Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	19T1.21
True Name	Porcine Reproductive & Respiratory Syndrome Vaccine, Reproductive & Respiratory Forms, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Prime Pac PRRS RR - Merck Animal Health Prime Pac PRRS RR - No distributor specified
Date of Compilation Summary	October 25, 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.

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Porcine Reproductive and Respiratory Syndrome Virus</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against respiratory disease caused by PRRS virus (PRRSv)</td></tr>
<tr><td>Product Administration</td><td>single dose</td></tr>
<tr><td>Study Animals</td><td>16 litters of 8 pigs each, divided into 4 vaccinates and 4 controls (128 total pigs), 22-23 days of age, negative for anti-PRRSv antibodies and PCV2 viremia at 2 independent study sites.</td></tr>
<tr><td>Challenge Description</td><td>All pigs were challenged with PRRSv, 4.5 weeks after vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>Lungs were evaluated 14 days post-challenge.</td></tr>
<tr><td>Results</td><td>Lung lesion score (LLS) reflects the approximate volume percentage of the lung that is affected by PRRS-associated pneumonia, and is expressed as %.

<table>
<tr><td colspan="6">5-number summary of the LLS across all litters</td></tr>
<tr><td></td><td>Minimum</td><td>Q 1</td><td>Median</td><td>Q 3</td><td>Maximum</td></tr>
<tr><td>Site 1--Vaccinate</td><td>0</td><td>4</td><td>8</td><td>15</td><td>37</td></tr>
<tr><td>Site 1-Placebo</td><td>6</td><td>20</td><td>30</td><td>38</td><td>75</td></tr>
<tr><td>Site 2--Vaccinate</td><td>0</td><td>2</td><td>7</td><td>14</td><td>38</td></tr>
<tr><td>Site 2--Placebo</td><td>7</td><td>27</td><td>31</td><td>39</td><td>60</td></tr>
</table>

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<tr><td>USDA Approval Date</td><td>April 25, 2017</td></tr>
</table>

Table 1: Lung Scores across all litters

Site 1:	LLS (%)	
	Vaccinate	Placebo
	0	6
	0	7
	1	7
	1	10
	3	10
	3	15
	3	17
	4	20
	4	20
	4	21
	5	25
	6	27
	7	27
	7	28
	8	29
	8	29
	8	30
	8	31
	9	32
	10	32
	10	34
	11	35
	12	37
	15	38
	15	39
	17	40
	18	41
	20	46
	21	53
	24	58
	25	60
	37	75

Site 2:	LLS (%)	
	Vaccinate	Placebo
	0	7
	0	17
	0	22
	1	22
	1	23
	2	25
	2	25
	2	25
	2	27
	3	28
	4	28
	4	29
	5	29
	5	30
	5	31
	7	31
	7	31
	7	32
	7	33
	8	34
	8	34
	10	37
	13	37
	13	38
	15	40
	15	43
	15	43
	16	47
	16	48
	18	48
	23	49
	38	60

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Porcine Reproductive and Respiratory Syndrome (PRRS)</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against reproductive disease caused by PRRS virus (PRRSv)</td></tr>
<tr><td>Product Administration</td><td>1 dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>20 vaccinates, 20 control 6-month-old gilts, negative for anti-PRRSv antibodies and PCV2 viremia. Pigs were bred 55-60 days following vaccination and confirmed bred.</td></tr>
<tr><td>Challenge Description</td><td>Pigs were challenged with PRRSv, at 83-85 days of gestation, 20 weeks post vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>For all challenged pigs, farrow metrics were recorded and offspring were observed until 21 days post farrow.</td></tr>
<tr><td>Results</td><td>Data Summary

<table>
<tr><th></th><th>Number of Gilts</th><th>Total Pigs Born</th><th>Pigs Born Live</th><th>Pigs Born Viable</th><th>Pigs Weaned</th></tr>
<tr><td>Vaccinate</td><td>20</td><td>262</td><td>209</td><td>175</td><td>149</td></tr>
<tr><td>Control</td><td>20</td><td>237</td><td>47</td><td>21</td><td>5</td></tr>
</table>

