

OSSAPIG-LD-NASH MINIATURE SWINE- pnpla3 hindiii restriction fragment length polymorphism (rflp) positive for one or two copies of pnpla3-i148m not applicable Recombinetics, Inc.

OssaPig-LD-NASH Miniature Swine

Identity: Transcription activator-like effector nuclease (TALEN) edit and homology dependent repair in Ossabaw breed porcine fetal fibroblasts to introduce a CTC>GAA base substitution at base pairs 5,087,871-5,087,873 that generates a HindIII restriction enzyme site used to genotype progeny from gene edited founders, a C>G base substitution at base pair 5,087,864 that creates a coding sequence change from isoleucine to methionine at amino acid 148 of the swine PNPLA3 protein, and synonymous base substitutions; T>C at base pair 5,087,861 and G>C at base pair 5,087,858 and GAC>CTG at base pairs 5,087,853-5,087,855.

Claim: Change of PNPLA3 gene function as a result of this gene edit in the Ossabaw breed of swine reproduces the human genetic polymorphism associated with diagnosis of non-alcoholic steatohepatitis (NASH).

Limitations: This is a model of progressive disease. Disease symptoms associated with non-alcoholic steatohepatitis 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-LD-NASH 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-LD-NASH animals, or any materials derived from the OssaPig-LD-NASH animals, are not intended to enter the human or animal food supply.

OssaPig-LD-NASH 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-LD-NASH animals, and all materials derived from the OssaPig-LD-NASH animals, from the time the animals are delivered to Purchaser through disposition by incineration. Final disposition notification must be made to Recombinetics, Inc.

 **OssaPig-LD-NASH Miniature Swine** 

Certificate of Animal Health & Identification

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

Genotype: PNPLA3 HindIII restriction fragment length polymorphism (RFLP) Positive for one or two copies of PNPLA3^{i148m}

Pedigree Description:

Pre-Shipment Veterinary Health Status Reviewed On: _____ Date: _____

WARNINGS & PRECAUTIONS:

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OssaPig-LD-NASH Miniature Swine (Sur srofo g./ NC_010447.5) 5087853-5087855GAC-CTG + 5087858G-C + 5087861T-C + 5087864C-G + 5087871-5087873CTC-GAA in Ossabaw breed miniature swine

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Manufactured, packaged & distributed by Recombinetics, Inc.

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Eagan, MN 55121 USA

OSSAPIG-LD-NASH MINIATURE SWINE

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Product Information				
Product Type		RECOMBINANT DEOXYRIBONUCLEIC ACID CONSTRUCT LABEL	Item Code (Source)	NDC:86086-004
Route of Administration		NOT APPLICABLE		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength		Strength
SUS SCROFA G.(NC_010447.5) 5087853-5087855GAC>CTG+5087858G>C+5087861T>C+5087864C>G+5087871-5087873CTC>GAA ALTERATION TO EXON 3 OF PNPLA3 GENE IN OSSABAW BREED MINIATURE SWINE (UNII: L6JJ1CLP4K) (SUS SCROFA G.(NC_010447.5) 5087853-5087855GAC>CTG+5087858G>C+5087861T>C+5087864C>G+5087871-5087873CTC>GAA ALTERATION TO EXON 3 OF PNPLA3 GENE IN OSSABAW BREED MINIATURE SWINE - UNII:L6JJ1CLP4K)		SUS SCROFA G.(NC_010447.5) 5087853-5087855GAC>CTG+5087858G>C+5087861T>C+5087864C>G+5087871-5087873CTC>GAA ALTERATION TO EXON 3 OF PNPLA3 GENE IN OSSABAW BREED MINIATURE SWINE		1 [arb'U] in 1 [arb'U]
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86086-004-01	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			01/06/2020	

Labeler - Recobimbinetics, Inc. (829874523)

Registrant - Recobimbinetics, Inc. (829874523)

Establishment			
Name	Address	ID/FEI	Business Operations
Recobimbinetics, Inc.		080987344	manufacture