

DELETION OF EXON 7 OF CD163 GENE IN DOMESTIC PIGS- deletion of exon 7 of cd163 gene in domestic pigs not applicable

Genus plc

Deletion of exon 7 of CD163 gene in domestic pigs

1. DESCRIPTION

1.1 Product Identification

Deletion of exon 7 of CD163 gene (abbreviated CD163^{ΔE7}) in domestic pigs (*Sus scrofa domestica*). Breeding lines containing one copy (heterozygous) or two copies (homozygous) of CD163^{ΔE7} may be identified with the registered tradename “EverThrive™ PRP”. However, only pigs carrying two copies of CD163^{ΔE7} (homozygous) are intended to be resistant to Porcine Reproductive and Respiratory Syndrome Virus (PRRSV).

1.2 Product Claim

Deletion of exon 7 of the CD163 gene in domestic pigs (*Sus scrofa domestica*) is intended to confer resistance to porcine reproductive and respiratory syndrome virus (PRRSV) in homozygous pigs. Pigs carrying one or two copies of CD163^{ΔE7}, and their offspring, are intended for breeding or to be used as sources of food.

1.3 Uses

Product Label 1: Homozygous Pigs.

Pigs bearing this label are CD163^{ΔE7} homozygous and are resistant to PRRSV.

Resistance to PRRSV in the progeny of this pig (and from semen derived from this pig) is affected by the genetic background of the other parent pig it is bred to:

- If the other parent is CD163^{ΔE7} homozygous (two copies), all progeny will be resistant to PRRSV.
- If the other parent is CD163^{ΔE7} heterozygous (one copy), approximately one half of the progeny will be resistant to PRRSV.
- If the other parent has no CD163^{ΔE7}, none of the progeny will be resistant to PRRSV.

Product Label 2: Semen from Homozygous Pigs.

Semen bearing this label will produce offspring that may or may not be resistant to PRRSV.

Resistance to PRRSV in the progeny of this semen is affected by the genetic background of the other parent pig it is bred to:

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- If the other parent has no CD163^{ΔE7}, none of the progeny will be resistant to

PRRSV.

Product Label 3: Heterozygous Pigs.

Pigs bearing this label are CD163^{ΔE7} heterozygous and are not resistant to PRRSV.

Resistance to PRRSV in the progeny of this pig (and from semen derived from this pig) is affected by the genetic background of the other parent pig it is bred to:

- If the other parent is CD163^{ΔE7} homozygous (two copies), approximately one half of the progeny will be resistant to PRRSV.
- If the other parent is CD163^{ΔE7} heterozygous (one copy), approximately one in four of the progeny will be resistant to PRRSV.
- If the other parent has no CD163^{ΔE7}, none of the progeny will be resistant to PRRSV.

Product Label 4: Semen from Heterozygous Pigs.

Semen bearing this label will produce offspring that may or may not be resistant to PRRSV.

Resistance to PRRSV in the progeny of this semen is affected by the genetic background of the other parent pig it is bred to:

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- If the other parent is CD163^{ΔE7} heterozygous (one copy), approximately one in four of the progeny will be resistant to PRRSV.
- If the other parent has no CD163^{ΔE7}, none of the progeny will be resistant to PRRSV.

Product Label 5: Ungenotyped Pigs.

Pigs bearing this label may contain one, two or no copies of CD163^{ΔE7} and are of unknown resistance to PRRSV.

2. WARNINGS AND PRECAUTIONS

Product Labels 1 and 3.

Deletion of exon 7 of the CD163 gene is a recessive genetic trait and only confers resistance to PRRSV in homozygous pigs (two copies). **Pigs bearing this label will produce offspring that may or may not be resistant to PRRSV. See 1.3 Uses for additional information.**

Product Labels 2 and 4.

Deletion of exon 7 of the CD163 gene is a recessive genetic trait and only confers resistance to PRRSV in homozygous pigs (two copies). **Semen bearing this label will produce offspring that may or may not be resistant to PRRSV. See 1.3 Uses for additional information.**

Product Label 5.

