

# FLEX ParvoPRRS®



2-mL dose, IM

For active immunization of gilts and sows from the age of 6 months

Aids in the prevention of reproductive disease caused by PPV and PRRS virus



- ✓ A new solution in one injection for essential control of PRRSV and PPV, two of the leading causes of pathogen-related reproductive losses in swine.
- ✓ Brings measurable value to reproductive performance, protecting progeny against transplacental infection caused by PPV while supporting increased average litter sizes.
- ✓ Supports mass-vaccination protocols in breeding herds with compatible and flexible reproductive protection that is safe for every stage of lactation and gestation.

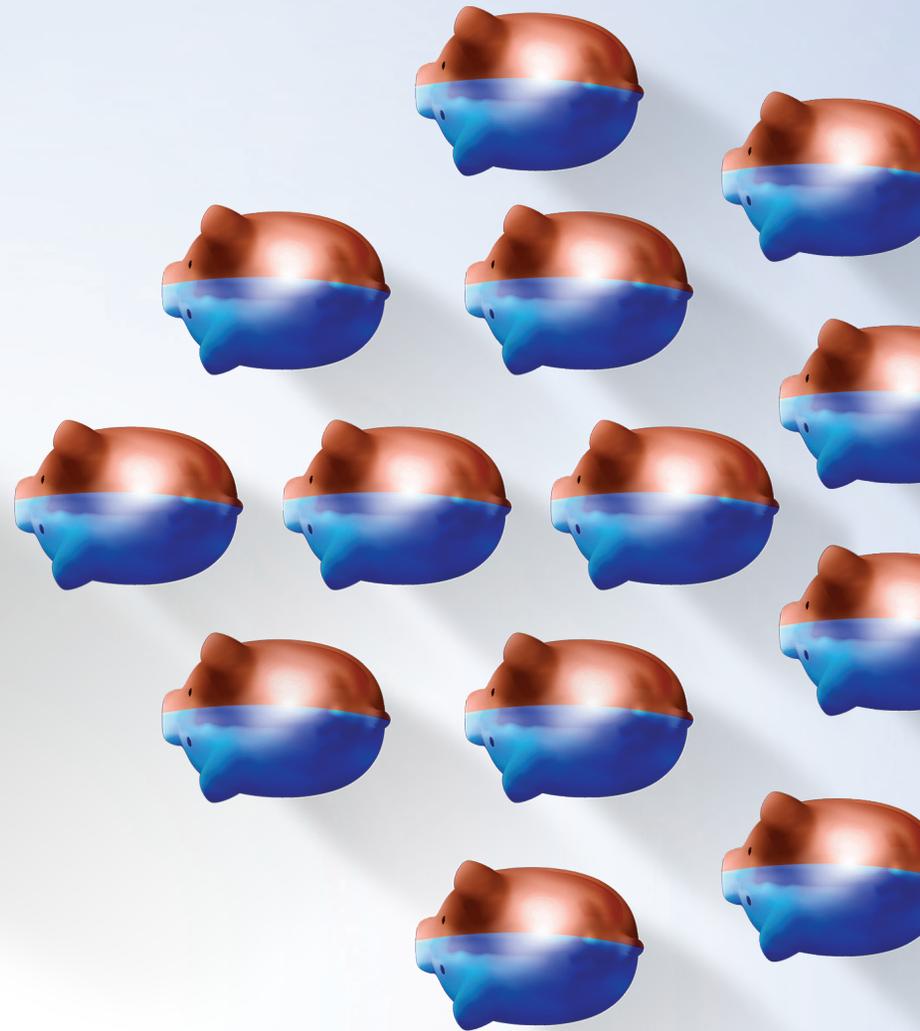
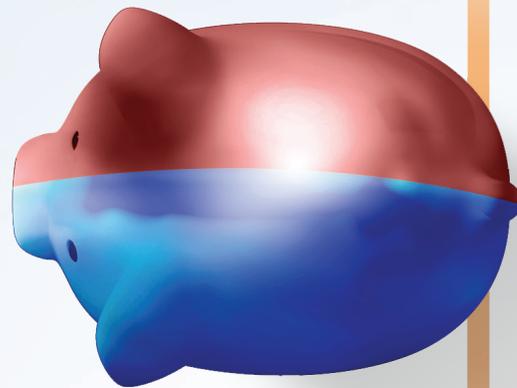
- <sup>1</sup> Salogni C, Lazzaro M, Giacomini E, et al. Infectious agents identified in aborted swine fetuses in a high-density breeding area: a three-year study. *J Vet Diagn Invest* 2016;28(5): 550–554.
- <sup>2</sup> Mengeling W, Lager K, Vorwald A. The effect of porcine parvovirus and porcine reproductive and respiratory syndrome virus on porcine reproductive performance. *Anim Reprod Sci* 2000;60–61:199–210.
- <sup>3</sup> Zeeuw E, Leinecker N, Herwig V, et al. Study of the virulence and cross-neutralization capability of recent porcine parvovirus field isolates and vaccine viruses in experimentally infected pregnant gilts. *J Gen Virol* 2007 Feb;88(Pt 2):420–427.
- <sup>4</sup> Martínez C, Dalsgaard K, López de Turiso J, et al. Production of porcine parvovirus empty capsids with high immunogenic activity. *Vaccine* 1992;10(10):684–690.
- <sup>5</sup> Mair K, Koinig H, Gerner W, et al. Carbopol improves the early cellular immune responses induced by the modified-live vaccine Ingelvac PRRS® MLV. *Vet Microbiol* 2015 176(3–4):352–357.
- <sup>6</sup> Ziron M, et al. Effect of different vaccine on the behavior of suckling piglets. Abstract WEL-028, ESPHM 2017.
- <sup>7</sup> Stadler J, Zoels S, Eddicks M, et al. Assessment of safety and reproductive performance after vaccination with a modified live-virus PRRS genotype 1 vaccine in pregnant sows at various stages of gestation. *Vaccine* 2016;34(33):3862–3866.
- <sup>8</sup> Data On File. BIAH USA Inc. study #2019003.

