Summary of Studies Supporting USDA Product Licensure

Establishment Name	Bimeda Biologicals, Inc.
USDA Vet Biologics Establishment Number	290
Product Code	1181.22
True Name	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Huvepharma, Inc Stimulator 5 - No distributor specified
Date of Compilation Summary	December 01, 2020

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus - Type 1a (BVDV 1a)
Study Purpose	Pivotal Efficacy against BVDV1a
Product Administration	Single Dose administered subcutaneously
Study Animals	30 mixed breed beef calves, 4 to 5 months of age randomly divided into 20 vaccinates and 10 controls
Challenge Description	BVDV Type 1a (field isolate) administered 21 days following vaccination
Interval observed after challenge	Observed daily for 14 days for rectal temperature and clinical signs (Nasal Lesions) daily and a nasal swab and a blood sample were collected from each animal daily. Nasal swabs were evaluated for BVDV by cell culture cytopathic effect (CPE) and PCR. Blood samples were utilized for determining antibody titer and buffy coat virus isolation analysis.
Results	Nineteen out of 20 (95%) vaccinates responded with BVDV type 1a serum neutralization (SN) antibody titer greater than or equal to 8 and all 10 (100%) control animals were sero-negative (SN titer <2) to BVDV type 1 and 2. BVDV type 1a was isolated in from 100% (10 of 10) in the nasal swabs and 70% (7 of 10) from the buffy coat samples on at least 1 day following challenge of the control animals. In the vaccinate group, the BVDV type 1a was isolated in nasal swab and buffy coat samples on at least 1 day following challenge from 25% (5 of 20) and 10% (2 of 20) of the animals, respectively.
USDA Approval Date	February 17, 2012

Virus-neutralizing Antibody Titer

		Pre-Vaccination Titers			Day of Challenge	Day 14 Post Challenge
Calf	grp	BVDV 1a	BVDV 1b	BVDV 2	BVDV 1a	BVDV 1a
2	V	<2	<2	<2	32	>256
5	V	<2	<2	<2	32	>256
6	V	<2	<2	<2	64	>256
8	V	<2	<2	<2	16	>256
10	V	<2	<2	<2	8	>256
11	V	<2	<2	<2	16	>256
13	V	<2	<2	<2	32	>256
15	V	<2	<2	<2	8	>256
18	V	<2	<2	<2	32	>256
20	V	<2	<2	<2	<2	>256
23	V	<2	<2	<2	16	>256
27	V	<2	<2	<2	32	>256
29	V	<2	<2	<2	8	>256
30	V	<2	<2	<2	16	>256
31	V	<2	<2	<2	32	>256
32	V	<2	<2	<2	8	>256
33	V	<2	<2	<2	8	>256
41	V	<2	<2	<2	8	128
49	V	<2	<2	<2	16	>256
82	V	<2	<2	<2	16	>256
1	C	<2	<2	<2	<2	8
4	C	<2	<2	<2	<2	64
9	C	<2	<2	<2	<2	32
19	C	<2	<2	<2	<2	>256
21	C	<2	<2	<2	<2	32
25	C	<2	<2	<2	<2	128
26	C	<2	<2	<2	<2	64
47	C	<2	<2	<2	<2	16
86	C	<2	<2	<2	<2	128
93	C	<2	<2	<2	<2	128

V = Vaccinate, C = Control

BVDV la Isolation from Nasal Swabs

Swab		Day															CPE	PCR
calf	grp	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Summ	Summ
2	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
5	V	-/-	-/-	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+	+
6	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
8	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
10	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
11	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
13	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
15	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
18	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
20	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
23	V	-/-	-/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	+	+
27	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
29	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
30	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
31	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+	-/-	-	+
32	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	+	-
33	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
41	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
49	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
82	V	-/-	-/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	+
1	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/+	+	+
4	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	-/-	-/-	-/-	-/-	-/-	+	+
9	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/+	+/+	+/+	-/-	-/-	-/-	-/-	+	+
19	C	-/-	+/+	+/+	+/+	+/+	+/+	-/-	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+	+
21	C	-/-	-/+	-/-	-/-	-/-	+/+	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	+	+
25	C	-/-	-/-	-/-	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+	+	+
26	C	-/-	+/+	-/-	-/-	-/-	+/+	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	+	+
47	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/-	+/+	-/-	-/-	-/-	-/+	-/-	+	+
86	C	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	+	+
93	C	-/-	+/+	-/-	-/-	+/+	-/-	+/+	+/+	-/-	+/+	-/-	-/-	-/-	-/-	-/-	+	+

V = Vaccinate, C = Control

-/- = Neg CPE / Neg PCR, -/+ = Neg CPE / Pos PCR, +/+ = Pos CPE / Pos PCR

BVDV Ia Isolation from Buffy Coats

Buffy Coat		Day															CPE	PCR
calf	grp	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Summ	Summ
2	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
5	V	-/-	-/-	-/-	-/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	+
6	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
8	V	-/-	-/-	-/-	-/-	-/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+	-	+
10	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-I-	-	-
11	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-I-	-	-
13	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-I-	-	-
15	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
18	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	- /-	-	-
20	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	- /-	-	-
23	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	- /-	-	-
27	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	- /-	-	-
29	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	- /-	-	-
30	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	- /-	-	-
31	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	- /-	-	-
32	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	- /-	-	-
33	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	- /-	-	-
41	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	- /-	-	-
49	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	.7-	-	-
82	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	- /-	-	-
1	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	+	+
4	C	-/-	-/-	-/-	-/+	-/-	-/+	-/-	-/-	-/-	+/+	-/-	-/-	-/-	+/+	-/-	+	+
9	C	-/-	-/-	-/-	-/-	-/+	-/-	+/+	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+	+
19	C	-/-	-/-	-/-	-/+	-/-	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+	+
21	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
25	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
26	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	+	+
47	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	-
86	C	-/-	-/-	-/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-	+
93	C	-/-	-/-	-/-	-/+	-/-	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/+	-/-	-/-	+	+

