Efficacy and field safety of Prime Pac® PRRS RR against reproductive disease caused by Porcine Reproductive and Respiratory Syndrome virus

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Introduction

Porcine Reproductive and Respiratory Syndrome virus (PRRSV) affects swine herds worldwide, with significant economic impact for pork producers. It has been estimated that in the US alone, the cost of this disease amounts to $2.36 per weaned pig and as much as $52.19 per sow per year (Holtkamp, 2013; summarized by Ramirez, 2015). The disease is characterized by respiratory signs in growing pigs as well as reproductive disorders in sows including abortions, fetal mummification, stillbirths, pre-weaning mortality and poor piglet viability. Close to 50% of the economic impact of PRRSV is incurred in breeding herds, and therefore prevention programs need to be effective against the reproductive impacts of PRRSV in mature females. Prime Pac PRRS RR is a modified-live virus vaccine for use in both young pigs and female breeding age swine. The vaccine is labeled for "the vaccination of healthy swine 3 weeks of age or older against respiratory disease caused by Porcine Reproductive and Respiratory Syndrome (PRRS) virus and for the vaccination of female breeding age swine against reproductive disease caused by PRRS virus."

In previous studies, we demonstrated that Prime Pac PRRS RR is safe and effective against respiratory disease caused by a virulent heterologous PRRSV challenge. In two challenge studies, vaccinated pigs had a 71% reduction in lung lesions versus controls.

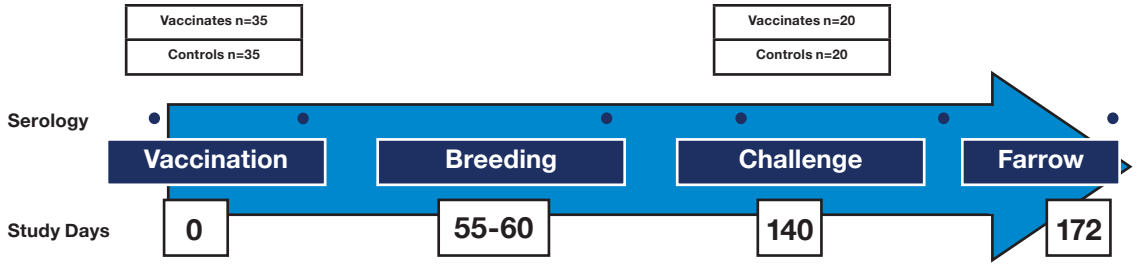
Two licensing studies summarized here demonstrate the protection Prime Pac PRRS RR affords gilts against reproductive disease in the face of a heterologous PRRSV challenge, while also being a safe vaccine when administered under field conditions.

Materials and Methods

Efficacy Study

The efficacy of Prime Pac PRRS RR for preventing reproductive disease was examined by vaccinating gilts eight weeks prior to breeding followed by challenge during late gestation with a heterologous PRRSV isolate. The experimental design is shown in Figure 1.

Figure 1. Efficacy study design



The gilts used in this study were 6 months old and were sourced from a commercial, health-stable sow herd. The animals were confirmed to be free of PRRS antibodies and PCV2 viremia prior to the start of the study. Seventy gilts were randomly divided into two groups of 35, and were housed in individual gestation stalls within separate rooms during the vaccination, breeding and pre-challenge gestation period of the study.

At the start of the study, all gilts in one room were vaccinated with 1 mL of Prime Pac PRRS RR by the intramuscular (IM) route.

All gilts in the control group were treated with 1 mL of a placebo vaccine by the same route. The treatment groups were not commingled to prevent the control group from becoming infected with vaccine virus before the experimental challenge.

The gilts were bred by artificial insemination at 55-60 days after vaccination. In order to synchronize estrus, all gilts were treated for 14 consecutive days with Matrix® (altrenogest, Merck Animal Health), according to label directions. Pregnancy was confirmed by transabdominal ultrasound at 30-35 days of gestation in 95% of vaccinates and 85% of controls.

At 140 days post vaccination (approximately 85 days of gestation) the treatment groups were reduced to 20 gilts per group in a randomized manner and the two groups were commingled and all gilts were challenged intranasally with a heterologous PRRSV strain (NADC 20, kindly supplied by Dr. Lager from the NADC, USDA-ARS).