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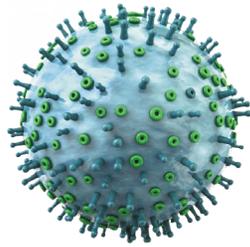
FLEX ParvoPRRS®

*When you lead with efficacy,*

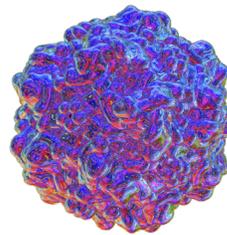
# PRODUCTIVITY FOLLOWS



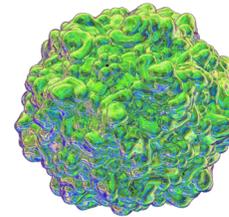
**Reproductive failure can easily go undetected until it is too late.**



Porcine reproductive and  
respiratory syndrome  
**(PRRS)**



Porcine  
parvovirus  
**(PPV)**



Porcine circovirus  
Type 2  
**(PCV2)**

**More than 70% of reproductive failures linked to an infectious agent are related to at least one of these three viruses.<sup>1</sup>**

# Main Reproductive Diseases

FLEX ParvoPRRS®

- ✓ PRRS and PPV are two of the three most common reproductive infectious diseases, along with PCV2.<sup>1</sup>
- ✓ The consequences of reproductive failure from PPV infection include a decrease in number of total born piglets, an increase in irregular return to estrus and mummified fetuses of progressively larger sizes.
- ✓ PRRSV is an important swine pathogen causing reproductive failure in dams and respiratory disease in pigs. Infection of pregnant sows in late-term gestation with PRRSV commonly causes severe reproductive failure including spontaneous abortions, the birth of stillborn pigs, mummified fetuses, and weak, non-viable piglets.
- ✓ Vaccines mostly protect against clinical signs in a herd, but do not prevent infection and shedding.<sup>2</sup>

# Efficacy Studies

PRRS Challenge

FLEX ParvoPRRS®

This vaccination-challenge study demonstrated that FLEX PARVOPRRS is efficacious in mitigating reproductive failure caused by virulent PRRSV when administered to gilts prior to breeding.



Sows in the vaccinated group (VC) farrowed **significantly more live, healthy piglets** than sows in the control group (NVC).



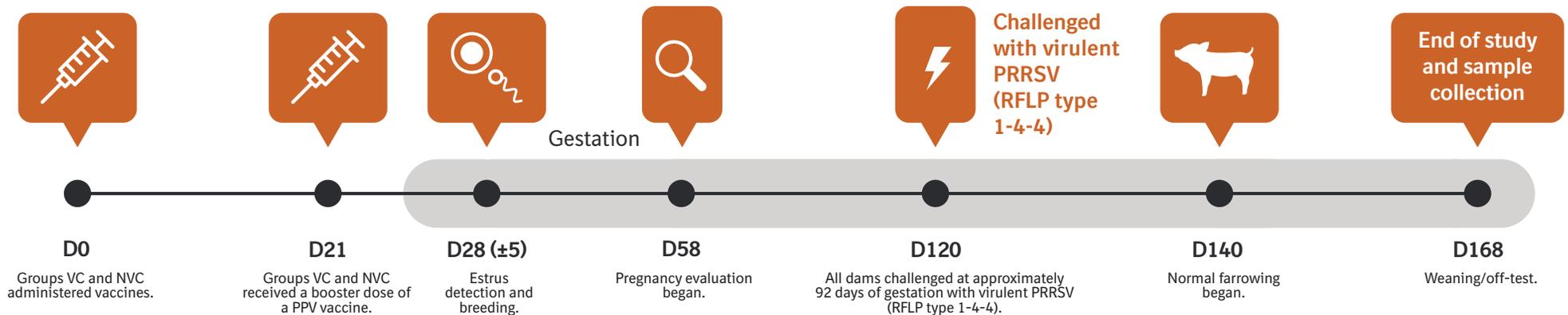
The VC group had a **significantly higher percentage of live pigs at weaning** than the NVC group.