V = Vaccinate, C = Control

-/- = Neg CPE / Neg PCR, -/+ = Neg CPE / Pos PCR, +/+ = Pos CPE / Pos PCR

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus - Type 2 (BVD 2)
Study Purpose	Pivotal Efficacy against BVD 2
Product Administration	Single Dose administered subcutaneously
Study Animals	30 mixed breed beef calves, 4 to 5 months of age randomly divided into 20 vaccinates and 10 controls
Challenge Description	BVDV Type 2a strain 1373 administered intranasally 21 days following vaccination
Interval observed after challenge	Observed daily for 17 days for rectal temperature and clinical signs daily and a nasal swab and a blood sample were collected from each animal daily
Results	Twenty out of 20 (100%) vaccinates responded with BVDV type 2 SN antibody titer greater than or equal to 8 and all 10 (100%) control animals were sero-negative (SN titer <2) to BVDV type 2. BVDV type 2 was isolated in nasal swab and buffy coat samples on at least 1 day following challenge from 100% (10 of 10) of the control animals. In the vaccinate group, the BVDV type 2 was isolated in nasal swab and buffy coat samples on at least 1 day following challenge from 60% (12 of 20) and 30% (6 of 20) of the animals, respectively. Ten of 10 (100%) animals in the control group, and 9 of 20 (45%) animals in the vaccinate group, had leukopenia (at least 40% decrease in white cells from the baseline) for at least a day following challenge. Ten of 10 control animals had pyrexia (at least 2 °F above the baseline temperature) and 1 of 20 (5%) animals in the vaccinate group had pyrexia on at least 1 day following challenge. Ten of 10 calves in the control group had clinical signs (respiration, coughing, nasal discharge, nasal lesions, ocular lesions, oral lesions, attitude and/or diarrhea) with 70% (7 of 10) mortality rate. Some of the animals in the vaccinate group had mild clinical disease (nasal discharges and lesions, ocular lesions and/or oral lesions) following challenge. None of the calves in the vaccinate group died (0% mortality) during the challenge phase due to BVDV type 2 challenge. The results are compliant with 9 CFR 113.311.
USDA Approval Date	February 17, 2012

Virus-neutralizing Antibody Titer

		Prevaccination			Day of Challenge	Day 14 Post-Challenge
Calf	Grp	BVDV2	BVDV1a	BVDV1b	BVDV2	BVDV2
2521	V	<2	<2	<2	16	>256
2543	V	<2	<2	<2	32	>256
2560	V	<2	<2	<2	8	>256
2561	V	<2	<2	<2	32	>256
2562	V	<2	<2	<2	16	128
2566	V	<2	<2	<2	16	>256
2569	V	<2	<2	<2	32	>256
2571	V	<2	<2	<2	32	>256
2574	V	<2	<2	<2	16	>256
2576	V	<2	<2	<2	32	>256
2588	V	<2	<2	<2	64	>256
2590	V	<2	<2	<2	16	>256
2591	V	<2	<2	<2	16	>256
2592	V	<2	<2	<2	32	>256
2599	V	<2	<2	<2	16	>256
2601	V	<2	<2	<2	16	>256
2602	V	<2	<2	<2	32	>256
2603	V	<2	<2	<2	16	>256
2615	V	<2	<2	<2	8	>256
2616	V	<2	<2	<2	32	>256
2523	C	<2	<2	<2	<2	Dead
2544	C	<2	<2	<2	<2	>256
2565	C	<2	<2	<2	<2	Dead
2570	C	<2	<2	<2	<2	Dead
2589	C	<2	<2	<2	<2	Dead
2598	C	<2	<2	<2	<2	16
2600	C	<2	<2	<2	<2	>256
2606	C	<2	<2	<2	<2	32
2609	C	<2	<2	<2	<2	Dead
2614	C	<2	<2	<2	<2	Dead

BVDV2 Isolation from Nasal Swabs

swabs		-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Calf	grp																				
2521	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2543	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2560	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2561	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+	-/-	-/+	-/+	-/-
2562	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+	-/-	-/-	-/-	-/-	-/-	-/-	-/+	-/-	-/-	-/-	-/-
2566	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+	-/-	-/-	-/-	-/-
2569	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2571	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+	-/-	-/-	-/-	-/-
2574	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+	-/-	-/-	-/-	-/-
2576	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2588	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2590	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+
2591	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/-	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2592	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2599	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2601	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2602	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2603	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2615	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2616	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2523	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	Dead	Dead	Dead	Dead	Dead	Dead
2544	C	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	+/+
2565	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	Dead	Dead	Dead	Dead	Dead	Dead
2570	C	-/-	-/-	-/-	-/-	+	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	Dead	Dead
2589	C	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	Dead	Dead	Dead	Dead	Dead	Dead
2598	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-
2600	C	-/-	-/-	-/-	-/-	+	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2606	C	-/-	-/-	-/-	-/-	+	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+
2609	C	-/-	-/-	-/-	-/-	+	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	Dead	Dead	Dead	Dead
2614	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	Dead	Dead	Dead	Dead

Day 0 is Day of Challenge

- / - = Neg CPE / Neg PCR, - / + = Neg CPE / Pos PCR, + /+ = Pos CPE / Pos PCR

BVDV2 Isolation from Buffy Coats

Calf #	grp	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
2521	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2543	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2560	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2561	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2562	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2566	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+
2569	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+
2571	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2574	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2576	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2588	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2590	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2591	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2592	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2599	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2601	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2602	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2603	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2615	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2616	V	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2523	C	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	Dead	Dead	Dead	Dead	Dead	Dead
2544	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-	-/-
2565	C	-/-	-/-	-/-	-/-	-/-	-/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	Dead	Dead	Dead	Dead	Dead	Dead
2570	C	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	Dead	Dead
2589	C	-/-	-/-	-/-	-/-	+/+	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	Dead	Dead	Dead	Dead	Dead	Dead
2598	C	-/-	-/-	-/-	-/+	-/-	-/+	+/+	+/+	+/+	+/+	-/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+
2600	C	-/-	-/-	-/-	-/+	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/+	-/-	-/-	-/-	-/-
2606	C	-/-	-/-	-/-	-/+	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+
2609	C	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	Dead	Dead	Dead	Dead
2614	C	-/-	-/-	-/-	-/+	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	Dead	Dead	Dead	Dead

Day 0 is Day of Challenge / - = Neg CPE / Neg PCR, - / + = Neg CPE / Pos PCR, + /+ = Pos CPE / Pos PCR