Following challenge, all gilts were observed daily for clinical signs of PRRS including lethargy, poor condition, off-feed, coughing, sneezing, tachypnea and dyspnea. Farrowing metrics recorded for all gilts were numbers of live pigs, stillbirths, low viability pigs, and mummified fetuses. The size of mummified fetuses was recorded to determine the timing of fetal death. Small mummies (<19 cm) were considered to have died before the time of the challenge and were not included in litter size calculations or study evaluation.

All piglets were evaluated for viability at birth by the attending veterinarian and piglets considered non-viable or small (< 2.2 lbs) were euthanized. The remaining live piglets were observed daily for general health and signs of PRRS related disease. Observations were concluded at 21 days post farrowing, to represent the typical weaning age in U.S. commercial operations.

Serum samples were obtained from the gilts on study days -1, 27, 90, 139, 173 and 193. Sera were evaluated for PRRS antibody levels by the IDEXX PRRSV X3 Ab test.

Statistical analysis of binary variables was performed by Fisher's Exact Test for binary variables. Statistical significance was assigned at $P < 0.05$.

Field Safety Study

Field safety evaluations were conducted at three separate sites in South Dakota, Iowa and Minnesota using a total of 664, six-month-old gilts. Gilts were vaccinated with 1 mL of Prime Pac PRRS RR intramuscularly in the neck. All vaccinated gilts were continually monitored for systemic or local reactions for at least one hour post-vaccination followed by daily observations for the subsequent 14 days. Injection sites were palpated one day after vaccination for evaluating localized reactions. In addition, gilts were observed daily for overall health and any mortalities were necropsied to determine cause of death.

Results

Efficacy Study: Serology

All gilts were seronegative for PRRSV antibodies at the start of the study as measured by the IDEXX PRRSV X3 Ab test. Of the 35 vaccinated gilts, 29 had seroconverted by four weeks after vaccination (83%, S/P ratio > 0.400), while the remaining gilts had S/P ratios between 0.100 and 0.400. At the time of challenge, 20 weeks after vaccination, 57% were still seropositive. All vaccinated gilts demonstrated an anamnestic response following PRRSV challenge. All control gilts were confirmed PRRSV ELISA negative prior to challenge and became positive by four weeks after challenge.

Efficacy Study: Reproductive Performance

After challenge, eight vaccinated gilts demonstrated clinical signs considered related to PRRS (lethargy and off-feed), totaling 17 daily observations for this group. One vaccinated gilt aborted all 15 fetuses at nine days post-challenge (data included in farrowing performance analysis). One vaccinated gilt died at 11 days after challenge. Necropsy and diagnostic testing revealed congestive heart and lung failure (data not included in farrowing performance analysis). The remaining 18 vaccinated gilts farrowed within a five-day window between 115 and 120 days of gestation.

Clinical signs of PRRS disease were observed in 12 control gilts, totaling 73 daily observations ($P < 0.05$). Three control gilts failed to farrow for at least 21 days after the calculated farrow date (data not included in farrowing performance analysis). Necropsy of these gilts confirmed the death of fetuses due to the challenge. Seventeen control gilts farrowed by natural means, but in a wide, 20-day period between 106 and 126 days of gestation.

Eighteen of 19 vaccinated gilts farrowed viable piglets, compared to eight of 17 controls ($P < 0.05$). All vaccinated gilts continued on to wean viable pigs, compared to only three control gilts.

Efficacy Study: Piglet Performance

Nineteen vaccinated gilts farrowed or aborted (one gilt) a total of 262 pigs (13.8 pigs/litter), 175 (67%) of which were viable at farrowing versus only 21 (9%) viable pigs of 237 pigs (13.9 pig/litter) from the seventeen control gilts. Likewise, at weaning, the vaccinated gilts weaned a total of 149 (85%) versus only 5 (24%) weaned by the control gilts (Table 1 and Figure 2). Pre-weaning mortality was 14.9% for vaccinated and 76.2% controls ($P < 0.05$) (Figure 3).