Piglets farrowed from the VC group had **significantly higher average daily weight gain (ADWG)** than pigs farrowed from the NVC group.

## STUDY DESIGN:

Forty gilts were randomized into two groups, and intramuscularly vaccinated with a 2-mL dose of either FLEX PARVOPRRS (Group VC, N = 20) or a PPV vaccine as a control product (Group NVC, N = 20).



# Efficacy Studies

PRRS Challenge

FLEX ParvoPRRS®

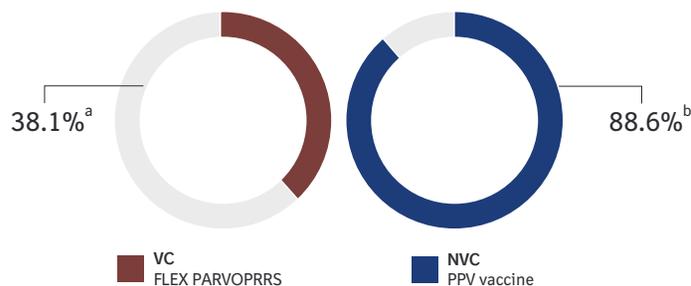
The efficacy of FLEX PARVOPRRS is primarily supported by the significant differences in healthy, live pigs at farrowing between gilts in the VC group (54.7%) and NVC group (16.9%).

Significantly more piglets from gilts in the VC group survived to wean, and these piglets also had **significantly higher ADWG** than pigs farrowed from gilts in the NVC group.

	Survival to Wean (%)	ADWG (lbs.)
VC FLEX PARVOPRRS	42% <sup>a</sup>	0.42 <sup>a</sup>
NVC PPV Vaccine	1.3% <sup>b</sup>	0.02 <sup>b</sup>

Different superscript letters indicate statistical significance ( $P < 0.05$ ).

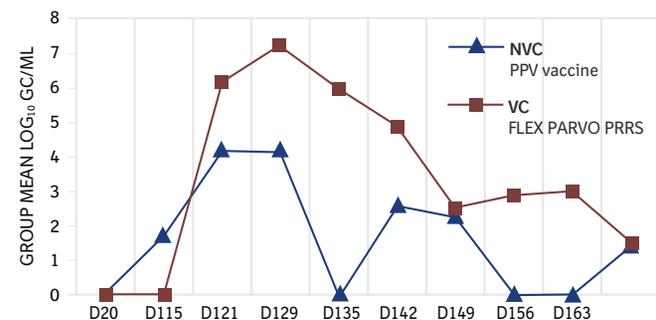
## VIREMIC PIGS BORN



Additionally, there was a **significant reduction in the incidence rate and magnitude of viremia** in piglets farrowed from dams in the VC group.

Efficacy is also supported by a **significant reduction in the incidence rate (15% vs. 100%)\***, **magnitude and duration of viremia** among dams in the VC group compared to the NVC group.

## AVERAGE VIRAL LOAD OF STUDY DAMS (GC/ML)



\*9 days post-challenge

Data on file. Boehringer Ingelheim Animal Health USA Inc. Study #2018009.



# Efficacy Studies

PPV Challenge

FLEX ParvoPRRS®

This vaccination-challenge study demonstrated that FLEX PARVOPRRS is efficacious in mitigating reproductive failure caused by virulent PPV when administered to gilts according to the label instructions.



**98% of fetuses from gilts in the vaccinated group (VC) were normal condition** compared to only 20% of fetuses from gilts in the control group (NVC).



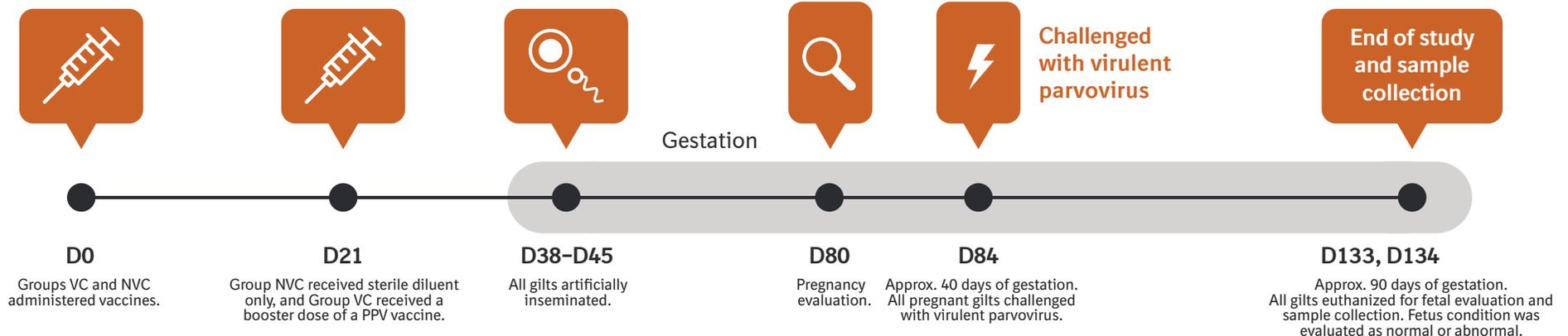
**Only 4 of 22 VC gilts were considered affected** compared to 19 of 22 NVC gilts (the difference was statistically significant). A gilt was considered affected if one or more fetuses in a litter was not normal (mummified or necrotic).