Leukocyte Counts

		-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Calf	grp																				
2521	V	7.8	7.2	7.7	7.6	8.2	7.7	7.3	6.7	6.3	6.6	7.8	6.8	6.1	5.9	7.1	6.9	7.2	6.7	7.7	6.4
2543	V	7	7.7	7	7.5	7.5	7.1	6	8.2	8.9	8.6	8.5	8.1	7.9	7.7	8.6	7.2	7.3	8.3	7.5	8.5
2560	V	8.8	7.7	8.7	9.2	9.4	7.8	9.4	7.9	6.9	6.1	6.8	5.2	6.6	5.7	6.7	7.6	5.5	6.9	5.9	7
2561	V	6.2	7.7	9	9.3	10.2	9.1	9.1	8.9	7.7	5.4	4.5	6.1	6.7	7.3	8.1	7.2	8.3	9	8.6	9.5
2562	V	10	11.3	10	9.1	9.5	9	8.5	8.9	6.5	6	6.9	8.4	7.4	5.8	7.9	7.2	8.6	9.1	9.9	9.8
2566	V	11.1	11.6	9.1	10	7	6.2	7.5	8.2	8.8	8.8	5.6	8.3	8.3	10.9	11.5	10.4	10.6	9.9	9.5	10.7
2569	V	7.2	7.5	6.7	10.2	8.6	8	8.1	6.4	6.6	4.9	6.6	5.7	5.5	5.3	8.4	8	8.9	8.5	9	8.4
2571	V	9.3	7.3	10.4	10	10.9	8.4	7.6	7.9	8.1	7.9	7.6	7.5	5.5	7	5.1	7	7.4	7.7	8.1	7.3
2574	V	9.4	6.8	10	10.4	11.2	11.8	9.7	9.9	7.8	5.4	5.2	6.8	8.2	7.3	8	8.6	9	8.2	7.3	9.2
2576	V	10.8	10	10.2	11.4	10.3	10.5	10.3	9.6	10.4	9.5	9.7	10.3	10.7	9.9	11	10.9	10.6	12	7.3	8.3
2588	V	7.6	7.7	6.8	6.8	6.7	7.5	8.9	9.1	11.8	14.5	10.2	8.1	5.6	5.9	7.1	6.7	7.7	8.4	8.2	11.4
2590	V	8.8	10.1	10	4.3	8.6	8.2	8.3	7.2	8	8.1	8.9	7.7	7.7	6.6	9.4	8.4	6.9	8.1	8.5	8.4
2591	V	4.4	9	10	10.8	9.4	7.9	7.2	8.5	8.7	8.8	8.4	7.9	5.4	2.6	5	5.6	6.1	7.4	6.9	5.7
2592	V	7.6	9	9.1	11.3	10.4	9.9	8.2	8.4	8.4	8.8	7.9	8.5	7.4	5.9	6.7	8.9	7.4	7.7	7.8	7.5
2599	V	12	12.5	11.2	10.3	11	10.9	9.7	9	7.1	7.3	7.6	7.9	7.2	6.2	7.9	7.5	6.6	7	5.8	8.1
2601	V	12.9	8.8	8.9	9.7	8.5	7.7	7.9	7.2	6.3	6.9	6.6	8.1	6.6	5.7	5.9	6.7	7.7	4.8	4.8	6.3
2602	V	7	8.4	9.8	11.7	12	13.9	14.2	12.2	13.8	11.9	11.2	12.7	10.6	10.8	10.6	10.4	9.7	9.7	10	11.3
2603	V	7.5	7.9	7.7	7.9	6.8	7.5	7.2	9	7.2	6.6	7.5	7.8	7.4	8.7	8	6.3	6.5	7.6	7.6	8.2
2615	V	7.5	8.2	11.8	10.6	9.7	8.5	6.2	7.8	8.5	11.3	12.5	14	12.5	11.7	12	11.2	11.5	11.3	10.9	9.8
2616	V	11.6	11.5	11.4	13.6	12.1	8	8.3	8.6	9.4	9.2	10.6	12.5	12.9	12.4	11	6.5	7.6	7.8	6.8	7.6
2523	C	11.9	13.1	13.8	12.9	11.5	7.6	6.1	6.1	5	5.3	4.9	4.2	6.1	7.5	Dead	Dead	Dead	Dead	Dead	Dead
2544	C	9.4	9.9	10.8	10.6	9.1	6	6.2	5.2	5.7	4.2	6.7	5.7	5.2	6	3.9	2.7	4.3	5.1	5.2	7
2565	C	7.6	7.4	7.6	9.8	9.7	5.8	4	3.6	3.6	3.7	2.5	1.7	2	2.3	Dead	Dead	Dead	Dead	Dead	Dead
2570	C	11.6	13.6	13.9	12.9	7.9	5.7	6.8	7.4	6.4	7	4.3	2.2	2.5	3	4.2	3.3	3.5	4.5	Dead	Dead
2589	C	8.7	9.2	8	7.4	5.8	3.7	3.7	5	5.3	3.5	3.5	3.8	4.5	2.6	Dead	Dead	Dead	Dead	Dead	Dead
2598	C	9	10.2	10.6	12.1	9.7	4.6	4	3.7	4.9	7.2	4.7	3.2	2.6	1.1	1.3	1.4	1.9	1.5	1.8	2.6
2600	C	13.5	10.1	13.9	12.4	11.6	7.2	7.1	6.3	5.8	5.4	4.1	4.6	5.4	3.9	4.5	5.4	5.7	7	8.6	8.8
2606	C	8.5	4.7	6.2	7.1	5.8	7.2	5.1	4	3.1	2.6	1.7	1.5	1.4	1.7	2.3	2.2	2.1	3	3.4	5.5
2609	C	12.4	11.4	11.5	11.7	10.5	6.9	5	4.7	4.7	5.2	4.3	3	1.4	2	1.9	1.8	Dead	Dead	Dead	Dead
2614	C	11.4	11.1	11.4	10.2	10.4	5.2	6	4.4	4.2	4.2	3.2	2.6	1.7	0.4	0.9	1.9	Dead	Dead	Dead	Dead