Deletion of exon 7 of the CD163 gene is a recessive genetic trait and only confers resistance to PRRSV in homozygous pigs (two copies). **Pigs bearing this label may**

contain one, two or no copies of the CD163^{ΔE7} gene and are of unknown resistance to PRRSV. Pigs bearing this label will produce offspring that may or may not be resistant to PRRSV. See 1.3 Uses for additional information.

3. EFFECTIVENESS

In six live animal viral challenge studies, CD163^{ΔE7} homozygous pigs of multiple consecutive generations demonstrated resistance to infection following inoculation with one of seven PRRSV Type II isolates and two PRRSV Type I isolates. In these controlled studies consisting of 101 CD163^{ΔE7} homozygous pigs and 108 age-matched controls (CD163^{ΔE7} heterozygous pigs and pigs without a CD163 alteration), resistance to PRRSV infection was determined by demonstrating undetectable PRRSV RNA in serum samples (via PCR) and undetectable PRRSV antibody seroconversion (by ELISA) 21 days following viral inoculation. All CD163^{ΔE7} homozygous pigs were resistant to infection following inoculation with one of seven PRRSV Type II isolates and two PRRSV Type I isolates listed in **Table 1**, whereas no control pigs demonstrated resistance.

Table 1. Live Animal Viral Challenge Study Results Organized by PRRSV Inoculant

PRRSV Type and Lineage (if applicable)	PRRSV Inoculant and RFLP* (if applicable)	Number of CD163^{ΔE7} Homozygous IGA Animals	Success Rate (%)** in CD163^{ΔE7} Homozygous Animals	Number of Control Animals	Success Rate (%)** in Control Animals
Type II, L8	NVSL97-7895	23	100	26	0
Type II, L1C	UIL21-0712 (RFLP 1-4-4)	21	100	16	0
Type II, L1H	USA/NE/2634-1/2022 (RFLP 1-8-4)	5	100	5	0
Type II, L1A	USA/IN/65239-GA/2014 (RFLP 1-7-4)	5	100	5	0
Type II, L1E	USA/OK/2791-12/2022 (RFLP 1-4-2)	5	100	5	0
Type II, L1D	MLV vaccine (RFLP 1-8-4)	5	100	5	0
Type II, L5	USA/IL/23295-GA-2022 (RFLP 2-5-2)	5	100	5	0
Type I	SD13-15	22	100	27	0
Type I	SD01-08	10	100	14	0

* RFLP = Restriction Fragment Length Polymorphism, a commonly used way of classifying PRRSV strains.

** Success rate is the proportion of animals with undetectable PRRSV RNA in serum samples and undetectable PRRSV antibody seroconversion on study day 21.

In two studies, two out of twenty-six CD163^{ΔE7} homozygous pigs demonstrated resistance following inoculation with a PRRSV Type II – KS06 inoculant (**Table 2**). The clinical relevance of the reported lack of resistance of CD163^{ΔE7} homozygous pigs to the KS06 isolate is undetermined; this isolate and the lineage to which it is classified were not reported in the commercial swine population of the United States at an appreciable level at the time of evaluation (2022-2023).

Table 2. Live Animal Viral Challenge Study Results Following PRRSV Type II - KS06 Inoculation

PRRSV Type and Lineage	PRRSV Inoculant	Number of CD163 ^{ΔE7} IGA Animals	Success Rate (%)* in CD163 ^{ΔE7} Homozygous Animals	Number of Control Animals	Success Rate (%)* in Control Animals
Type II, L6	KS06-72109	26	8	22	0

* Success rate is the proportion of animals with undetectable PRRSV RNA in serum samples and undetectable PRRSV antibody seroconversion on study day 21.

