YORKAPIG-HF-RBM20 SWINE- rbm20 bglii restriction fragment length polymorphism (rflp) positive for one or two copies of rbm20-r636s not applicable
Recombinetics, Inc.

YorkaPig-HF-RBM20 Swine

Identity: Transcription activator-like effector nuclease (TALEN) edit and homology dependent repair in Yorkshire breed porcine fetal fibroblasts to introduce a C>A base substitution at base pair 121,244,982 that generates a BglII restriction enzyme site used to genotype progeny from gene edited founders, a CG>TC base substitution at base pairs 121,244,988-121,244,989 that creates a coding sequence change from arginine to serine at amino acid 638 of the swine RBM20 protein, and a synonymous AG>TC base substitution at base pairs 121,244,991-121,244,992.

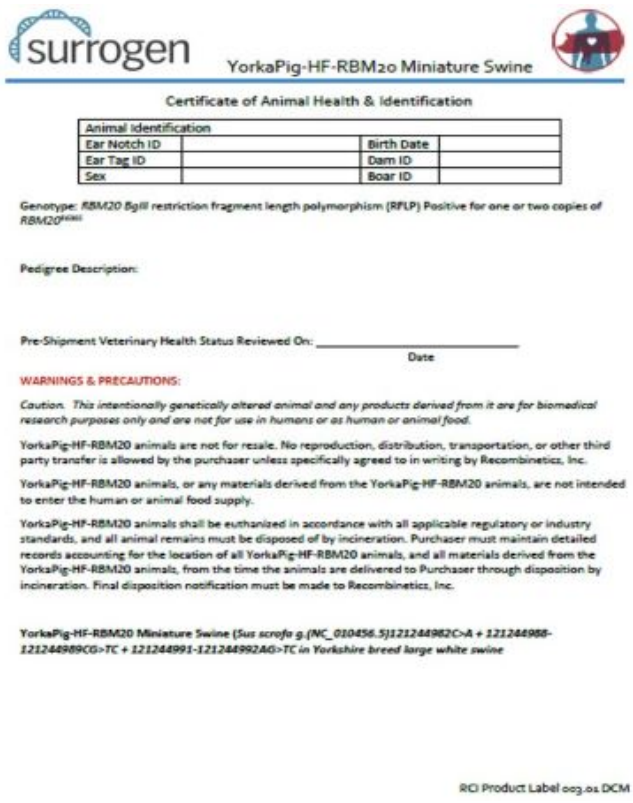
Claim: Loss of RBM20 gene function as a result of this gene edit in the Yorkshire breed of swine produces symptoms consistent with the criteria for diagnosis of familial dilated cardiomyopathy disease in humans.

Limitations: This is a model of progressive disease. Some of the disease symptoms associated with familial dilated cardiomyopathy 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.

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.
YorkaPig-HF-RBM20 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.
YorkaPig-HF-RBM20 animals, or any materials derived from the YorkaPig-HF-RBM20 animals, are not intended
to enter the human or animal food supply.
YorkaPig-HF-RBM20 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 YorkaPig-HF-RBM20 animals, and all materials derived from the
YorkaPig-HF-RBM20 animals, from the time the animals are delivered to Purchaser through disposition by
incineration. Final disposition notification must be made to Recombinetics, Inc.



surrogen YorkaPig-HF-RBM20 Miniature Swine

Certificate of Animal Health & Identification

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

Genotype: *RBM20 BglII* restriction fragment length polymorphism (RFLP) Positive for one or two copies of *RBM20*^{R636S}

Pedigree Description:

Pre-Shipment Veterinary Health Status Reviewed On: _____
Date

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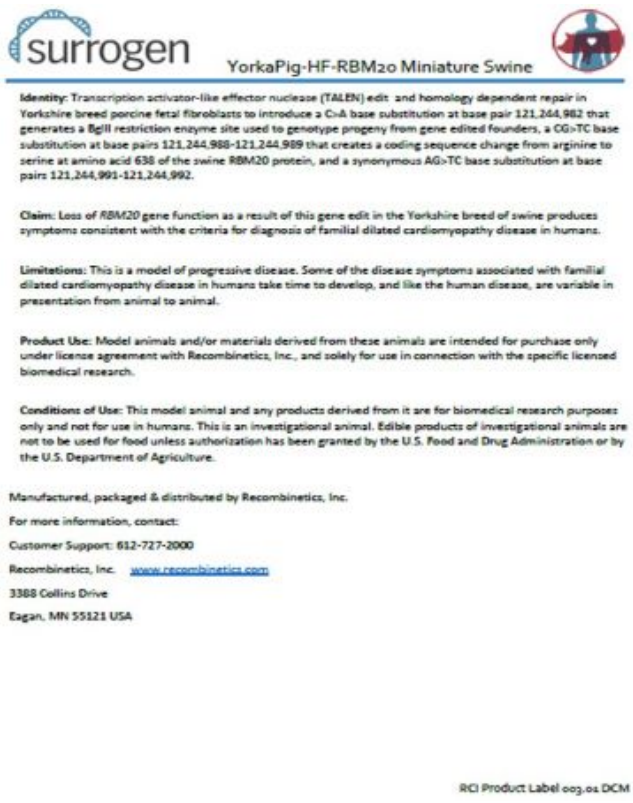
YorkaPig-HF-RBM20 Miniature Swine (*Sus scrofa g.(NC_010456.5)121244982C>A + 121244988-121244989CG>TC + 121244991-121244992AG>TC in Yorkshire breed large white swine*)

RCI Product Label 003.01 DCM



surrogen YorkaPig-HF-RBM20 Miniature Swine

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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 003.01 DCM

YORKAPIG-HF-RBM20 SWINE

rbm20 bglii restriction fragment length polymorphism (rflp) positive for one or two copies of rbm20-r636s not applicable

Product Information

Product Type	RECOMBINANT DEOXYRIBONUCLEIC ACID CONSTRUCT LABEL	**Item Code (Source)**	NDC:86086-003
Route of Administration	NOT APPLICABLE		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SUS SCROFA G.(NC_010456.5)121244982C>A + 121244988-121244989CG>TC + 121244991-121244992AG>TC ALTERATION TO EXON 9 OF RBM20 GENE IN YORKSHIRE BREED LARGE WHITE SWINE (UNII: O4OJ2CP48E) (SUS SCROFA G.(NC_010456.5)121244982C>A + 121244988-121244989CG>TC + 121244991-121244992AG>TC ALTERATION TO EXON 9 OF RBM20 GENE IN YORKSHIRE BREED LARGE WHITE SWINE - UNII:O4OJ2CP48E)	SUS SCROFA G.(NC_010456.5)121244982C>A + 121244988-121244989CG>TC + 121244991-121244992AG>TC ALTERATION TO EXON 9 OF RBM20 GENE IN YORKSHIRE BREED LARGE WHITE SWINE	1 [arb'U] in 1 [arb'U]

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86086-003-01	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 - Recombinetics, Inc. (829874523)

Registrant - Recombinetics, Inc. (829874523)

Establishment

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

Revised: 10/2020 Recombinetics, Inc.