Day 0 is Day of Challenge

Rectal Temperatures

Calf	Group	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
2521	V	102.1	102.3	102	101.8	101.7	101.9	102.1	101.4	102.1	101.8	101.4	101.7	101.7	101.8	101.7	101.1	101.8	100.4	100.4	102.1
2543	V	101.2	101	100.6	101.6	101.9	101.7	101.6	101.5	101.1	100.9	101.1	101.1	100.6	101.1	101.3	101.3	101.4	100.8	101.3	101.3
2560	V	100.3	102.1	101.7	101	101.9	101.5	101.4	101.4	101.2	101.3	101.1	100.8	101	101.4	101.4	101.1	101.1	100.6	100.5	101.2
2561	V	101.6	101.5	101.5	100.6	101.5	102.1	101.7	101.8	101.5	101.4	101.7	101.5	101.6	101.4	100.6	100.7	101.2	101.2	100.2	101.6
2562	V	102.0	101.5	101.4	102.1	102.6	102.2	102.1	102.4	102.1	101.2	102	101.8	101.7	101.3	101.4	101.2	101	100.7	100.8	101.4
2566	V	101.6	101.3	100.3	101.4	103.7	101.7	101.4	101.1	100.9	100.7	100.8	100.6	100.7	101.4	101.4	100.5	101.3	100.7	101.2	101.5
2569	V	102.1	100.4	100.8	100.6	101.7	101.4	101.7	101.5	102.1	101.6	100.2	101.1	100.4	100.6	100.9	100.6	101.3	100.5	101.1	101.6
2571	V	102.2	101.9	101.6	101	102.1	101.8	101.4	101.7	101.2	100.8	101.3	101.3	101.2	100.5	101.2	101	101.3	101.1	100.7	101.5
2574	V	101.5	102.1	100.6	100.3	101.2	101.6	101.9	101.4	101.2	102.1	101.8	101.2	100.6	100.8	101.2	101.2	101.3	101.1	100.3	101.1
2576	V	102.4	101.5	102.3	100.3	101.7	102.4	101.1	101.2	101.3	100.8	101.4	101.1	101.5	101.3	101.6	101.4	100.8	101.6	100	102
2588	V	101.3	100.9	101.1	101.7	101.9	102.2	102	102.9	102	101.8	101.4	102.4	101.4	101.3	101.3	100.7	100.9	101.2	101	101.8
2590	V	101.7	100.2	100.4	101.1	101.9	101.9	101.6	102.1	101.4	101.6	101.3	101.2	101.4	101.7	101.5	101.3	101.6	101.2	101.7	101.2
2591	V	101.4	101.9	101.1	101.4	101.3	101.4	102	101.8	101.4	101.3	102	101.4	101.7	102	101.6	101.3	101.4	100.5	101.3	102.5
2592	V	102.8	102.5	101.4	102.2	102.7	102.1	102.5	102.3	101.9	101.3	101.9	101.8	102.1	102.2	101.8	NA	102.2	101.6	101.8	103.1
2599	V	102.2	102.4	102	101.6	102.5	102.3	101.9	102	100.5	101.3	101.6	101.3	100.7	101.3	100.7	100.9	101.7	100.5	100.3	101.9
2601	V	101.6	100.6	101.9	101.2	101.5	101.4	101.7	101.5	100.6	100.3	101.5	101.1	101.1	101	100.7	100.7	101.1	101.7	99.4	101.3
2602	V	100.6	100.7	101.9	100.7	102.1	101.6	102	102	101.3	101.3	101.8	101.8	101.4	101.1	101.5	101.2	101.4	100.2	100.2	101.7
2603	V	101.9	101.4	101.5	101.6	102.1	102	101.7	101.1	101.2	101.3	100.7	101.8	101.7	100.5	101.5	101	101.5	100.2	100.8	101
2615	V	102.3	100.8	101.7	100.6	100.7	101.8	102.3	101.2	100.2	100.2	100.2	101.3	101.1	101.6	100.7	101	100.6	100.5	100.3	101.2
2616	V	102.5	100.9	102.3	102	102.2	101.6	102.8	102	101.8	101.5	102.1	101.9	102.1	101.9	101.8	103.7	102.1	101.8	101.2	101.7
2523	C	101.9	101	102.5	100.5	103.1	102.4	102.8	102.8	102.4	105.1	105	103.7	104.1	102.3	Dead	Dead	Dead	Dead	Dead	Dead
2544	C	101.5	101.6	101.9	101.1	102.3	101.9	102.4	102.1	101.7	104.4	104.6	105	103.1	101.6	101.6	101	101.4	100.9	101.2	101.4
2565	C	100.8	101.1	102.4	100.6	101.4	103.4	102.5	102.8	103.3	104.3	106.4	106.2	105.8	101.8	Dead	Dead	Dead	Dead	Dead	Dead
2570	C	102.3	101.5	101.3	101.4	102.9	103.1	102.5	102.7	102.7	105.1	105.2	104.5	105.9	104.6	104.5	104.7	103.5	102.5	Dead	Dead
2589	C	102.5	100.2	101.2	100.3	101.5	101.7	102.7	102.4	103.7	104.2	104.6	104.9	104.5	100.4	Dead	Dead	Dead	Dead	Dead	Dead
2598	C	102.3	100.6	101.9	101.9	102.6	102.4	102.8	102.9	102.2	104.3	105.2	104.6	106	105.1	103.1	102	101.7	102.1	102.4	102.7
2600	C	101.5	101.2	101.3	102.3	102.6	103.5	103	103.1	104.7	105.1	105.8	105.3	104.6	104.2	103.1	102.2	101.4	102.2	101.3	102.1
2606	C	102.5	101.6	101.9	100.5	103.6	103.7	104.1	104.2	104.9	104.7	105.1	105.4	105.6	105.6	105.4	105.7	104.8	104.6	104.5	104.4
2609	C	101.7	101	101.8	100.2	102.6	102	102.9	102.6	102.5	103.3	105.3	105.7	106	106.1	105.3	104.5	Dead	Dead	Dead	Dead
2614	C	101.4	100.6	101.9	101.6	102.3	102.8	101.4	102.9	103.5	104.4	106	105.5	106.2	107.1	105.7	104.7	Dead	Dead	Dead	Dead

Day 0 is Day of Challenge

Post Challenge Observations - Respiratory

Respiratory		-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Calf	Group																				
2521	V	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
2543	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2560	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2561	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2562	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2566	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2569	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2571	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2574	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2576	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2588	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2590	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2591	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2592	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2599	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2601	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2602	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2603	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2615	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2616	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2523	C	0	0	0	0	0	0	0	0	0	0	0	1	1	1	Dead	Dead	Dead	Dead	Dead	Dead
2544	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2565	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Dead	Dead	Dead	Dead	Dead	Dead
2570	C	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	2	0	Dead	Dead
2589	C	0	0	0	0	0	0	0	0	0	0	0	0	1	2	Dead	Dead	Dead	Dead	Dead	Dead
2598	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
2600	C	0	0	0	0	0	0	0	0	0	0	0	1	2	0	0	1	0	0	0	0
2606	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	2
2609	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	Dead	Dead	Dead	Dead
2614	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	Dead	Dead	Dead	Dead