4. TARGET ANIMAL SAFETY

In controlled farm studies, pigs containing two copies (homozygous) or one copy (heterozygous) of CD163^{ΔE7} showed no significant differences from unedited (null) pigs for most phenotypic characteristics observed across the lifecycle of the pigs. Differences observed between groups in the studies were not clinically significant and were consistent with reported ranges for commercial pigs.

Tables 3-4 summarize the results of the observational studies on pigs of Genus PIC elite breeding line L03. Similar data were collected for three additional breeding lines (L02, L65, and L800), demonstrating consistent safety outcomes across all lines studied.

Table 3. Phenotypic Characterization Across Life Stages

Least squares mean (LS Mean) and tests of significance among homozygous (CD163^{ΔE7/ΔE7}), heterozygous edited (CD163^{ΔE7/+}), and unedited (null, CD163^{+/+}) pigs for phenotypic characteristics across the lifecycle of the pigs. N (number of animals observed); BWT (individual piglet birth weight, kg); TEAT (total teat count); WT140 (individual bodweight of pig at 140 days of age, kg); LDG (lifetime daily gain, g per day); BF (ultrasound predicted 10th rib backfat depth, mm); LD (ultrasound predicted 10th rib loin depth, mm); *p < 0.05. **p < 0.01.

Trait	CD163 ^{ΔE7/ΔE7}		CD163 ^{ΔE7/+}		CD163 ^{+/+}	
	N	LS Mean	N	LS Mean	N	LS Mean
Early Life Traits						
BWT	121	1.30	298	1.23	138	1.26
TEAT	121	15.91	298	16.16	138	15.97
Finishing Traits						

WT140	55	93.17	58	88.41	55	88.77
LDG	55	636.96	58	614.38	55	611.83
BF	55	8.98	58	10.17**	55	9.99*
LD	55	63.54	58	64.60	55	65.09

Table 4. Female Reproductive Traits

Least squares mean (LS Mean) and tests of significance among homozygous (CD163^{ΔE7/ΔE7}), heterozygous edited (CD163^{ΔE7/+}), and unedited (null, CD163^{+/+}) pigs for female reproductive traits. N (number of litters); GL (gestation length, days); TNB (total number of piglets born); NBA (number of piglets born alive per litter); NBD (number of piglets born dead per litter); MUM (number of mummified piglets per litter). No differences were significant at the $p < 0.05$ level.

Trait	CD163 ^{ΔE7/ΔE7}		CD163 ^{ΔE7/+}		CD163 ^{+/+}	
	N	LS Mean	N	LS Mean	N	LS Mean
GL	6	116.2	6	116.5	6	116.8
TNB	6	12.7	6	12.7	6	13.3
NBA	6	11.8	6	11.7	6	13.0
NBD	6	0.8	6	1.0	6	0.3
MUM	6	0.2	6	0.0	6	0.0

In these studies, morbidity and mortality rates were calculated for each group at various life stages (pre-weaning, nursery, finishing, and reproductive). No clinically significant differences were observed between groups. Morbidity and mortality rates for all groups were consistent with reported ranges for commercial pigs.

Separately, larger populations of pigs were evaluated for morbidity and mortality. **Table 5** shows summaries of morbidity and mortality data collected from a larger population of pigs that were homozygous CD163^{ΔE7} pigs.

Table 5. Mortality and morbidity rates of homozygous CD163^{ΔE7} pigs under normal Genus PIC production practices.

	Percentage (Mean ± SD)
Mortality*	
Adult breeding herd	0.2% ± 0.2%
Piglets, pre-weaning	5.0% ± 1.3%
Piglets, post-weaning	0.7% ± 0.6%
Morbidity**	
Adult breeding herd	0.8% ± 0.3%
Piglets, post-weaning	12.5% ± 10.8%
Piglets, post-weaning	0.1% ± 0.1%

* Mortality was calculated as the number of mortality events (animals dead or culled for health reasons) in the given sub- population in one week relative to the total number of pigs from the sub-population in the same week, taken from farm-level data across two farms (July to December 2024).