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<tr><td>USDA pproval Date</td><td>July 7, 2017</td></tr>
</table>

Table 1: Farrow metrics – ordered by number of pigs weaned

Group	Animal ID	Litter Size	Live Born Viable	Born Dead	Non-Viable Live Born	Pre-Wean Mortality	Pigs Weaned
Vaccinate	128	15	14	0	1	2	12
Vaccinate	133	16	12	3	1	0	12
Vaccinate	142	13	12	1	0	0	12
Vaccinate	113	15	11	1	3	0	11
Vaccinate	126	16	12	1	3	1	11
Vaccinate	146	14	13	1	0	2	11
Vaccinate	124	16	13	0	3	3	10
Vaccinate	122	13	9	3	1	0	9
Vaccinate	136	12	12	0	0	3	9
Vaccinate	106	12	10	0	2	2	8
Vaccinate	116	15	12	1	2	5	7
Vaccinate	120	15	9	3	3	2	7
Vaccinate	145	14	7	1	6	0	7
Vaccinate	121	10	8	2	0	2	6
Vaccinate	132	15	7	5	3	1	6
Vaccinate	180	8	7	1	0	1	6
Vaccinate	129	14	5	4	5	1	4
Vaccinate	105	14	2	11	1	1	1
Vaccinate	156	15	0	15	0	0	0
Vaccinate	101[1]	13	na	na	na	na	na
Placebo	123	15	3	7	5	0	3
Placebo	151	13	2	8	3	1	1
Placebo	153	14	3	9	2	2	1
Placebo	104	18	0	16	2	0	0
Placebo	112	12	1	11	0	1	0
Placebo	119	17	0	16	1	0	0
Placebo	125	8	0	8	0	0	0
Placebo	134	14	1	9	4	1	0
Placebo	141	15	0	15	0	0	0
Placebo	143	18	4	14	0	4	0
Placebo	152	15	0	15	0	0	0
Placebo	154	14	4	4	6	4	0
Placebo	165	14	0	14	0	0	0
Placebo	166	15	0	14	1	0	0
Placebo	167	11	0	11	0	0	0
Placebo	170	13	0	13	0	0	0
Placebo	174	11	3	6	2	3	0
Placebo	108[2]	8	na	na	na	na	na
Placebo	168[2]	13	na	na	na	na	na
Placebo	177[2]	7	na	na	na	na	na

1 : Animal died at 11 days post challenge of congestive heart and lung failure
2 : Animal failed to farrow
na : Not applicable

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Porcine Reproductive and Respiratory Syndrome Virus (PRRSv)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate 23-week duration of immunity against respiratory disease caused by PRRS virus (PRRSv)</td></tr>
<tr><td>Product Administration</td><td>1 dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>Total 62 pigs, 32 vaccinates and 30 placebo controls</td></tr>
<tr><td>Challenge Description</td><td>All pigs were challenged with PRRSv, 23 weeks after vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Lungs were evaluated 10 days post-challenge.</td></tr>
<tr><td>Results</td><td>Lung lesion score (LLS) reflects the approximate volume percentage of the lung that is affected by PRRS-associated pneumonia, and is expressed as %.

Five-number summary of the LLS

<table><tr><th>Group</th><th>Minimum</th><th>Q1</th><th>Median</th><th>Q3</th><th>Maximum</th></tr><tr><td>Vaccinate</td><td>0</td><td>1</td><td>4</td><td>8</td><td>19</td></tr><tr><td>Control</td><td>9</td><td>17</td><td>26</td><td>40</td><td>52</td></tr></table>
Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>July 15, 2020</td></tr>
</table>

Table 1: LUNG LESION SCORES (LLS)