Day 0 is Day of Challenge

0 = Normal, 1 = Short/rapid, 2 = Mild dyspnea, 3 = Severe dyspnea

Post Challenge Observations – Coughing

Coughing		-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Calf	Group																				
2521	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2543	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2560	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2561	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2562	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2566	V	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2569	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2571	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2574	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2576	V	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
2588	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2590	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2591	V	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
2592	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2599	V	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
2601	V	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-
2602	V	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
2603	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2615	V	-	+	-	+	+	+	+	-	+	+	-	-	+	-	+	-	+	-	-	+
2616	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-
2523	C	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Dead	Dead	Dead	Dead	Dead	Dead
2544	C	-	-	-	-	-	-	-	-	-	+	+	+	-	+	-	+	-	-	+	-
2565	C	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Dead	Dead	Dead	Dead	Dead	Dead
2570	C	-	-	-	-	-	-	-	-	-	-	-	+	+	-	+	+	-	-	Dead	Dead
2589	C	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Dead	Dead	Dead	Dead	Dead	Dead
2598	C	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-
2600	C	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	-	-	-	-
2606	C	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	-	+
2609	C	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	Dead	Dead	Dead	Dead
2614	C	-	-	-	-	-	-	-	-	-	-	-	+	+	+	-	+	Dead	Dead	Dead	Dead

+ = Coughing, - = No Coughing

Day 0 is Day of Challenge

Post Challenge Observations – Nasal Discharge

Nasal Discharge		-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Calf	Group																				
2521	V	0	1	0	0	1	1	0	0	0	0	1	1	0	0	1	0	0	0	1	0
2543	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
2560	V	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
2561	V	0	1	0	0	1	0	1	0	0	1	2	1	0	0	0	0	0	0	0	0
2562	V	2	0	0	2	1	0	1	0	2	2	0	0	0	0	0	1	0	0	0	0
2566	V	0	0	0	1	1	1	0	0	0	0	2	1	0	1	1	0	0	0	0	0
2569	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2571	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2574	V	0	0	0	0	0	2	0	0	0	0	1	1	0	0	0	0	0	0	0	0
2576	V	0	0	1	0	0	0	0	0	0	0	1	0	1	0	0	1	0	0	1	1
2588	V	0	2	0	0	2	1	0	2	1	2	1	0	2	1	1	0	0	0	0	1
2590	V	0	0	0	0	0	0	0	0	1	1	0	2	0	0	1	0	0	1	0	1
2591	V	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
2592	V	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0
2599	V	0	1	0	0	0	0	0	0	0	1	1	0	0	1	0	0	0	0	0	1
2601	V	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0
2602	V	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
2603	V	0	0	0	0	1	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0
2615	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2616	V	0	0	0	0	0	0	0	0	0	1	0	0	0	2	0	3	2	2	1	0
2523	C	0	0	0	0	0	0	1	0	1	2	2	1	2	2	Dead	Dead	Dead	Dead	Dead	Dead
2544	C	0	0	0	0	0	0	2	0	0	2	2	2	3	3	3	3	0	0	0	0
2565	C	0	0	0	0	0	0	0	0	0	0	0	2	2	1	Dead	Dead	Dead	Dead	Dead	Dead
2570	C	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	1	0	Dead	Dead
2589	C	1	0	0	0	0	0	0	0	0	0	0	0	2	3	Dead	Dead	Dead	Dead	Dead	Dead
2598	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	0	0
2600	C	0	0	0	0	0	0	0	0	0	0	1	2	3	3	3	2	0	2	0	0
2606	C	0	0	0	0	0	0	0	0	0	0	0	1	0	2	3	2	1	2	1	1
2609	C	0	0	0	0	0	0	0	1	0	2	0	0	2	2	2	2	Dead	Dead	Dead	Dead
2614	C	0	0	0	0	0	0	0	0	0	0	0	0	2	2	2	2	Dead	Dead	Dead	Dead

Day 0 is Day of Challenge

0 = No/slight, 1 = Mucous, 2 = Mucopurulent, 3 = Purulent, 1 = Blood-tinged

Post Challenge Observations – Oral Lesions

Oral Lesions		-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Calf	Group																				
2521	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2543	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2560	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2561	V	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
2562	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2566	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
2569	V	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
2571	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2574	V	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
2576	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2588	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
2590	V	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
2591	V	0	0	0	0	0	0	0	0	2	1	1	0	0	0	0	0	0	0	0	0
2592	V	0	0	0	0	0	0	0	0	2	2	0	0	1	2	0	0	1	0	0	0
2599	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2601	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2602	V	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	1	0
2608	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2615	V	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0
2616	V	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
2523	C	0	0	0	0	0	0	0	0	0	1	2	0	2	2	Dead	Dead	Dead	Dead	Dead	Dead
2544	C	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	2	1	0	0	0
2565	C	0	0	0	0	0	0	0	0	0	1	0	2	1	0	Dead	Dead	Dead	Dead	Dead	Dead
2570	C	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	Dead	Dead
2589	C	0	0	0	0	0	0	0	0	0	1	0	1	2	2	Dead	Dead	Dead	Dead	Dead	Dead
2598	C	0	0	0	0	0	0	0	0	0	0	1	1	0	0	2	0	2	2	0	0
2600	C	0	0	0	0	0	0	0	0	0	1	0	1	0	2	2	2	0	0	0	0
2606	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2609	C	0	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0	Dead	Dead	Dead	Dead
2614	C	0	0	0	0	0	0	0	0	1	0	1	0	0	0	2	2	Dead	Dead	Dead	Dead

Day 0 is Day of Challenge

0 = Normal, 1 = 1-3 Lesions, 2 = >3 Lesions

Post Challenge Observations – Ocular Lesions

Ocular Lesions		-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Calf	Group																				
2521	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2545	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2560	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2561	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2562	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2566	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2569	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2571	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2574	V	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2576	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2588	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2590	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2591	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2592	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2599	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2601	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2602	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2603	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2615	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2636	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2533	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Dead	Dead	Dead	Dead	Dead	Dead
2544	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2565	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Dead	Dead	Dead	Dead	Dead	Dead
2570	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	Dead	Dead
2589	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Dead	Dead	Dead	Dead	Dead	Dead
2598	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
2600	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2606	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2609	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Dead	Dead	Dead	Dead
2614	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Dead	Dead	Dead	Dead