** Morbidity was calculated as the number of morbidity events (animals treated for a morbidity) in the given sub-population in one week relative to the total number of pigs from the sub-population in the same week, taken from farm-level data across two farms (October to December 2024).

5. CONTACT INFORMATION

To report suspected adverse events or for technical assistance, contact Customer Support at 800-325-3398 or www.pic.com.

For additional information about adverse experience reporting, contact FDA at 1.888.FDA.VETS or www.fda.gov/reportanimalae.

6. NAME AND PLACE OF BUSINESS

Produced and distributed by Genus plc and PIC, its wholly owned U.S. subsidiary.

Genus plc
Matrix House
Basing View
Basingstoke, Hampshire
RG21 4DZ
United Kingdom

PIC
100 Bluegrass Commons Blvd, Suite #2200
Hendersonville, TN 37075

Revision Date: October 2025
Approved by FDA under NADA # 141-609

7. PACKAGE LABEL PRINCIPAL DISPLAY PANELS

Label 1: Homozygous Pigs

DELETION OF EXON 7 OF CD163 GENE IN DOMESTIC PIGS

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Deletion of exon 7 of *CD163* gene in domestic pigs.

A heritable intentional genomic alteration (IGA).

1. DESCRIPTION

1.1 Product Identification

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2. WARNINGS AND PRECAUTIONS

Deletion of exon 7 of the *CD163* gene is a recessive genetic trait and only confers resistance to PRRSV in homozygous pigs (two copies). Pigs bearing this label will produce offspring that may or may not be resistant to PRRSV. See 1.3 Uses for additional information.

3. EFFECTIVENESS

In six live animal viral challenge studies, CD163^{ΔE7} homozygous pigs of multiple consecutive generations demonstrated resistance to infection following inoculation with one of seven PRRSV Type II isolates and two PRRSV Type I isolates. In these controlled studies consisting of 101 CD163^{ΔE7} homozygous pigs and 108 age-matched controls (CD163^{ΔE7} heterozygous pigs and pigs without a CD163 alteration), resistance to PRRSV infection was determined by demonstrating undetectable PRRSV RNA in serum samples (via PCR) and undetectable PRRSV antibody seroconversion (by ELISA) 21 days following viral inoculation. All CD163^{ΔE7} homozygous pigs were resistant to infection following inoculation with one of seven PRRSV Type II isolates and two PRRSV Type I isolates listed in Table 1, whereas no control pigs demonstrated resistance.

¹ Chromosome 5, SSC5:63322964-63323378, based upon the *Sscrofa11.1* (GCA_000003025.6) genome assembly.

Label 2: Semen from Homozygous Pigs

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deletion of exon 7 of cd163 gene in domestic pigs not applicable

Product Information

Product Type		Item Code (Source)	NDC:86205-001
Route of Administration	NOT APPLICABLE		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Deletion of exon 7 of CD163 gene in domestic pigs (UNII: G2FPY6HLB3) (Deletion of exon 7 of CD163 gene in domestic pigs - UNII:G2FPY6HLB3)	Deletion of exon 7 of CD163 gene in domestic pigs	1 [arb'U] in 1 [arb'U]

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86205-001-01	1 [arb'U] in 1 NOT APPLICABLE		
2	NDC:86205-001-02	1 [arb'U] in 1 NOT APPLICABLE		
3	NDC:86205-001-03	1 [arb'U] in 1 NOT APPLICABLE		
4	NDC:86205-001-04	1 [arb'U] in 1 NOT APPLICABLE		
5	NDC:86205-001-05	1 [arb'U] in 1 NOT APPLICABLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141609	04/13/2026	

Labeler - Genus plc (835053570)

Registrant - Genus plc (835053570)

Establishment

Name	Address	ID/FEI	Business Operations
ABS Global Inc		035332321	analysis

Establishment

Name	Address	ID/FEI	Business Operations
PIC USA Inc		119785715	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
PIC USA Inc		119190951	api manufacture