

# Bulletin

Boehringer Ingelheim Vetmedica, Inc.

TECHNICAL

## Single Pathogen Challenge Study Confirms Efficacy of 3FLEX™ Vaccine Mixture

3FLEX™ is the trade name associated with the mixture of Ingelvac CircoFLEX®, Ingelvac MycoFLEX®, and Ingelvac® PRRS MLV swine vaccines. Three laboratory studies were conducted to evaluate the efficacy of the trivalent vaccine mixture against single-agent infections by challenging vaccinated pigs with each specific pathogen.

### Materials & Methods

The efficacy of the PRRS vaccine fraction was evaluated in the pig host animal efficacy model. This allowed for the evaluation of the PRRS-specific parameters in the appropriate host animal challenge model. The PRRS efficacy evaluation was performed in conventional pigs approximately three weeks old. Pigs were tested and determined to be seronegative for antibodies to PRRS virus by ELISA.

At approximately three weeks of age, animals were vaccinated with a mixture containing Ingelvac MycoFLEX®, Ingelvac CircoFLEX® and Ingelvac® PRRS MLV in a single 2 mL dose. The trivalent vaccine treatment was created by mixing equal volumes of the Ingelvac MycoFLEX and Ingelvac CircoFLEX products (each labeled as 1 mL/dose) and rehydrating Ingelvac PRRS MLV. The mixture was then administered as a 2 mL/dose vaccination. Twenty eight days after vaccination, animals were challenged with a virulent heterologous PRRS virus isolate MN/01/A2. Animals were necropsied 14 days after challenge and the lungs were removed and scored for percent lung pathology consistent with PRRS virus infection.

To demonstrate efficacy of the Ingelvac® PRRS MLV vaccine in combination with the other two vaccines, the vaccinated group must demonstrate statistically significant reduction ( $p < 0.05$ ) for total % lung pathology compared with challenge control pigs following a virulent heterologous challenge with PRRS virus.

### Results

Percent lung pathology was significantly reduced by trivalent vaccination (Table 1).

**Table 1. Efficacy of Ingelvac® PRRS MLV after mixing with Ingelvac MycoFLEX® and Ingelvac CircoFLEX® (Wilcoxon Rank Sum Analysis of lung scores).**

Treatment	Number of animals	Group Average Lung Score (%)
M hyo-PCV2-PRRS	20	4.5 <sup>a</sup>
Challenge Controls	20	32.9 <sup>b</sup>

a,b:  $P < 0.0001$

There was no injection site or other adverse reactions that could be attributed to the vaccine mixture in any of these studies. Separate single agent challenge studies were also performed to evaluate *M hyo* and PCV2 protection in trivalent vaccinates. Statistically significant differences between vaccinates and controls for outcomes relevant to each specific agent were observed.

### Conclusions

The mixture of Ingelvac PRRS MLV rehydrated with Ingelvac MycoFLEX and Ingelvac CircoFLEX delivered in a single combined 2.0 mL intramuscular injection was safe and effective against a heterologous PRRS virus challenge. The trivalent vaccine mixture also induced protection against virulent challenges with *M. hyo* and PCV2 in separate studies. **The ability to confidently mix and administer these three single-dose products reduces the number of injection sites, animal stress, time and labor, yet provides confirmed efficacy and safety as demonstrated by these controlled studies.**

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