Day 0 is Day of Challenge

0 = Normal/slightly watery, 1 = Moderate watery, 2 = Conjunctivitis, 1 = Purulent

Post Challenge Observations – Attitude

Attitude		-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Calf	Group																				
2521	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2543	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2560	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2561	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2562	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2566	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2569	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2571	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2574	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2576	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2588	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2590	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2591	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2592	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2599	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2601	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2602	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2603	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2615	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2616	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
2523	C	0	0	0	0	0	0	0	0	0	1	0	1	2	3	50	Dead	Dead	Dead	Dead	Dead
2544	C	0	0	0	0	0	0	0	0	0	0	0	1	2	2	1	2	1	0	0	0
2565	C	0	0	0	0	0	0	0	0	0	0	0	1	2	2	50	Dead	Dead	Dead	Dead	Dead
2570	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	3	3	50	Dead	Dead
2589	C	0	0	0	0	0	0	0	0	0	0	0	0	1	3	50	Dead	Dead	Dead	Dead	Dead
2598	C	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	3	2	1	1	1
2600	C	0	0	0	0	0	0	0	0	0	0	0	2	2	2	1	2	1	1	0	0
2606	C	0	0	0	0	0	0	0	0	0	0	0	1	1	1	2	2	2	2	2	2
2609	C	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	3	50	Dead	Dead	Dead
2614	C	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	3	50	Dead	Dead	Dead

0 = Normal, 1 = Mild depression, 2 = Moderate depression, 3 = Severe depression, 50 = Comatose / Dead

Day 0 is Day of Challenge

Post Challenge Observations – Gastrointestinal

GI		-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Calf	Group																				
2521	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2543	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2560	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2561	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2562	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2566	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2569	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2571	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2574	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2576	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2588	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2590	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2591	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2592	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2599	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2601	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2602	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2603	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2615	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2616	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2523	C	0	0	0	0	0	0	0	0	0	0	0	0	0	3	Dead	Dead	Dead	Dead	Dead	Dead
2544	C	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0
2565	C	0	0	0	0	0	0	0	0	0	0	0	0	0	3	Dead	Dead	Dead	Dead	Dead	Dead
2570	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	3	3	0	Dead	Dead
2589	C	0	0	0	0	0	0	0	0	0	0	0	0	3	0	Dead	Dead	Dead	Dead	Dead	Dead
2598	C	0	0	0	0	0	0	0	0	0	0	0	0	0	3	3	0	0	0	0	1
2600	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
2606	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2609	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	3	Dead	Dead	Dead	Dead
2614	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	3	Dead	Dead	Dead	Dead

Day 0 is Day of Challenge

0 = Normal, 1 = Pasty, 2 = Loose, 3 = Watery, 4 = Bloody

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Bovine Rhinotracheitis (IBR)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against respiratory disease</td></tr>
<tr><td>Product Administration</td><td>Single dose administered subcutaneously</td></tr>
<tr><td>Study Animals</td><td>33 mixed-breed beef calves, 4 to 5 months of age, randomly divided into 22 vaccinates and 11 controls</td></tr>
<tr><td>Challenge Description</td><td>IBR virus administered 28 days following vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed daily for 14 days. Vaccinates and controls were monitored daily for nasal lesions) daily, and a nasal swab was collected from each animal daily as well. Swabs were evaluated for IBR virus by cell culture and polymerase chain reaction (PCR).</td></tr>
<tr><td>Results</td><td>Presence of nasal lesions:
11/11 Controls
4/22 Vaccinates

Severity of nasal lesions:
Controls All 11 calves had with lesions affecting more than 50% of the visible nasal mucus membrane
Vaccinates The 4 affected calves had nasal lesions that did not exceed 10% of the visible nasal mucus membrane

Duration of nasal lesions
Controls 10/11 controls had unresolved nasal lesions at the end of the observation period
Vaccinates No lesions evident by the end of the study.

Duration of nasal shedding of virus, in days:

<table>
<tr><th></th><th>Min</th><th>1st Quartile</th><th>Median</th><th>3rd Quartile</th><th>Max</th></tr>
<tr><td>Control (CPE*)</td><td>9</td><td>10</td><td>11</td><td>12</td><td>13</td></tr>
<tr><td>Vaccinate (CPE)</td><td>6</td><td>8</td><td>9</td><td>10</td><td>14</td></tr>
<tr><td>Control (PCR)</td><td>10</td><td>10</td><td>11</td><td>12</td><td>13</td></tr>
<tr><td>Vaccinate (PCR)</td><td>6</td><td>8</td><td>9</td><td>10</td><td>14</td></tr>
</table>
*CPE= cytopathic effect in cell culture

See Next Page for Raw Data.</td></tr>
<tr><td>USDA Approval Date</td><td>September 25, 2012</td></tr>
</table>

Bovine Nasal Lesion Scores

		Observation Day (Challenge administered on Day 0)																
Calf ID	Group	Day -2	Day -1	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
2	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	Vaccinate	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0
11	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	Vaccinate	0	0	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0
15	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
25	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
27	Vaccinate	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0
28	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
31	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
101	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
103	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
108	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
111	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
112	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
115	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
117	Vaccinate	0	0	0	0	0	0	1	1	1	1	1	0	0	0	0	0	0
1	Control	0	0	0	0	0	0	1	4	4	4	4	4	4	4	4	4	4
4	Control	0	0	0	0	0	1	2	4	4	4	4	4	4	4	4	4	3
9	Control	0	0	0	0	0	0	1	1	3	4	3	3	2	1	0	0	0
17	Control	0	0	0	0	0	1	2	3	4	4	4	4	4	4	4	2	1
21	Control	0	0	0	0	0	1	1	3	4	4	4	4	4	4	3	3	3
22	Control	0	0	0	0	0	0	1	3	4	4	4	4	3	3	3	2	2
23	Control	0	0	0	0	0	0	1	3	4	4	4	4	4	4	4	3	3
30	Control	0	0	0	0	0	1	1	2	3	4	4	4	4	4	4	3	2
116	Control	0	0	0	0	0	1	3	4	4	4	4	4	3	3	3	3	2
118	Control	0	0	0	0	0	0	1	3	4	4	4	4	4	3	2	2	2
124	Control	0	0	0	0	0	0	1	2	3	4	4	4	4	4	3	2	1

Score	Description
0	Absence of definitive lesions of IBR virus disease.
1	The presence of lesions characteristic of IBR disease not to exceed 10% of the visible nasal mucous membrane.
2	The presence of lesions characteristic of IBR disease affecting 11-25% of the visible nasal mucous membrane.
3	The presence of lesions characteristic of IBR disease affecting 26-50% of the visible nasal mucous membrane.
4	The presence of lesions characteristic of IBR disease affecting greater than 50% of the visible nasal mucous membrane.

