



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	1F31.R0
True Name	Fowl Pox-Laryngotracheitis Vaccine, Live Fowl Pox Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	<p>Biomune Company VECTORMUNE FP-LT - ACI Limited, Bangladesh VECTORMUNE FP-LT - Agrosvet S.R.L. VECTORMUNE FP-LT - Axis Agency Services Ltd. VECTORMUNE FP-LT - Biomune - Biomune Company VECTORMUNE FP-LT - Biomune Company VECTORMUNE FP-LT - CEVA Animal Health (Pty) Ltd VECTORMUNE FP-LT - CEVA Animal Health (Thailand) Ltd VECTORMUNE FP-LT - CEVA Saude Animal Ltda. (Brazil) VECTORMUNE FP-LT - CEVA Saude Animal Ltda. (Brazil) - Biomune Company VECTORMUNE FP-LT - Ceva Salud Animal S.A. de C.V. (Mexico) VECTORMUNE FP-LT - Ceva Salud Animal S.A. de C.V. (Mexico) - Biomune Company VECTORMUNE FP-LT - Ceva Salud Animal SRL - Biomune Company VECTORMUNE FP-LT - Ceva Sante Animale VECTORMUNE FP-LT - MAS Veterinary Services VECTORMUNE FP-LT - No distributor specified VECTORMUNE FP-LT - SARL Cevavet - Biomune Company</p>
Date of Compilation Summary	January 14, 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	Fowl pox virus and Infectious Laryngotracheitis virus
Study Purpose	To demonstrate effectiveness against Fowl pox virus (FPV) and Infectious Laryngotracheitis virus (ILTV)
Product Administration	<p>One dose administered via the <i>in ovo</i> route at 18 days of incubation followed by a dose administered via wing web administration at seven days of age.</p> <p>The study contained five randomized groups of specific pathogen free chickens with different treatments.</p> <p>Group 1: Embryos at 18 days of incubation were vaccinated <i>in ovo</i> with FPV/ILTV followed by wing web administration at the minimum dose of seven days of age</p> <p>Group 2: Embryos at 18 days of incubation were vaccinated <i>in ovo</i> with FPV/ILTV followed by mock (placebo diluent) wing web administration at the minimum dose of seven days of age</p> <p>Group 3: Embryos at 18 days of incubation were vaccinated <i>in ovo</i> with placebo diluent followed by FPV/ILTV mock (placebo diluent) wing web administration at the minimum dose of seven days of age</p> <p>Group 4: Embryos at 18 days of incubation were vaccinated <i>in ovo</i> with placebo diluent without wing web administration and challenged, positive controls</p> <p>Group 5: Non-vaccinated, non-challenged negative controls</p>
Study Animals	SPF Chicken embryos at 18 days of incubation.
Challenge Description	Chickens were challenged at four weeks of age with the USDA ILTV challenge strain or the USDA FPV challenge strain
Interval observed after challenge	Chickens were observed each day for 10 days post challenge.
Results	<p>The results met the requirements in 9 CFR 113.326 for FPV.</p> <p>The results met the requirements in 9 CFR 113.328 for ILTV.</p> <p>See Table 1 below for a summary of the study results.</p> <p>See Tables 2-10 below for raw data.</p>
USDA Approval Date	December 11, 2007

Table 1 Summary of Treatment Group Results

Purpose	Group	Treatment	Hatchability	# Chicks placed	# Chicks challenged	% Protected	
						ILTV ⁶	FPV ⁷
Vaccinates	1	FPV/ILTV <i>in ovo</i> + ww ¹	90% (140/156)	70	60	93% 28/30	100% 30/30
Controls	2	FPV/ILTV <i>in ovo</i> + mock ww ²		70	60	57% 17/30	77% 23/30
	3	Mock FPV/ILT <i>in ovo</i> ³ + ww	90% (141/157)	70	60	90% 27/30	100% 30/30
	4	Positive Controls ⁴		71	60	3% 1/30	3% 1/30
	5	Negative Controls ⁵	100% (21/21)	21	0	N/A ⁸	N/A

¹ww= wing web

²Mock ww is placebo

³Mock FPV/ILT *in ovo* is placebo

⁴Positive Controls= mock *in ovo* placebo without ww + challenge

⁵Negative Controls= non-vaccinated, non-challenged

⁶Infectious laryngotracheitis virus challenge

⁷Fowl pox virus challenge

⁸N/A= Not Applicable

Table 2. (Group 1)- FPV/ILTV *in ovo* and wing web vaccinated chickens that were challenged with the USDA ILTV challenge strain

Tag Number	Clinical Signs
1	Neg ¹
8	Neg
13	Neg
18	Neg
334	Neg
341	Neg
357	Neg
363	Neg
379	Neg
385	Pos ²
390	Neg
677	Neg
696	Neg
752	Pos
772	Neg
783	Neg
784	Neg
788	Neg
806	Neg
817	Neg
833	Neg
845	Neg
861	Neg
862	Neg
863	Neg
866	Neg
868	Neg
889	Neg
989	Neg
990	Neg

