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## **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 5,087,851 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.

Certificate of Animal	Health & Identification	Identity: Transcription activator-like effector nuclease (TALEN) edit and homology dependent repair in
Animal Identification   Ear Netch 10   Gar Tag 10   Set Tag 10   Set Tag 10   Set Notice 11   Genotype: PNPCA3 Modil restriction fregment length   PNPCA3****	Birth Date Dan 10   Dan 10 Ber 10   Ber 10 Image: Second	Orazibaia Interfacional factal filosofista to introduce a CFC GAA base substitutio at base pairs 507,271- 500,279 bat generates a Holl Interciciona promo Robusco de promospongene (Mongero e Edited Founders, e C-D, base substitution at base pair 5007,364 have orazina a subsing requestres durage from the substitution of the substitution of the substitution of the substitution of the substitution T-C at leave pair-5007,363 and G-C at leave pair 5007,364 and GA-CFC at leave pairs 5007,263-5007,263 Chaim Change of PIRA/S gene flunction as a securit of this gene e Alti in the Oscibulo breader of humine reproduce the human genetic polymorphism associated with diagnosis of non-alsoholic iteratolegatios (MSH).
Pedigree Description:		UniNations: This is a model of progressive disease. Disease symptom associated with new alsoholic stratochapathic disease in humana take time to develop, and like the human disease, are variable in presentation from animal to animal.
Pre-Shipment Veterinary Health Status Reviewed On WARNINGS & PRECAUTIONS:	Date	Product Use: Model unimals 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.
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	RC Product_abeloog.co NASH	RCI Product Label on L so NASS

OSSAPIG-LD-NASH MINIATURE SWINE pnpla3 hindiii restriction fragment length polymorphism (rflp) positive for one or two copies of pnpla3-i148m not applicable								
<b>Product Information</b>								
Product Type			Item Code (Source)			NDC:86086-004		
Route of Administration No		NOT APPLICABLE						
Active Ingredient/Active Moiety								
Ingredient Name			Basis of Strength				Strength	
OSSABAW BREED MINIATURE SWINE (UNII: L6JJ1CLP4K) (SUS SCROFA			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 SWNE					
Packaging								
# Item Code	Pack	age Description	Marketi	ng Start Date		Marketing End D	ate	
<b>1</b> NDC:86086-004-01	1 [arb'U] in 1 NC	OT APPLICABLE						
Marketing Information								
Marketing Category	Applicat	ion Number or Monograph	Citation	Marketing Start I	Date	Marketing En	nd Date	
unapproved drug other				01/06/2020				

Labeler - Recobimbinetics, Inc. (829874523)

Registrant - Recombinetics, Inc. (829874523)							
Establishment							
Name	Address	ID/FEI	Business Operations				
Recombinetics, Inc.		080987344	manufacture				

Revised: 7/2024

Recobimbinetics, Inc.