**None of the VC gilts became viremic following challenge** while 20 of the 22 NVC gilts were viremic at seven days post challenge.

## STUDY DESIGN:

Fifty gilts were randomized into two groups and intramuscularly vaccinated, with 2 mL of either FLEX PARVOPRRS (Group VC, N = 25) or Ingelvac PRRSFLEX® MLV as controls (Group NVC, N = 25) on day 0 of the study.

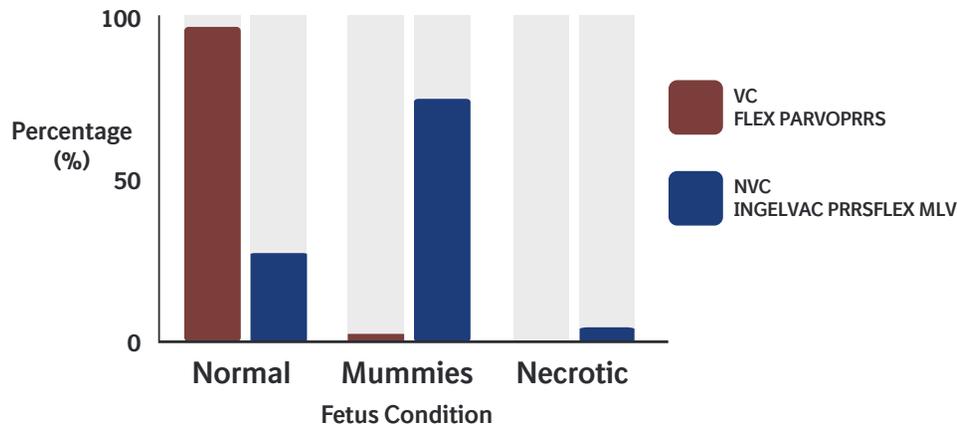


# Efficacy Studies

PPV Challenge

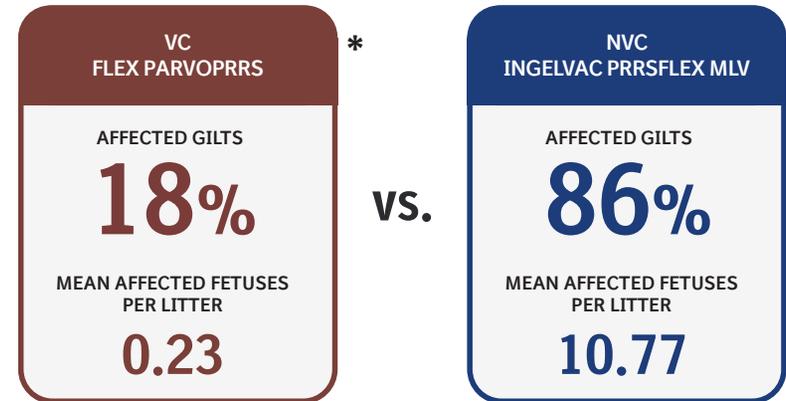
FLEX ParvoPRRS®

## SUMMARY OF FETUS CONDITION RESULTS



## AFFECTED GILTS (%) BASED ON CLINICAL CONDITION OF FETUSES

A gilt with at least one abnormal fetus was considered affected.



\*Statistical significance in prevented fraction analysis.

## MEAN FETUS SIZE (CM)

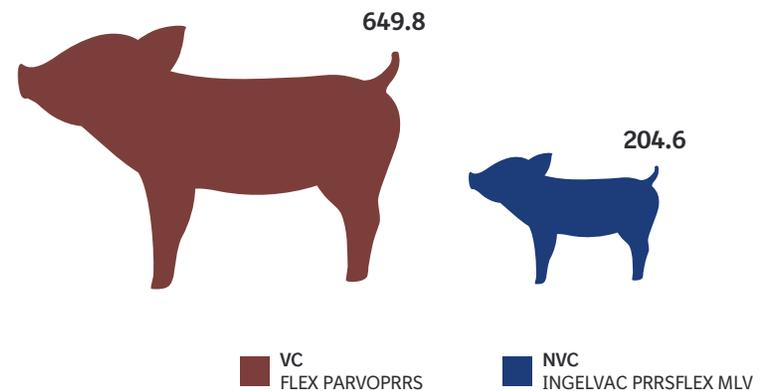
VC FLEX PARVOPRRS



NVC INGELVAC PRRSFLEX MLV



## MEAN FETUS WEIGHT (GRAMS)



# Safety Study

FLEX ParvoPRRS®

A non-blinded, uncontrolled observational field safety study was conducted at two swine production farms, which demonstrated that FLEX PARVOPRRS is safe for use in pregnant animals and gilts.



