large Intestine
1456	4	3	1	0	0
1457	2	1	0	0	0
1458	3	4	1	0	0
1459	3	1	0	0	0
1460	4	2	0	0	0
1461	0	0	0	0	0
1467	3	2	1	0	0
1470	3	2	1	0	0
1475	4	2	0	0	0
1478	1	0	0	0	0
1486	4	2	1	0	0
1490	1	1	0	0	0
1492	4	2	2	0	0
1496	4	3	0	0	0
1498	0	0	0	0	0
1499	4	2	0	0	0
1504	3	1	0	0	0
1505	4	2	1	0	0
1506	3	2	2	0	0
1507	4	2	1	0	0
1513	4	2	1	0	0
1514	4	2	1	0	0
1521	4	2	0	0	0
1523	4	2	1	0	0
1524	4	2	0	0	0
1525	0	0	0	0	0

1532	3	3	0	0	0
1535	3	1	0	0	0
1541	3	2	0	0	0
1543	3	1	0	0	0
1544	2	2	1	0	0
1549	4	2	0	0	0
1552	4	2	1	0	0
1562	3	2	0	0	0
1568	3	2	0	0	0
1572	4	2	2	0	0
1573	3	2	0	0	0
1577	1	0	0	0	0
1581	4	3	0	0	0
1584	0	0	0	0	0
1588	3	1	0	0	0
1590	3	2	1	0	0
1591	4	2	1	1	0
1592	3	1	1	0	0
1594	3	1	0	0	0

**Table 3. Negative Control Group**

Bird Tag No.	Lesion Scores				
	Duodenum	Jejunum	Ileum	Ceca	Large Intestine
1471	0	0	0	0	0
1474	0	0	0	0	0
1480	0	0	0	0	0
1481	0	0	0	0	0
1495	0	0	0	0	0
1501	0	0	0	0	0
1503	0	0	0	0	0
1511	0	0	0	0	0
1512	0	0	0	0	0
1516	0	0	0	0	0
1536	0	0	0	0	0
1542	0	0	0	0	0
1545	0	0	0	0	0
1557	0	0	0	0	0
1558	0	0	0	0	0
1560	0	0	0	0	0
1563	0	0	0	0	0

1566	0	0	0	0	0
1575	0	0	0	0	0
1585	0	0	0	0	0

Key:

- 0 No gross lesions
- +1 Congestion and petechial hemorrhages on the mucosal surface
- +2 Yellow mucoid exudate with increased petechial hemorrhages
- +3 Marked thickening of the mucosal surfaces with the presence of cheesy caseous material and limited hemorrhage
- +4 Extensive necrosis, ulceration, mucosal thickening, and extensive hemorrhage visible on mucosal surface

<b>Study Type</b>	Safety																												
<b>Pertaining to</b>	ALL																												
<b>Study Purpose</b>	To demonstrate safety under field conditions.																												
<b>Product Administration</b>	Single dose, gel droplet administration																												
<b>Study Animals</b>	Commercial turkeys at day of age. Two independent study sites with a total of 22,300 vaccinates and 20, 800 controls.																												
<b>Challenge Description</b>	NA																												
<b>Interval observed after challenge</b>	Turkeys were observed daily for 21 days																												
<b>Results</b>	<table border="1"> <thead> <tr> <th rowspan="2">Site</th> <th rowspan="2">House</th> <th rowspan="2">Num Birds Placed</th> <th colspan="2">Dead Birds</th> </tr> <tr> <th>Number</th> <th>Percent</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td>Vaccinates</td> <td>5,000</td> <td>312</td> <td>6.24</td> </tr> <tr> <td>Controls</td> <td>3,500</td> <td>163</td> <td>4.66</td> </tr> <tr> <td rowspan="2">2</td> <td>Vaccinates</td> <td>17,300</td> <td>1,006</td> <td>5.81</td> </tr> <tr> <td>Controls</td> <td>17,300</td> <td>398</td> <td>2.30</td> </tr> </tbody> </table>				Site	House	Num Birds Placed	Dead Birds		Number	Percent	1	Vaccinates	5,000	312	6.24	Controls	3,500	163	4.66	2	Vaccinates	17,300	1,006	5.81	Controls	17,300	398	2.30
Site	House	Num Birds Placed	Dead Birds																										
			Number	Percent																									
1	Vaccinates	5,000	312	6.24																									
	Controls	3,500	163	4.66																									
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	Controls	17,300	398	2.30																									
<b>USDA Approval Date</b>	November 28, 2016																												