Isolation of IBR virus from nasal swabs

		4/11/2012	4/12/2012	4/13/2012	4/14/2012	4/15/2012	4/16/2012	4/17/2012	4/18/2012	4/19/2012	4/20/2012	4/21/2012	4/22/2012	4/23/2012	4/24/2012	4/25/2012
Calf	Group	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
2	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	+/+	-/-	-/-
7	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-	-/-	+/+
11	Vaccinate	-/-	+/+	+/+	-/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-
12	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-	+/+	-/-
13	Vaccinate	-/-	+/+	+/+	-/-	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-
14	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-	-/-
15	Vaccinate	-/-	+/+	+/+	+/+	-/-	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-
16	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-
19	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-
20	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-	-/-
25	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-
27	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/+	-/-	-/-	-/-	-/-	-/-
28	Vaccinate	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-	-/-
29	Vaccinate	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-	-/-
31	Vaccinate	-/-	+/+	+/+	+/+	-/-	+/+	-/-	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-
101	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-
103	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-	-/-
108	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	-/+	-/-	+/+	-/-	-/-	-/-	-/-	-/-	-/-
111	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-
112	Vaccinate	-/-	+/+	-/-	-/-	-/-	+/+	+/+	+/+	-/-	+/+	+/+	-/+	-/-	-/-	-/-
115	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	+/+	-/-	+/+	-/-	+/+	-/+	-/-	-/-	-/-
117	Vaccinate	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-	-/-	-/-
1	Control	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-
4	Control	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-
9	Control	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-
17	Control	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-
21	Control	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-
22	Control	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-
23	Control	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-
30	Control	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-
116	Control	-/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-	-/-
118	Control	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	-/-	-/-	-/-
124	Control	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	-/-	+/+	+/+	-/-

- / - = Neg CPE/Neg PCR, - / + = Neg CPE / Pos PCR, + / + = Pos CPE / Pos PCR

Study Type	Efficacy
Pertaining to	Parainfluenza Virus Type 3.
Study Purpose	Pivotal Efficacy against PI3
Product Administration	Single Dose administered subcutaneously
Study Animals	30 mixed breed beef calves, 4 to 5 months of age randomly divided into 20 vaccinates and 10 controls
Challenge Description	PI3 administered 28 days following vaccination
Interval observed after challenge	Observed daily for 14 days clinical signs and a nasal swab was collected from each animal daily as well.
Results	An animal was considered affected if virus was detected from cultured nasal swabs. Results are provided in the tables below. There were no clinical signs observed in either group.
USDA Approval Date	January 24, 2013

Viral Isolation determined by Cytopathic Event (CPE)

Calf	Grp	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Total Days
1	v	-	+	+	+	-	+	+	-	-	-	-	-	-	-	-	5
2	v	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-	5
4	v	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-	6
5	v	-	-	+	+	-	+	-	+	-	-	-	-	-	-	-	4
6	v	-	+	+	-	-	+	-	-	-	-	-	-	-	-	-	3
10	v	-	+	+	+	+	-	+	-	-	-	-	-	-	-	-	5
11	v	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-	2
13	v	-	+	+	+	-	-	-	+	-	-	-	-	-	-	-	4
15	v	-	-	+	+	-	+	+	+	-	-	-	-	-	-	-	5
16	v	-	+	+	+	-	-	+	-	-	-	-	-	-	-	-	4
17	v	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	2
18	v	-	-	+	-	+	+	-	-	-	-	-	-	-	-	-	3
19	v	-	+	+	-	-	-	-	+	-	-	-	-	-	-	-	3
20	v	-	+	+	-	-	+	+	-	-	-	-	-	-	-	-	4
21	v	-	+	+	+	-	-	+	-	-	-	-	-	-	-	-	4
22	v	-	+	+	-	-	+	-	-	-	-	-	-	-	-	-	3
25	v	-	+	+	+	-	-	-	-	+	-	-	-	-	-	-	4
26	v	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	2
27	v	-	+	+	+	-	-	-	-	-	+	-	-	-	-	-	4
30	v	-	+	+	+	+	-	+	-	-	-	-	-	-	-	-	5
3	c	-	-	+	+	+	+	+	-	+	+	+	-	-	-	-	8
7	c	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-	7
8	c	-	+	+	+	+	+	+	+	+	+	+	-	-	-	-	10
9	c	-	-	+	+	+	+	+	+	+	+	-	-	-	-	-	8
12	c	-	+	+	+	+	+	+	+	+	+	+	+	-	+	+	13
14	c	-	+	+	-	+	+	+	+	+	+	-	-	-	-	-	8
23	c	-	-	+	-	+	+	+	+	+	+	+	-	-	-	-	8
24	c	-	+	+	+	+	+	+	+	+	+	-	+	-	-	-	10
28	c	-	-	+	+	+	+	+	+	+	+	-	-	-	+	+	10
29	c	-	-	+	+	+	+	+	+	+	+	-	+	+	-	-	10

v = vaccinate
c = control

+ = positive
- = negative

Viral Isolation determine by Polymerase Chain Reaction (PCR)