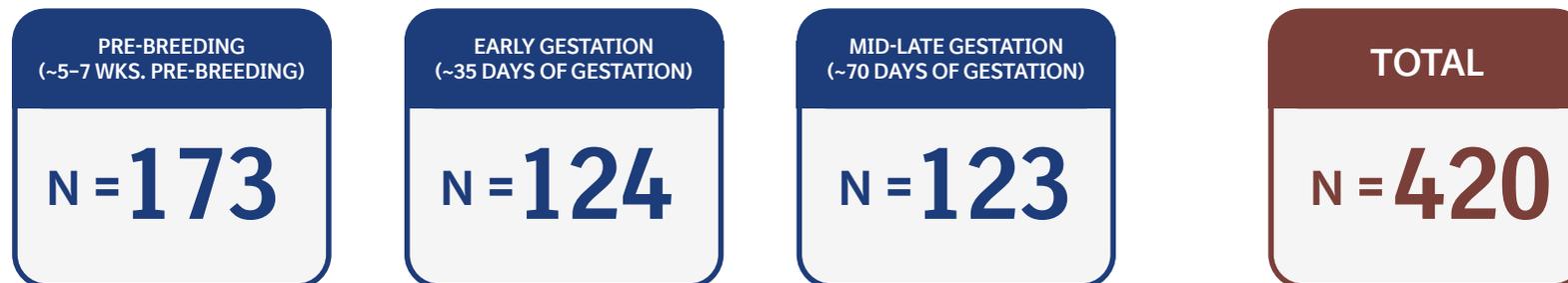
Overall, **94.3% of vaccinated sows/gilts were observed as healthy for all days** enrolled in the study.



Of the dams that remained in the study through farrowing (384), 368 (95.8%) were observed as healthy on all days. **None of the adverse events recorded were considered to be vaccine-related.**

## STUDY DESIGN:

The study included a total of 420 adult sows and gilts from different stages of production.



All 420 adult breeding-age females were vaccinated with one dose (2 mL) of FLEX PARVOPRRS, followed by a booster of 2 mL PPV vaccine three weeks later. Individual health observations were recorded daily for all enrolled dams until removal from the study.

# Safety Study

The pregnant, vaccinated dams were observed until farrowing, loss of pregnancy, removal for humane reasons or mortality occurred. At farrowing, the number of healthy, weak-born, stillborn and mummified piglets per litter was recorded.

The results of this study demonstrated that **FLEX PARVOPRRS is safe to use in pregnant animals and gilts vaccinated prior to breeding.**

## SUMMARY OF HEALTHY ANIMALS (NO CLINICAL SIGNS)

Daily Observations	Total Animals	Percent Animals
Healthy (no signs) All enrolled sows / gilts	396	94.3%
Healthy (no signs) Dams remaining to farrowing	368	95.8%

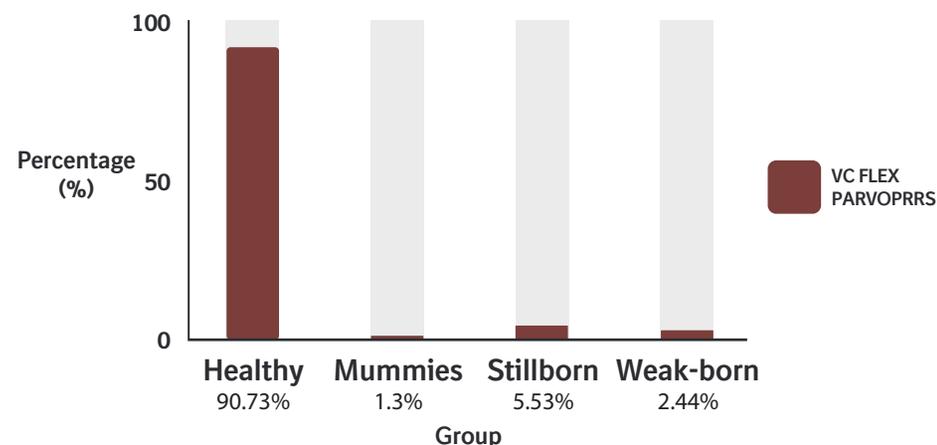
## SUMMARY OF ANIMALS WITH ADVERSE EVENTS (%)

1.4% / Anorexia	0.2% / Skin Abscess
1.2% / Lameness	0.2% / Ear Infection NOS
0.7% / Cough	0.2% / Skin Scab
0.7% / Death	0.2% / Wound
0.2% / Head Tilt – Ear Disorder	0.8% / Abortion
0.2% / Injection-Site Granuloma	0.5% / Vaginal Tear

