



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Hygieia Biological Laboratories
USDA Vet Biologics Establishment Number	407
Product Code	1621.10
True Name	Fowl Pox Vaccine, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	January 11, 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>	Fowl Pox Virus (FPV)
<b>Study Purpose</b>	Demonstrate efficacy against challenge with virulent FPV.
<b>Product Administration</b>	One dose administered through wing-web at 8 weeks of age
<b>Study Animals</b>	<p>Eight-week-old specific pathogen free chickens divided into 3 groups:</p> <p>Group 1: 32 chickens vaccinated and challenged with virulent FPV</p> <p>Group 2: 32 chickens sham vaccinated and challenged with virulent FPV (positive control)</p> <p>Group 3: 21 chickens left as sentinels (negative control) and not challenged</p>
<b>Challenge Description</b>	Chickens were challenged at 3 weeks post-vaccination using a virulent strain of FPV obtained from USDA
<b>Interval observed after challenge</b>	The FPV challenged chickens were observed at 2 to 4 days interval for 10 days post-challenge for clinical signs of FPV infection.
<b>Results</b>	<p>Vaccinates and controls were evaluated in terms of FPV induced specific clinical signs.</p> <p>Birds with positive clinical signs and/or mortality:</p> <p>Group 1: 0/32 positive for FPV</p> <p>Group 2: 32/32 positive for FPV</p> <p>Group 3: 0/21 positive for FPV</p> <p>The requirements of 9 CFR 113.326 were met for FPV.</p> <p>See table on attached page</p>
<b>USDA Approval Date</b>	06/25/2012

Table below is for the birds classified as positive for FPV induced clinical signs. All other birds remained normal.

Group	Bird ID	FPV clinical signs
2	384	x
2	452	x
2	462	x
2	478	x
2	486	x
2	492	x
2	516	x
2	573	x
2	584	x
2	609	x
2	639	x
2	691	x
2	696	x
2	702	x
2	706	x
2	728	x
2	740	x
2	760	x
2	777	x
2	805	x
2	816	x
2	843	x
2	853	x
2	855	x
2	856	x
2	861	x
2	897	x
2	907	x
2	931	x
2	971	x
2	979	x
2	999	x

No mortality was observed in any of the challenged birds.

<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 administered through wing-web route						
<b>Study Animals</b>	Commercial layer type chickens aged 8 to 11 weeks and representing three independent study sites were used. For site 1: 74,684 vaccinates and 75,705 controls. For site 2: 39,766 vaccinates and 40,147 controls. For site 3: 71,198 vaccinates and 68,208 controls.						
<b>Challenge Description</b>	Not applicable						
<b>Interval observed after challenge</b>	Chickens were observed daily for mortality and adverse reactions up to 3 weeks post vaccination						
<b>Results</b>	<b>Site</b>	<b>Group</b>	<b>Total Birds</b>	<b>Average daily mortality (%)</b>			<b>Total Mortality (%)</b>
				<b>Week 1</b>	<b>Week 2</b>	<b>Week 3</b>	
	1	Vaccine	74,684	0.01	0.01	0.02	0.38
		Control	75,705	0.01	0.01	0.01	0.32
	2	Vaccine	39,766	0.01	0.01	0.01	0.70
		Control	40,147	0.01	0.00	0.01	0.48
	3	Vaccine	71,198	0.03	0.04	0.15	2.56
		Control	68,208	0.02	0.01	0.01	0.31
	No adverse reactions attributable to the vaccine were reported from any site.						
<b>USDA Approval Date</b>	08/21/2013						