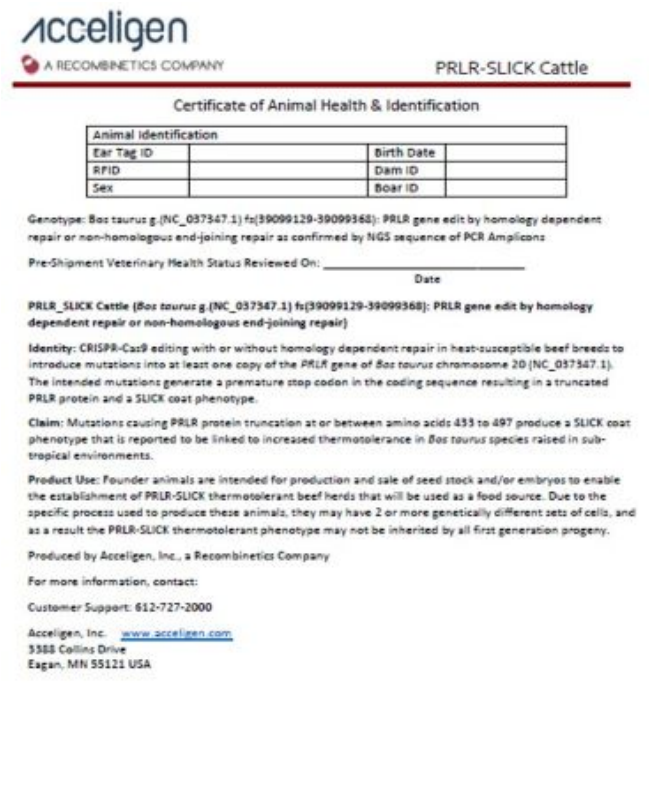
PRLR-SLICK CATTLE- prlr gene edit in at least one copy producing protein truncation at or between amino acids 433 to 497 not applicable
Recombinetics, Inc.

PRLR-SLICK Cattle

Identity: CRISPR-Cas9 editing with or without homology dependent repair in heat-susceptible beef breeds to introduce mutations into at least one copy of the PRLR gene of Bos taurus chromosome 20 (NC_037347.1). The intended mutations generate a premature stop codon in the coding sequence resulting in a truncated PRLR protein and a SLICK coat phenotype.

Claim: Mutations causing PRLR protein truncation at or between amino acids 433 to 497 produce a SLICK coat phenotype that is reported to be linked to increased thermotolerance in Bos taurus species raised in sub-tropical environments.

Product Use: Founder animals are intended for production and sale of seed stock and/or embryos to enable the establishment of PRLR-SLICK thermotolerant beef herds that will be used as a food source. Due to the specific process used to produce these animals, they may have 2 or more genetically different sets of cells, and as a result the PRLR-SLICK thermotolerant phenotype may not be inherited by all first generation progeny.



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Certificate of Animal Health & Identification

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

Genotype: Bos taurus g.(NC_037347.1) fs(39099129-39099368): PRLR gene edit by homology dependent repair or non-homologous end-joining repair as confirmed by NGS sequence of PCR Amplicons

Pre-Shipment Veterinary Health Status Reviewed On: _____
Date

PRLR_SLICK Cattle (*Bos taurus* g.(NC_037347.1) fs(39099129-39099368): PRLR gene edit by homology dependent repair or non-homologous end-joining repair)

Identity: CRISPR-Cas9 editing with or without homology dependent repair in heat-susceptible beef breeds to introduce mutations into at least one copy of the *PRLR* gene of *Bos taurus* chromosome 20 (NC_037347.1). The intended mutations generate a premature stop codon in the coding sequence resulting in a truncated PRLR protein and a SLICK coat phenotype.

Claim: Mutations causing PRLR protein truncation at or between amino acids 433 to 497 produce a SLICK coat phenotype that is reported to be linked to increased thermotolerance in *Bos taurus* species raised in sub-tropical environments.