Animal ID	Group	LLS (%)
470	vaccinate	0
503	vaccinate	0
507	vaccinate	0
513	vaccinate	0
517	vaccinate	0
534	vaccinate	0
546	vaccinate	0
469	vaccinate	1
478	vaccinate	1
521	vaccinate	1
547	vaccinate	1
531	vaccinate	2
542	vaccinate	2
500	vaccinate	3
526	vaccinate	3
532	vaccinate	3
468	vaccinate	4
465	vaccinate	5
479	vaccinate	5
487	vaccinate	5
523	vaccinate	6
462	vaccinate	7
483	vaccinate	7
481	vaccinate	8
511	vaccinate	8
535	vaccinate	10
515	vaccinate	12
541	vaccinate	12
508	vaccinate	14
473	vaccinate	15
480	vaccinate	16
520	vaccinate	19

Animal ID	Group	LLS (%)
548	placebo	9
509	placebo	10
476	placebo	11
484	placebo	12
527	placebo	12
522	placebo	14
537	placebo	14
486	placebo	17
489	placebo	17
533	placebo	18
524	placebo	19
536	placebo	20
540	placebo	20
518	placebo	22
543	placebo	24
461	placebo	27
516	placebo	27
519	placebo	31
504	placebo	32
530	placebo	32
466	placebo	40
467	placebo	40
472	placebo	40
471	placebo	43
460	placebo	44
477	placebo	44
505	placebo	46
512	placebo	49
502	placebo	50
499	placebo	52

<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>Demonstrate safety of product under typical use conditions</td></tr>
<tr><td>Product Administration</td><td>1 mL dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>677 pigs, 3 weeks of age (17-24 days) at 3 study sites</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for one hour after vaccination and then daily for 14 days</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Frequency of adverse events (total 677 pigs)</th><th>Number</th></tr>
<tr><td>Injection Site Swelling</td><td>0</td></tr>
<tr><td>Lethargy</td><td>29</td></tr>
<tr><td>Poor feed conversion</td><td>8</td></tr>
<tr><td>Conjunctivitis</td><td>6</td></tr>
<tr><td>Loss of condition</td><td>6</td></tr>
<tr><td>Tachypnea</td><td>6</td></tr>
<tr><td>Arthritis</td><td>4</td></tr>
<tr><td>Cough</td><td>4</td></tr>
<tr><td>Death*</td><td>4</td></tr>
<tr><td>Dehydration</td><td>4</td></tr>
<tr><td>Lameness</td><td>4</td></tr>
<tr><td>Anorexia (a)</td><td>3</td></tr>
<tr><td>Diarrhea</td><td>3</td></tr>
<tr><td>Rhinitis</td><td>3</td></tr>
<tr><td>Trauma NOS (b)</td><td>2</td></tr>
<tr><td>Dermatitis and eczema</td><td>1</td></tr>
<tr><td>Respiratory tract disorder NOS</td><td>1</td></tr>
<tr><td>Weight loss</td><td>1</td></tr>
<tr><td>No adverse events</td><td>639</td></tr>
</table>
*Affirmed by licensee to have a cause other than vaccination.
</td></tr>
<tr><td>USDA Approval Date</td><td>December 23, 2016</td></tr>
</table>

<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>Demonstrate safety of product under typical use conditions</td></tr>
<tr><td>Product Administration</td><td>1 dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>664 gilts, 173-185 days of age at 3 geographically distinct study sites.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for one hour after vaccination and then daily for 14 days.</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Frequency of adverse events (total 664 pigs)</th><th>Number</th></tr>
<tr><td>Injection Site Reaction NOS[1]</td><td>1</td></tr>
<tr><td>Lameness</td><td>6</td></tr>
<tr><td>Death</td><td>2</td></tr>
<tr><td>Behavioral Disorder NOS[2]</td><td>2</td></tr>
<tr><td>No adverse events</td><td>653</td></tr>
</table>
[1]Not Otherwise Specified. The localized swelling was approximately 1 cm and was present from 7 through 12 days after vaccination.
[2]Pen-jumping (1 pig); subject of aggression from pen-mates (1-pig)

Lameness, Death, and Behavioral adverse events were affirmed by the licensee to a have cause other than vaccination.
</td></tr>
<tr><td>USDA Approval Date</td><td>January 3, 2018</td></tr>
</table>