Table 1. Farrowing Performance

Variable	Unit	Vaccinated	Control
No. litters	Count	19	17
Total Born	Total	262	237
	Per Litter	13.8	13.9
Viable liveborn	Total	175	21
	Per litter	9.2	1.2
	% of Total Born	**66.8**	**8.9**
Stillborn and large mummies	Total	53	190
	Per litter	2.8	11.2
	% of Total Born	**20.2**	**80.2**
Non-viable liveborn	Total	34	26
	Per litter	1.8	1.5
	% of Total Born	13.0	11.0
Pre-wean mortality	Total	26	16
	% of Viable liveborn pigs	**14.9**	**76.2**
Pigs weaned	Total	149	5
	% of Viable liveborn pigs	85.1	23.8

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Figure 2. Number of viable piglets at the time of farrowing

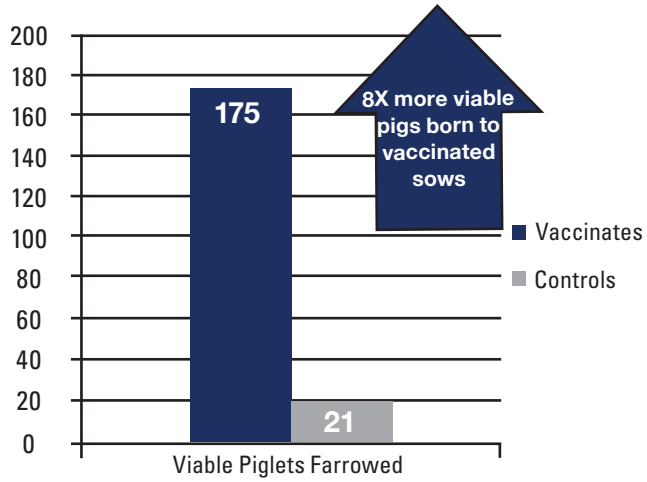
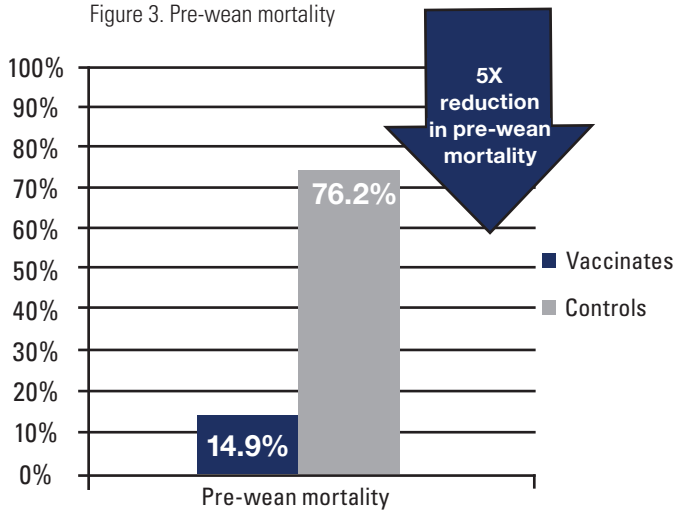


Figure 3. Pre-wean mortality



Observations for clinical signs of PRRS were conducted daily on all piglets. For piglets born to vaccinated gilts, 1.3% of observations were considered PRRS related, compared to 31.2% of all observations of piglets from control gilts ($P < 0.05$).

The pre-weaning mortality (Figure 3) of 14.9% in offspring from vaccinated gilts was close to the historic incidence reported for the source herd under stable disease conditions (10.7% - 12.0%).

Field Safety Study

Of the 664 gilts, 653 presented with no injection site or systemic reactions attributable to vaccination. One gilt presented with a localized injection site swelling, approximately 1 cm in size, between seven and 12 days after vaccination. Throughout the study, two mortalities occurred, but these were attributed to causes unrelated to vaccination with Prime Pac PRRS RR. Eight gilts presented with recorded events unrelated to vaccination with PRRS (ex. lameness).

Conclusions

Prime Pac PRRS RR was shown in this study to be an effective tool to improve gilt reproductive performance in the face of a heterologous PRRSV challenge. Post-vaccination clinical monitoring indicated that Prime Pac PRRS RR is safe to use in six-month-old female pigs. Prime Pac PRRS RR is a safe product that can be incorporated into vaccination protocols as a tool to help mitigate the impact of PRRSV in swine.

Highlights

- Prime Pac PRRS RR significantly reduces the reproductive effects of PRRSV in breeding age female swine, resulting in significantly improved litter viability.
- Prime Pac PRRS RR is a safe product to include in your pre-breeding vaccination protocols.

Holtkamp, D., et al. Assessment of the economic impact of porcine reproductive and respiratory syndrome virus on the United States pork producers. *Journal of Swine Health and Production.* 2013. 72-84.

Ramirez, A. PRRSv Guide. Reprinted by Merck Animal Health. 2015.

Data on file, Merck Animal Health.

Prime Pac® RR PRRS

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