**None of the adverse events recorded were considered to be vaccine-related.**

## REPRODUCTION PERFORMANCE

Average Percentage of Piglets per Litter



# FLEX PARVOPRRS Characteristics and Benefits

FLEX ParvoPRRS®

## HIGHLY IMMUNOGENIC

### Efficacy and Productivity

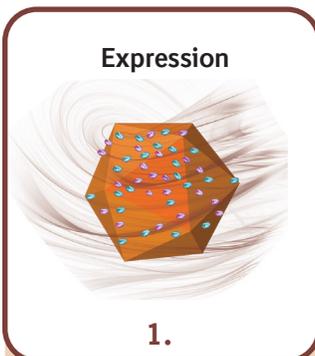
- ✓ Research has shown that the recent PPV strain 27a can provide a broad spectrum of protection when incorporated into vaccines.<sup>3</sup>
- ✓ VP2 is a capsid protein from the structural ORF of the PPV that is the main target for neutralizing antibodies and is highly conserved. (More than 90% of the PPV-neutralizing antibodies are directed against the VP2 protein.)
- ✓ The VP2 of a PPV 27a virulent strain was expressed using the same technology used for Ingelvac CircoFLEX® (baculovirus expression system).

**FLEX**  
**ParvoPRRS®**  
is developed from  
**PPV strain 27a**

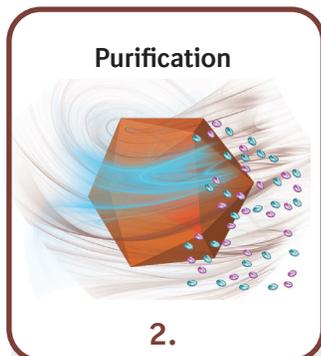
Within the same amount of antigen, a higher immunogenic response was obtained with VLPs compared to inactivated virus (used in conventional vaccines).<sup>4</sup>

## NON-VIRUCIDAL

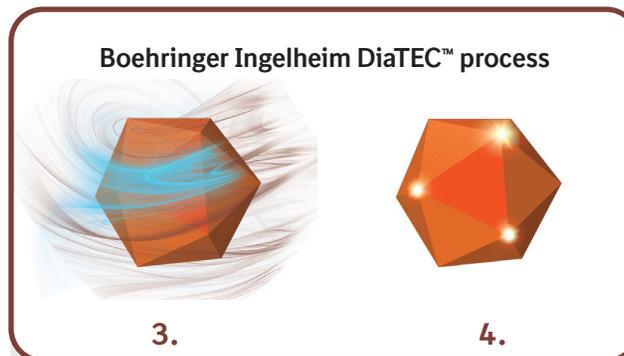
### Dual Protection



Key PPV protein (VP2) is produced in a non-pathogenic baculovirus expression system and forms antigenic, virus-like particles (VLPs)

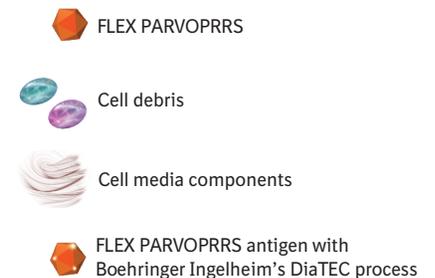


Non-specific proteins and cell debris are separated, leaving purified VLPs



The DiaTEC process from Boehringer Ingelheim is applied, removing residual cell media components from the VLPs

The unique DiaTEC process results in a **highly immunogenic and non-virucidal** vaccine composed of concentrated VLPs



