



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	ARKO Laboratories, Ltd.
USDA Vet Biologics Establishment Number	337
Product Code	10L1.20
True Name	Lawsonia Intracellularis Vaccine, Avirulent Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Nitro Ileitis Vac FF - No distributor specified
Date of Compilation Summary	September 05, 2019

**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>Lawsonia intracellularis</i>
<b>Study Purpose</b>	Efficacy (Duration of Immunity) against <i>Lawsonia intracellularis</i> infection
<b>Product Administration</b>	Single dose orally
<b>Study Animals</b>	Forty pigs, 3 weeks of age. 20 vaccinates and 20 controls.
<b>Challenge Description</b>	Virulent <i>Lawsonia intracellularis</i> administered 4 months post vaccination.
<b>Interval observed after challenge</b>	Pigs were observed daily. The ileum of each pig was examined for gross and microscopic lesions at 21 days post challenge.
<b>Results</b>	<p>Animals were considered to be affected if gross and microscopic lesions of ileitis were demonstrated.</p> <p>Totals:  14/20 controls affected  0/20 vaccinates affected</p> <p>Raw data:  See attached.</p>
<b>USDA Approval Date</b>	1/21/2016

## Lawsonia Duration of Immunity

Vacc ID	Gross Lesions	Microscopic Lesions	Control ID	Gross Lesions	Microscopic Lesions
1	-	-	1	-	-
2	-	-	2	+	+
3	-	-	3	+	+
4	-	-	4	+	+
5	-	-	5	+	+
6	-	-	6	-	-
7	-	-	7	+	+
8	-	-	8	+	+
9	-	-	9	+	+
10	-	-	10	-	+
11	-	-	11	-	-
12	-	-	12	+	+
13	-	-	13	-	-
14	-	-	14	-	+
15	-	-	15	+	+
16	-	-	16	+	+
17	-	-	17	+	+
18	-	-	18	+	+
19	-	-	19	+	+
20	-	-	20	+	+

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Lawsonia intracellularis</i>
<b>Study Purpose</b>	Efficacy against <i>Lawsonia intracellularis</i> infection
<b>Product Administration</b>	Single dose orally
<b>Study Animals</b>	Forty pigs, 3 weeks of age. 20 vaccinates and 20 controls.
<b>Challenge Description</b>	Virulent <i>Lawsonia intracellularis</i> administered 21 days post vaccination.
<b>Interval observed after challenge</b>	Pigs were observed daily. The ileum of each pig was examined for gross and microscopic lesions at 21 days post challenge.
<b>Results</b>	<p>Animals were considered to be affected if gross and microscopic lesions of ileitis were demonstrated.</p> <p>Totals:  16/20 controls affected  1/20 vaccinates affected</p> <p>Raw data:  See attached.</p>
<b>USDA Approval Date</b>	1/21/2016

## Lawsonia Efficacy

Vacc ID	Gross Lesions	Microscopic Lesions	Control ID	Gross Lesions	Microscopic Lesions
1	-	-	1	+	+
2	-	-	2	-	-
3	-	-	3	+	+
4	-	-	4	+	+
5	-	-	5	+	+
6	-	-	6	+	+
7	-	-	7	+	+
8	-	-	8	-	+
9	-	-	9	-	-
10	-	-	10	+	+
11	-	+	11	+	+
12	-	-	12	+	+
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14	-	-	14	+	+
15	-	-	15	+	+
16	-	-	16	+	+
17	-	-	17	+	+
18	+	+	18	+	+
19	-	-	19	-	-
20	-	-	20	+	+

<b>Study Type</b>	Safety																																																										
<b>Pertaining to</b>	ALL																																																										
<b>Study Purpose</b>	Demonstrate safety under typical field conditions at three different geographical locations-Iowa, Minnesota, and Indiana																																																										
<b>Product Administration</b>	Single dose orally in water line.																																																										
<b>Study Animals</b>	2107 pigs, 3 weeks of age at three locations.																																																										
<b>Challenge Description</b>	Not applicable																																																										
<b>Interval observed after challenge</b>	Pigs were observed daily for 21 days																																																										
<b>Results</b>	<p>Numbers of pigs by site with clinical observations post vaccination:</p> <table border="1"> <thead> <tr> <th></th> <th>IA Site</th> <th>MN Site</th> <th>IN Site</th> </tr> </thead> <tbody> <tr> <td></td> <td>N=780</td> <td>N=925</td> <td>N=402</td> </tr> <tr> <td>Clinical Observation</td> <td></td> <td></td> <td></td> </tr> <tr> <td><b>None*</b></td> <td><b>775</b></td> <td><b>910</b></td> <td><b>402</b></td> </tr> <tr> <td>Loss of Condition</td> <td>1</td> <td>1</td> <td>0</td> </tr> <tr> <td>Anorexia</td> <td>1</td> <td>1</td> <td>0</td> </tr> <tr> <td>Fibrinous polyserositis - <i>Haemophilus parasuis</i></td> <td>3</td> <td>1</td> <td>0</td> </tr> <tr> <td>Fibrinous peritonitis - <i>Streptococcus suis</i></td> <td>0</td> <td>6</td> <td>0</td> </tr> <tr> <td>Unthrifty/Poor feed conversion</td> <td>1</td> <td>1</td> <td>0</td> </tr> <tr> <td>Prolapsed rectum</td> <td>0</td> <td>1</td> <td>0</td> </tr> <tr> <td>Gastric perforation</td> <td>2</td> <td>0</td> <td></td> </tr> <tr> <td>Gastric ulcer</td> <td>2</td> <td>0</td> <td></td> </tr> <tr> <td>Cardiomyopathy - Mulberry Heart Disease</td> <td>0</td> <td>6</td> <td>0</td> </tr> <tr> <td>Humane euthanasia</td> <td>1</td> <td>1</td> <td>0</td> </tr> </tbody> </table> <p>*For “None” a pig had to be observed without clinical observations for the entire observation period.</p> <p>Observations of adverse events were not attributable to administration of the vaccination as affirmed by the licensee.</p>				IA Site	MN Site	IN Site		N=780	N=925	N=402	Clinical Observation				<b>None*</b>	<b>775</b>	<b>910</b>	<b>402</b>	Loss of Condition	1	1	0	Anorexia	1	1	0	Fibrinous polyserositis - <i>Haemophilus parasuis</i>	3	1	0	Fibrinous peritonitis - <i>Streptococcus suis</i>	0	6	0	Unthrifty/Poor feed conversion	1	1	0	Prolapsed rectum	0	1	0	Gastric perforation	2	0		Gastric ulcer	2	0		Cardiomyopathy - Mulberry Heart Disease	0	6	0	Humane euthanasia	1	1	0
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