calf	grp	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Total Days
1	v	-	+	+	+	-	+	+	-	-	-	-	-	-	-	-	5
2	v	-	+	+	+	+	+	-	-	-	-	-	-	-	-	-	5
4	v	-	+	+	+	+	+	+	-	-	-	-	-	-	-	-	6
5	v	-	-	+	+	-	+	-	+	-	-	-	-	-	-	-	4
6	v	-	+	+	-	-	+	-	-	-	-	-	-	-	-	-	3
10	v	-	+	+	+	+	-	+	-	-	+	-	-	-	-	-	6
11	v	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-	2
13	v	-	+	+	+	-	-	-	+	-	-	-	-	+	-	-	5
15	v	-	-	+	+	-	+	+	+	-	-	-	-	-	-	-	5
16	v	-	+	+	+	-	-	+	-	-	-	-	-	-	-	-	4
17	v	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	2
18	v	-	+	+	-	+	+	-	-	-	-	-	-	-	-	-	4
19	v	-	+	+	-	-	-	-	+	-	-	-	-	-	-	-	3
20	v	-	+	+	-	-	+	+	-	-	-	-	-	-	-	-	4
21	v	-	+	+	+	-	-	+	-	-	-	-	-	-	-	-	4
22	v	-	+	+	-	-	+	-	-	-	-	-	-	-	-	-	3
25	v	-	+	+	+	-	-	-	-	+	-	-	-	+	-	-	5
26	v	-	+	-	+	-	-	-	-	-	+	-	-	-	-	-	3
27	v	-	+	+	+	-	-	-	-	-	+	-	-	-	-	-	4
30	v	-	+	+	+	+	-	+	-	-	+	-	-	-	-	-	6
3	c	-	-	+	+	+	+	+	-	+	+	+	-	-	-	-	8
7	c	-	+	+	+	+	+	+	+	-	-	-	-	-	-	-	7
8	c	-	+	+	+	+	+	+	+	+	+	+	-	-	-	-	10
9	c	-	-	+	+	+	+	+	+	+	+	-	-	-	-	-	8
12	c	-	+	+	+	+	+	+	+	+	+	+	+	-	+	+	13
14	c	-	+	+	-	+	+	+	+	+	+	-	-	-	-	-	8
23	c	-	-	+	-	+	+	+	+	+	+	+	-	-	-	-	8
24	c	-	+	+	+	+	+	+	+	+	+	+	+	-	-	-	11
28	c	-	-	+	+	+	+	+	+	+	+	+	-	-	+	+	11
29	c	-	-	+	+	+	+	+	+	+	+	-	+	+	-	-	10

v = vaccinate
c = control

+ = positive
- = negative

Study Type	Efficacy
Pertaining to	Bovine Respiratory Syncytial Virus (BRSV)
Study Purpose	Pivotal Efficacy against BRSV
Product Administration	Single dose administered subcutaneously
Study Animals	33 mixed breed beef calves, 4 to 5 months of age randomly divided in 22 vaccinates and 11 controls
Challenge Description	BRSV administered intranasally 22 days following vaccination
Interval observed after challenge	Observed daily for 14 days clinical signs of discharge and a nasal swab were collected from each animal daily as well.
Results	An animal was considered affected if nasal shedding for BRSV occurred for ≥1 day with clear nasal discharge. **Summary of Results for affected animals:** Controls 11/11 Vaccinates 3/22 Raw data is presented in the tables below.
USDA Approval Date	August 19, 2011

BRSV Isolation

Calf	Group	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Freq
1	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
3	V	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	1
8	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
12	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
15	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
17	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
19	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
24	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
26	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
32	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
33	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
35	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
38	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
42	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
44	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
48	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
50	V	-	-	-	-	+	-	+	-	-	-	+	-	-	-	-	3
51	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
54	V	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	1
58	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
61	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
64	V	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
4	C	-	-	-	-	+	+	+	+	+	+	+	+	+	-	-	9
10	C	-	-	-	-	+	+	+	+	+	+	-	-	-	-	-	6
13	C	-	-	-	-	-	+	+	+	+	+	+	-	-	-	-	6
16	C	-	-	-	-	+	+	+	+	+	+	+	-	-	+	-	8
21	C	-	-	-	-	-	-	+	+	+	+	-	-	-	-	-	4
31	C	-	-	-	-	+	+	+	+	+	+	+	-	-	-	-	7
34	C	-	-	-	-	-	+	+	-	+	+	-	-	-	-	-	4
45	C	-	-	-	-	-	-	+	+	+	+	-	-	-	-	-	4
52	C	-	-	+	-	-	+	-	+	+	+	+	+	-	-	-	7
56	C	-	-	-	-	+	+	-	+	+	+	-	-	-	-	-	5
62	C	-	-	-	-	.	+	+	+	+	+	+	-	-	-	-	6

Clinical Signs

Calf	Group	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
1	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
3	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
8	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
12	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
15	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
17	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
19	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
24	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
26	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
32	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
33	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
35	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
38	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
42	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
44	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
48	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
50	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
51	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
54	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
58	V	N	N	N	N	N	NI	N	N	N	N	N	N	N	N	N
61	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
64	V	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4	C	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
10	C	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
13	C	N	N	N	N	N	N	CND	N	N	N	N	N	N	N	N
16	C	N	N	CND	CND	N	N	N	CND	CND	N	N	N	N	N	N
21	C	N	N	N	N	N	N	N	CND	N	N	N	N	N	N	N
31	C	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
34	C	N	N	N	N	N	N	CND	CND	N	N	N	N	N	N	N
45	C	N	N	N	N	N	N	CND	N	N	N	N	N	N	N	N
52	C	N	N	N	N	N	N	CND	N	N	N	N	N	N	N	N
56	C	N	N	CND	CND	N	NI	CND	N	. N	N	N	N	N	N	N
62	C	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N = Normal CND = Clear Nasal Discharge

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety under typical field conditions</td></tr>
<tr><td>Product Administration</td><td>1 dose subcutaneously</td></tr>
<tr><td>Study Animals</td><td>776 head of cattle ranging in age of 3 to 9 months with 70% at or below the minimum age of 5 months.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed daily for 21 days after vaccination</td></tr>
<tr><td>Results</td><td>No local or systemic reactions or adverse events related to vaccination were observed.

Summary of Field Safety Test

<table>
<tr><th>Group</th><th>No. Head</th><th>Treated*</th><th>Deaths</th></tr>
<tr><td>1</td><td>86</td><td>0</td><td>0</td></tr>
<tr><td>2</td><td>61</td><td>0</td><td>0</td></tr>
<tr><td>3**</td><td>83</td><td>1</td><td>2</td></tr>
<tr><td>4</td><td>257</td><td>8</td><td>0</td></tr>
<tr><td>5</td><td>135</td><td>0</td><td>0</td></tr>
<tr><td>6***</td><td>154</td><td>1</td><td>0</td></tr>
<tr><td>Total</td><td>776</td><td>10</td><td>2</td></tr>
</table>
*Calves treated for pneumonia; unrelated to vaccine as affirmed by licensee.
** Two calves died of polioencephalomalacia during the study; unrelated to vaccine as affirmed by licensee.
***An umbilical hernia was observed in one calf, 2 days post vaccination; this calf was removed from the other calves for the remainder of the study, and never exhibited any adverse events related to vaccine.</td></tr>
<tr><td>USDA Approval Date</td><td>May 7, 2013</td></tr>
</table>