# FLEX PARVOPRRS Characteristics and Benefits

FLEX ParvoPRRS®

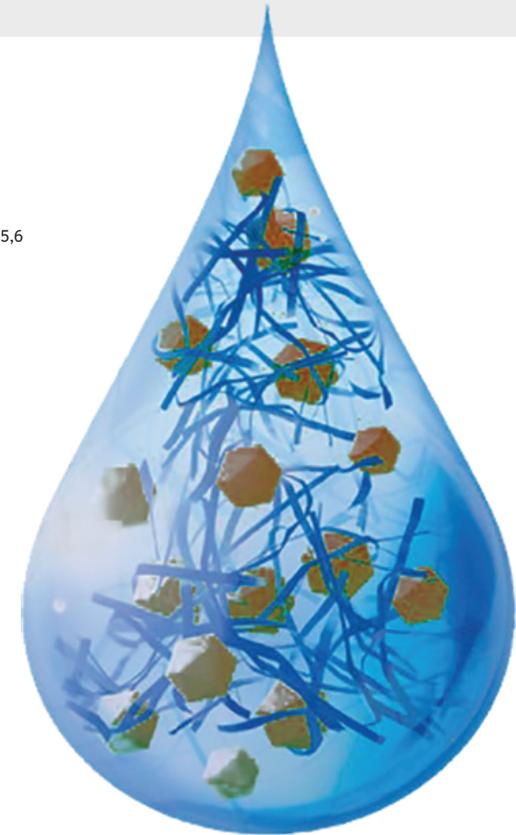
## SUPPORTS MASS VACCINATION

### Convenience and Safety

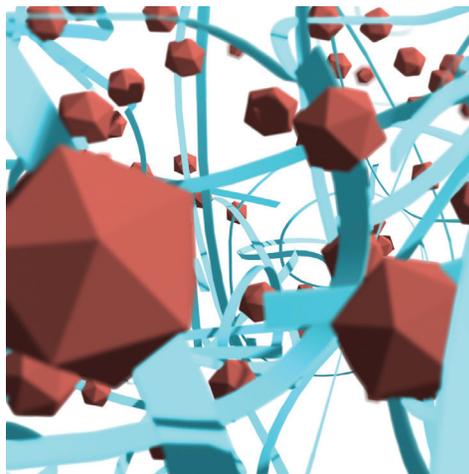
FLEX PARVOPRRS includes ImpranFLEX®, a proprietary, water-based polymer adjuvant that maximizes immunity without producing reactions experienced with mineral oil-based adjuvants.<sup>5,6</sup>

FLEX PARVOPRRS has been shown to be safe in all stages of gestation and lactation, allowing whole-herd mass vaccination as well as pre-breeding protocols.<sup>7</sup>

- IMPRANFLEX is as safe as saline, offering an exceptional safety profile with minimal injection-site reactions.
- IMPRANFLEX improves the immune response of the vaccine, resulting in faster, long-lasting disease protection.
- IMPRANFLEX is a non-virucidal adjuvant that allows FLEX PARVOPRRS to offer protection against PPV- and PRRSV-related reproductive failure.<sup>7</sup>

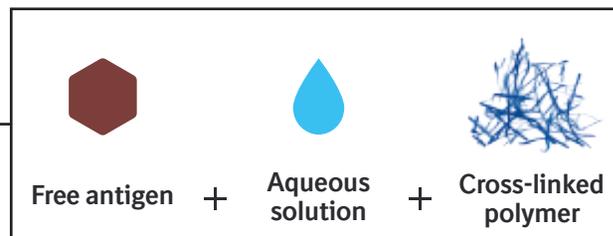


**IMPRANFLEX promotes rapid onset of immunity** due to immediate presentation of free antigen, and long-lasting immunity from the aqueous polymer.<sup>5</sup>



## IMPRANFLEX

Outstanding safety profile  
Excellent syringeability  
100% oil-free

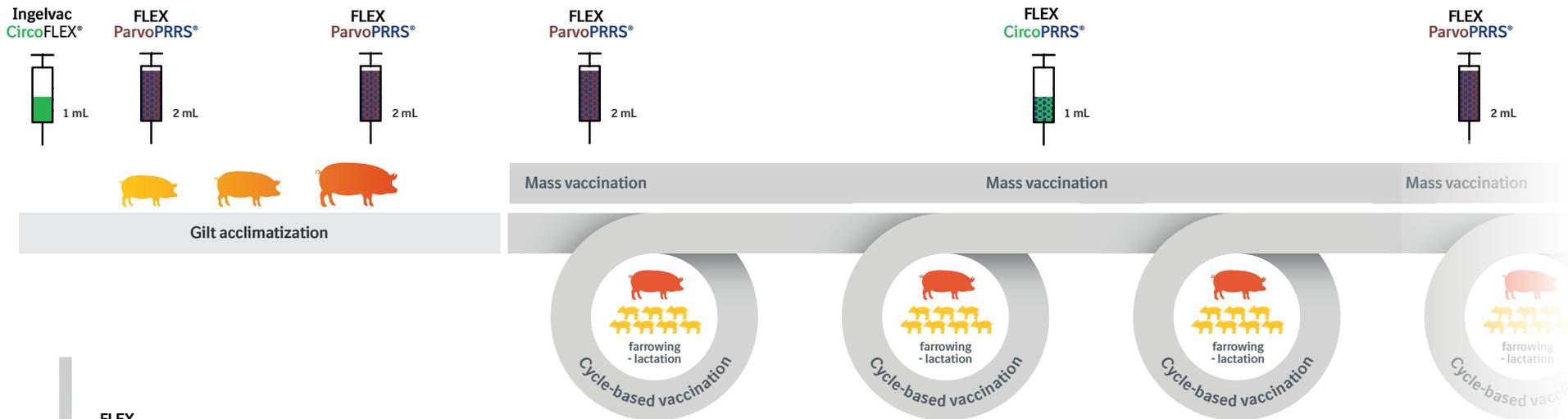




# Suggested Vaccination Protocol

FLEX ParvoPRRS®

FLEX PARVOPRRS supports mass vaccination, as well as pre-breeding vaccination protocols, in breeding herds with compatible and flexible reproductive protection that is safe for every stage of lactation and gestation.