¹Neg= negative for clinical signs of infectious laryngotracheitis virus

²Pos= positive for clinical signs of infectious laryngotracheitis virus

Table 3. (Group 2)- FPV/ILTV *in ovo* vaccinated and mock wing web vaccinated chickens that were challenged with the USDA ILTV challenge strain

Tag Number	Clinical Signs
12	Neg ¹
331	Pos ²
336	Neg
345	Neg
347	Neg
358	Pos
360	Pos
365	Neg
367	Neg
378	Neg
386	Neg
662	Pos
667	Pos
671	Pos
687	Pos
688	Pos
736	Neg
777	Neg
796	Pos
808	Pos
810	Pos
825	Pos
836	Neg
838	Neg
844	Pos
860	Neg
869	Neg
883	Neg
897	Neg
998	Neg

¹Neg= negative for clinical signs of infectious laryngotracheitis virus

²Pos= positive for clinical signs of infectious laryngotracheitis virus

Table 4. (Group 3)- Mock *in ovo* vaccinated and FPV/ILTV wing web vaccinated chickens that were challenged with the USDA ILTV challenge strain

Tag Number	Clinical Signs
4	Pos ¹
5	Neg ²
338	Neg
339	Neg
342	Neg
349	Pos
351	Neg
356	Neg
368	Neg
370	Neg
377	Neg
384	Neg
395	Neg
400	Neg
672	Neg
675	Neg
678	Neg
684	Neg
767	Neg
770	Neg
781	Neg
789	Neg
815	Neg
828	Neg
829	Neg
832	Neg
850	Neg
854	Neg
879	Pos
890	Neg

¹Pos= positive for clinical signs of infectious laryngotracheitis virus

²Neg= negative for clinical signs of infectious laryngotracheitis virus

Table 5. (Group 4)- Positive control chickens challenged with the USDA ILTV challenge strain

Tag Number	Clinical Signs
14	Pos ¹
15	Pos
17	Pos
344	Pos
355	Pos
362	Pos
372	Pos
387	Pos
388	Pos
398	Pos
665	Pos
668	Pos
676	Pos
679	Pos
699	Pos
746	Pos
753	Pos
782	Pos
785	Pos
818	Pos
837	Pos
843	Pos
848	Pos
858	Pos
855	Pos
859	Pos
884	Pos
900	Pos
994	Pos
999	Neg ²

¹Pos= positive for clinical signs of infectious laryngotracheitis virus

²Neg= negative for clinical signs of infectious laryngotracheitis virus

Table 6. (Group 1)- FPV/ILTV *in ovo* vaccinated and wing web vaccinated chickens that were challenged with the USDA FPV challenge strain

Tag Number	Clinical Signs
7	Neg ¹
10	Neg
16	Neg
332	Neg
333	Neg
382	Neg
397	Neg
392	Neg
673	Neg
680	Neg
681	Neg
692	Neg
695	Neg
748	Neg
750	Neg
775	Neg
792	Neg
804	Neg
816	Neg
821	Neg
827	Neg
842	Neg
847	Neg
857	Neg
867	Neg
871	Neg
872	Neg
986	Neg
988	Neg
996	Neg

¹Neg= negative for clinical signs of Fowl pox virus

Table 7. (Group 2)- rFPV/LT *in ovo* vaccinated and mock wing web vaccinated chickens that were challenged with the USDA FPV challenge strain

Tag Number	Clinical Signs
2	Neg ¹
9	Pos ²
19	Neg
348	Neg
350	Pos
374	Pos
380	Neg
397	Neg
694	Neg
397	Neg
747	Neg
771	Neg
773	Pos
793	Pos
795	Pos
809	Neg
814	Neg
820	Neg
822	Neg
831	Neg
841	Neg
856	Pos
877	Neg
878	Neg
885	Neg
886	Neg
898	Neg
899	Neg
987	Neg
992	Neg

¹Neg= negative for clinical signs of Fowl pox virus

²Pos= positive for clinical signs of Fowl pox virus

Table 8. (Group 3)- Mock *in ovo* vaccinated and rFPV/LT wing web vaccinated chickens that were challenged with the USDA FPV challenge strain

Tag Number	Clinical Signs
335	Neg ¹
346	Neg
352	Neg
354	Neg
393	Neg
663	Neg
669	Neg
685	Neg
690	Neg
737	Neg
740	Neg
741	Neg
756	Neg
768	Neg
769	Neg
778	Neg
787	Neg
800	Neg
811	Neg
812	Neg
835	Neg
846	Neg
851	Neg
864	Neg
870	Neg
881	Neg
882	Neg
895	Neg
896	Neg
995	Neg

¹Neg= negative for clinical signs of Fowl pox virus

Table 9. (Group 4)- Positive control chickens challenged with the USDA FPV challenge strain

Tag Number	Clinical Signs
20	Pos ¹
340	Pos
353	Neg ²
359	Pos
381	Pos
389	Pos
399	Pos
670	Pos
682	Pos
683	Pos
742	Pos
743	Pos
745	Pos
749	Pos
755	Pos
774	Pos
779	Pos
794	Pos
798	Pos
799	Pos
801	Pos
803	Pos
819	Pos
826	Pos
834	Pos
840	Pos
849	Pos
874	Pos
893	Pos
997	Pos

