

**OSSAPIG-NF-NF1(FS41) MINIATURE SWINE- nf1 hindiii restriction fragment length polymorphism (rflp) positive for nf1-r1947 stop codon in ossabaw breed swine not applicable
Recombinetics, Inc.**

OssaPig-NF-NF1(FS41) Miniature Swine

Identity: Transcription activator-like effector nuclease (TALEN) edit and homology dependent repair in Ossabaw breed porcine fetal fibroblasts to introduce a C>T base substitution at base pair 43,530,892 and insertion of five nucleotides between base pairs 43,308,890 and 43,530,889 of Sus scrofa chromosome 12 (NC_010454.4). The base substitution generates a premature stop codon in the coding sequence for the neurofibromin protein and the five nucleotide insertion generates a HindIII restriction enzyme site used to genotype progeny from gene edited founders.

Claim: Loss of NF1 gene function as a result of this gene edit in the Ossabaw breed of swine produces symptoms consistent with the National Institutes of Health (NIH) criteria for diagnosis of Neurofibromatosis Type I disease in humans.

Limitations: This is a model of progressive disease. Some of the disease symptoms associated with Neurofibromatosis Type I disease in humans take time to develop, and like the human disease, are variable in presentation from animal to animal.

Product Use: Model animals and/or materials derived from these animals are intended for purchase only under license agreement with Recombinetics, Inc., and solely for use in connection with the specific licensed biomedical research.

Conditions of Use: This model animal and any products derived from it are for biomedical research purposes only and not for use in humans. This is an investigational animal. Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.

Caution. This intentionally genetically altered animal and any products derived from it are for biomedical research purposes only and are not for use in humans or as human or animal food.

OssaPig-NF-NF1(FS41) animals are not for resale. No reproduction, distribution, transportation, or other third party transfer is allowed by the purchaser unless specifically agreed to in writing by Recombinetics, Inc.

OssaPig-NF-NF1(FS41) animals, or any materials derived from the OssaPig-NF-NF1(FS41) animals, are not intended to enter the human or animal food supply. OssaPig-NF-NF1(FS41) animals shall be euthanized in accordance with all applicable regulatory or industry standards, and all animal remains must be disposed of by incineration. Purchaser must maintain detailed records accounting for the location of all OssaPig-NF-NF1(FS41) animals, and all materials derived from the OssaPig-NF-NF1(FS41) animals, from the time the animals are delivered to Purchaser through disposition by incineration. Final disposition notification must be made to Recombinetics, Inc.



OssaPig-NF-NF1(FS41) Miniature Swine



Certificate of Animal Health & Identification

| Animal Identification | | Birth Date | |
|-----------------------|--|------------|--|
| Ear Notch ID | | | |
| Ear Tag ID | | Dam ID | |
| Sex | | Boar ID | |

Genotype: NF1 HindIII restriction fragment length polymorphism (RFLP) Positive for NF1^{R1947}

Pedigree Description:

Pre-Shipment Veterinary Health Status Reviewed On: _____ Date

WARNINGS & PRECAUTIONS:

Caution: This intentionally genetically altered animal and any products derived from it are for biomedical research purposes only and are not for use in humans or as human or animal food.

OssaPig-NF-NF1(FS41) animals are not for resale. No reproduction, distribution, transportation, or other third party transfer is allowed by the purchaser unless specifically agreed to in writing by Recombinetics, Inc.

OssaPig-NF-NF1(FS41) animals, or any materials derived from the OssaPig-NF-NF1(FS41) animals, are not intended to enter the human or animal food supply.

OssaPig-NF-NF1(FS41) animals shall be euthanized in accordance with all applicable regulatory or industry standards, and all animal remains must be disposed of by incineration. Purchaser must maintain detailed records accounting for the location of all OssaPig-NF-NF1(FS41) animals, and all materials derived from the OssaPig-NF-NF1(FS41) animals, from the time the animals are delivered to Purchaser through disposition by incineration. Final disposition notification must be made to Recombinetics, Inc.

OssaPig-NF-NF1(FS41) Miniature Swine [Sus scrofa g.(NC_010454.4)43530892C>T + 43530890_43530889insAGCTT in Ossabaw breed miniature swine]

Identity: Transcription activator-like effector nuclease (TALEN) edit and homology dependent repair in Ossabaw breed porcine fetal fibroblasts to introduce a C>T base substitution at base pair 43,530,892 and insertion of five nucleotides between base pairs 43,508,890 and 43,530,889 of Sus scrofa chromosome 12 (NC_010454.4). The base substitution generates a premature stop codon in the coding sequence for the neurofibromin protein and the five nucleotide insertion generates a HindIII restriction enzyme site used to genotype progeny from gene edited founders.

RCI Product Label 002.05 NFs-F5



OssaPig-NF-NF1(FS41) Miniature Swine



Claim: Loss of NF1 gene function as a result of this gene edit in the Ossabaw breed of swine produces symptoms consistent with the National Institutes of Health (NIH) criteria for diagnosis of Neurofibromatosis Type 1 disease in humans.

Limitations: This is a model of progressive disease. Some of the disease symptoms associated with Neurofibromatosis Type 1 disease in humans take time to develop, and like the human disease, are variable in presentation from animal to animal.

Product Use: Model animals and/or materials derived from these animals are intended for purchase only under license agreement with Recombinetics, Inc., and solely for use in connection with the specific licensed biomedical research.

Conditions of Use: This model animal and any products derived from it are for biomedical research purposes only and not for use in humans. This is an investigational animal. Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.

Manufactured, packaged & distributed by Recombinetics, Inc.

For more information, contact:

Customer Support: 612-727-2000

Recombinetics, Inc. www.recombinetics.com

3388 Collins Drive

Eagan, MN 55121 USA

RCI Product Label 002.05 NFs-F5

OSSAPIG-NF-NF1(FS41) MINIATURE SWINE

nf1 hindiii restriction fragment length polymorphism (rflp) positive for nf1-r1947 stop codon in ossabaw breed swine not applicable

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | | Item Code (Source) | NDC:86086-002 |
| Route of Administration | NOT APPLICABLE | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--|------------------------|
| SUS SCROFA G.(NC_010454.4)43530892C>T + 43530890_43530889insAGCTT IN OSSABAW MINIATURE SWINE (UNII: FY9NU6D8JD) (SUS SCROFA G.(NC_010454.4)43530892C>T + 43530890_43530889insAGCTT IN OSSABAW MINIATURE SWINE - UNII:FY9NU6D8JD) | SUS SCROFA G.(NC_010454.4)43530892C>T + 43530890_43530889insAGCTT IN OSSABAW MINIATURE SWINE | 1 [arb'U] in 1 [arb'U] |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------|----------------------|--------------------|
| 1 | NDC:86086-002-01 | 1 [arb'U] in 1 NOT APPLICABLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| | | | |

| | | | |
|--------------------------|--|------------|--|
| unapproved drug other | | 06/03/2019 | |
|--------------------------|--|------------|--|

Labeler - Recombinetics, Inc. (829874523)

Registrant - Recombinetics, Inc. (829874523)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|---------------------|
| Recombinetics, Inc. | | 080987344 | manufacture |

Revised: 7/2024

Recombinetics, Inc.