FLEX  
ParvoPRRS®

Initial vaccination: Two doses administered three weeks apart  
One dose for revaccination for maintenance of immunity protocols

Ingelvac  
CircoFLEX®

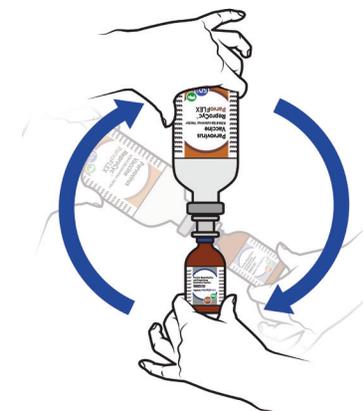
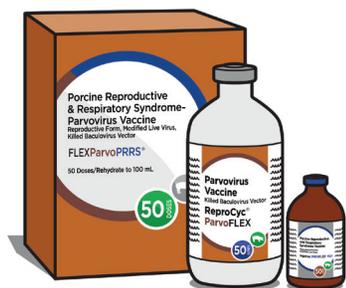
One dose recommended for replacement gilts

FLEX  
CircoPRRS®

One dose in healthy pigs three weeks of age or older

# Mixing Guide

FLEX ParvoPRRS®



## STEP 1:

FLEX PARVOPRRS contains one bottle of **Reprocyc® ParvoFLEX** and one glass amber bottle of **INGELVAC PRRSFLEX MLV**.

## STEP 2:

Insert vented transfer spike into **REPROCYC PARVOFLEX** bottle.

## STEP 3:

Slowly insert the vented transfer spike into the **INGELVAC PRRSFLEX MLV** vaccine bottle, releasing the vacuum.

## STEP 4:

While still connected by transfer spike, rotate the vials so **REPROCYC PARVOFLEX** is on top.

## PASO 1:

FLEX PARVOPRRS contiene una botella de **REPROCYC® PARVOFLEX** y una botella de **INGELVAC PRRSFLEX® MLV** liofilizada.

## PASO 2:

Inserte la aguja de transferencia ventilada dentro de la botella de **REPROCYC PARVOFLEX**.

## PASO 3:

Inserte lentamente la aguja de transferencia ventilada dentro de la botella de vacuna **INGELVAC PRRSFLEX MLV**, liberando el vacío.

## PASO 4:

Mientras aún están conectados por la aguja de transferencia, gire los viales de manera que la botella de **REPROCYC PARVOFLEX** esté en la parte superior.

More Information: Effective PRRS management requires a systematic approach utilizing complementary components of PRRS control along with an MLV vaccine. Boehringer Ingelheim Animal Health USA Inc. provides a complete toolbox that includes technical support, education, training, diagnostic services, science-based strategies, leading knowledge and more.

El manejo efectivo de PRRS requiere un abordaje sistemático, utilizando los diferentes elementos que conforman el control de PRRS junto con una vacuna viva modificada. Boehringer Ingelheim Animal Health USA Inc. proporciona un conjunto completo de herramientas que incluyen soporte técnico, educación, entrenamiento, servicios de diagnóstico, estrategias basadas en la ciencia, conocimiento líder y mucho más.

# Mixing Guide

FLEX ParvoPRRS®



## STEP 5:

Transfer a portion of the vaccine from the **REPROCYC PARVOFLEX** bottle into the **INGELVAC PRRSFLEX MLV** bottle. The amount transferred needs to be enough to rehydrate the **INGELVAC PRRSFLEX MLV** product.

## PASO 5:

Transfiera una porción de vacuna de la botella de **REPROCYC PARVOFLEX** a la botella de **INGELVAC PRRSFLEX MLV**.

La cantidad transferida tiene que ser suficiente para rehidratar el producto **INGELVAC PRRSFLEX MLV**.



## STEP 6:

With the vented transfer spike still in place, flip the **INGELVAC PRRSFLEX MLV** and **REPROCYC PARVOFLEX** bottles so all product transfers into the **REPROCYC PARVOFLEX** bottle.

## PASO 6:

Con la aguja de transferencia ventilada todavía en su lugar, voltee las botellas **INGELVAC PRRSFLEX MLV** y **REPROCYC PARVOFLEX** para que todo el contenido se transfiera a la botella de **REPROCYC PARVOFLEX**.



## STEP 7:

Shake well and use immediately.

## PASO 7:

Agite bien y utilice de inmediato.



## STEP 8:

Administer 2-mL dose intramuscularly (in the neck per PQA® Plus guidelines).

## PASO 8:

Administre una dosis de 2-mL intramuscular (en el cuello siguiendo las directrices de PQA® Plus).

For additional information or questions, contact your Boehringer Ingelheim Animal Health USA Inc. representative or call 1-888-637-4257.

Para información adicional o preguntas, contacta a tu representante de Boehringer Ingelheim Vetmedica, Inc. representante o llama al 1-888-637-4257.