¹Pos= positive for clinical signs of Fowl pox virus

²Neg= negative for clinical signs of Fowl pox virus

Table 10. (Group 5)- Non-vaccinated, non-challenged, negative controls

Tag Number	Clinical Signs
329	Neg ¹
337	Neg
361	Neg
364	Neg
375	Neg
396	Neg
664	Neg
674	Neg
698	Neg
776	Neg
786	Neg
797	Neg
802	Neg
823	Neg
824	Neg
873	Neg
888	Neg
891	Neg
991	Neg
993	Neg
1000	Neg

¹Neg= negative for clinical signs of Fowl pox virus

Study Type	Efficacy
Pertaining to	Fowl Pox Virus and Laryngotracheitis
Study Purpose	Demonstrate efficacy against Fowl Pox Virus and Laryngotracheitis
Product Administration	Wing web
Study Animals	Chickens
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	October 26, 2000

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety of product under typical use conditions
Product Administration	Wing web
Study Animals	
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	August 23, 2002

Study Type	Safety																						
Pertaining to	All fractions																						
Study Purpose	To demonstrate safety of the product under typical use conditions																						
Product Administration	<p>One dose administered via the <i>in ovo</i> route at 18 days of incubation followed by a dose administered via wing web administration at seven days of age.</p> <p>Group 1: Embryos at 18 days of incubation were vaccinated <i>in ovo</i></p> <p>Group 2: Embryos at 18 days of incubation were vaccinated <i>in ovo</i> followed by wing web administration at the minimum dose of seven days of age</p> <p>Group 3: Embryos at 18 days of incubation were mock vaccinated with placebo diluent</p>																						
Study Animals	SPF Chicken embryos at 18 days of incubation.																						
Challenge Description	Not Applicable																						
Interval observed after challenge	Not Applicable																						
Results	<table border="1"> <thead> <tr> <th>Purpose</th> <th>Group</th> <th>Treatment</th> <th>Hatchability</th> <th># Chicks placed</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Vaccinates</td> <td>1</td> <td><i>in ovo</i></td> <td rowspan="2">93% 66/71</td> <td>30</td> </tr> <tr> <td>2</td> <td><i>in ovo</i> + ww¹</td> <td>30</td> </tr> <tr> <td>Controls</td> <td>3</td> <td>Negative Controls²</td> <td>88% 15/17</td> <td>10</td> </tr> </tbody> </table> <p>¹ww= wing web ²Negative Controls= mock <i>in ovo</i> placebo diluent</p> <p>Adverse vaccine reactions were not observed.</p>					Purpose	Group	Treatment	Hatchability	# Chicks placed	Vaccinates	1	<i>in ovo</i>	93% 66/71	30	2	<i>in ovo</i> + ww ¹	30	Controls	3	Negative Controls ²	88% 15/17	10
Purpose	Group	Treatment	Hatchability	# Chicks placed																			
Vaccinates	1	<i>in ovo</i>	93% 66/71	30																			
	2	<i>in ovo</i> + ww ¹		30																			
Controls	3	Negative Controls ²	88% 15/17	10																			
USDA Approval Date	December 11, 2007																						

Study Type	Safety							
Pertaining to	All fractions							
Study Purpose	To demonstrate safety of the product under typical use conditions							
Product Administration	Vaccinate group: One dose administered via the <i>in ovo route</i> at 18 days of incubation followed by a dose administered via wing web administration at seven days of age. Control group: Vaccinated according to the cooperator normal vaccination program							
Study Animals	Chicken embryos at 18 days of incubation in three distinct geographical areas							
Challenge Description	Not Applicable							
Interval observed after challenge	Chickens were observed for 21 days post vaccination (DPV)							
Results	Location	Treatment Group	Hatchability		# Chicks placed	21-DPV ² Mortality		
			#hatched/ #embryos	Percent		Total # of deaths	% total	
	1	Vaccinates	2,152/ 2,350	91.6%	2,152	41	1.91%	
		Controls	23,790/ 26,000	91.5%	2,150	54	2.51%	
	2	Vaccinates	7,200/ 8,480	84.9%	7,200	154	2.14%	
		Controls	17,100/ 20,700	82.6%	17,100	608	3.56%	
	3	Vaccinates	34,800/ 40,324	86.3%	2,000	13 ³	0.65%	
		Controls	N/A	N/A ¹	103,600	3,086	2.98%	
	¹ N/A is not applicable ² 21-DPV mortality= The mortality from 1 day of age through 21 days post wing web vaccination (from 1 day through 28 days of age). ³ This mortality was observed during the 21-day post wing web vaccination period only, not including 1 day of age through 2 days of age. For these chickens, this 21-day observation was from 8 days to 29 days of age. Adverse vaccine reactions were not observed in any groups during the observation period.							
	USDA Approval Date	April 1, 2009						