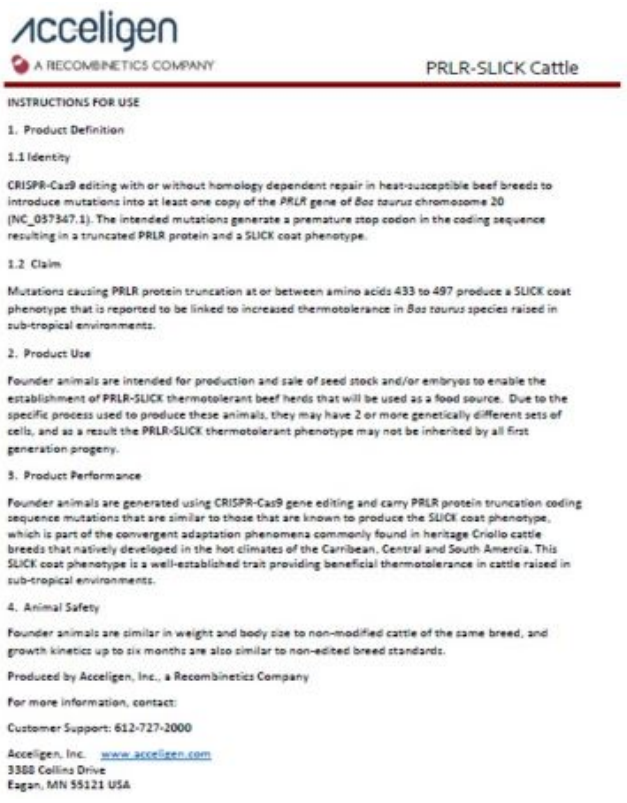
Product Use: Founder animals are intended for production and sale of seed stock and/or embryos to enable the establishment of PRLR-SLICK thermotolerant beef herds that will be used as a food source. Due to the specific process used to produce these animals, they may have 2 or more genetically different sets of cells, and as a result the PRLR-SLICK thermotolerant phenotype may not be inherited by all first generation progeny.

Produced by Acceligen, Inc., a Recombinetics Company

For more information, contact:

Customer Support: 612-727-2000

Acceligen, Inc. www.acceligen.com
3388 Collins Drive
Eagan, MN 55121 USA



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A RECOMBINETICS COMPANY PRLR-SLICK Cattle

INSTRUCTIONS FOR USE

1. Product Definition

1.1 Identity

CRISPR-Cas9 editing with or without homology dependent repair in heat-susceptible beef breeds to introduce mutations into at least one copy of the *PRLR* gene of *Bos taurus* chromosome 20 (NC_037347.1). The intended mutations generate a premature stop codon in the coding sequence resulting in a truncated PRLR protein and a SLICK coat phenotype.

1.2 Claim

Mutations causing PRLR protein truncation at or between amino acids 433 to 497 produce a SLICK coat phenotype that is reported to be linked to increased thermotolerance in *Bos taurus* species raised in sub-tropical environments.

2. Product Use

Founder animals are intended for production and sale of seed stock and/or embryos to enable the establishment of PRLR-SLICK thermotolerant beef herds that will be used as a food source. Due to the specific process used to produce these animals, they may have 2 or more genetically different sets of cells, and as a result the PRLR-SLICK thermotolerant phenotype may not be inherited by all first generation progeny.

3. Product Performance

Founder animals are generated using CRISPR-Cas9 gene editing and carry PRLR protein truncation coding sequence mutations that are similar to those that are known to produce the SLICK coat phenotype, which is part of the convergent adaptation phenomena commonly found in heritage Criollo cattle breeds that natively developed in the hot climates of the Carribean, Central and South Amercia. This SLICK coat phenotype is a well-established trait providing beneficial thermotolerance in cattle raised in sub-tropical environments.

4. Animal Safety

Founder animals are similar in weight and body size to non-modified cattle of the same breed, and growth kinetics up to six months are also similar to non-edited breed standards.

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PRLR-SLICK CATTLE

prlr gene edit in at least one copy producing protein truncation at or between amino acids 433 to 497 not applicable

Product Information			
Product Type		**Item Code (Source)**	NDC:86086-006

Route of Administration	NOT APPLICABLE

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SLICK ALTERATION DISRUPTING BOS TAURUS G.(NC_037347.1) FS(39099129-39099368) IN EXON 9 OF PRLR GENE IN BOS TAURUS (UNII: B8K52Z76YK) (SLICK ALTERATION DISRUPTING BOS TAURUS G.(NC_037347.1) FS(39099129-39099368) IN EXON 9 OF PRLR GENE IN BOS TAURUS - UNII:B8K52Z76YK)	SLICK ALTERATION DISRUPTING BOS TAURUS G.(NC_037347.1) FS(39099129-39099368) IN EXON 9 OF PRLR GENE IN BOS TAURUS	1 [arb'U] in 1 [arb'U]

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86086-006-01	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		03/01/2022	

Labeler - Recombinetics, Inc. (829874523)

Registrant - Acceligen, Inc. (108237218)

Establishment

Name	Address	ID/FEI	Business Operations
Recombinetics, Inc.		829874523	manufacture

Revised: 7/2024 Recombinetics, Inc.