



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Bimeda Biologicals, Inc.
USDA Vet Biologics Establishment Number	290
Product Code	45B9.21
True Name	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus, Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Respivax 5 + PH-M - Huvepharma, Inc - Allied Biologics Company, Inc.
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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bovine Viral Diarrhea Virus - Type 1a (BVDV 1a)
<b>Study Purpose</b>	Pivotal Efficacy against BVDV1a
<b>Product Administration</b>	Single Dose administered subcutaneously
<b>Study Animals</b>	30 mixed breed beef calves, 4 to 5 months of age randomly divided into 20 vaccinates and 10 controls
<b>Challenge Description</b>	BVDV Type 1a (field isolate) administered 21 days following vaccination
<b>Interval observed after challenge</b>	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.
<b>Results</b>	<p>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 &lt;2) to BVDV type 1 and 2.</p> <p>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.</p>
<b>USDA Approval Date</b>	February 17, 2012

### Virus-neutralizing Antibody Titer

Calf	grp	Pre-Vaccination Titers			Day of Challenge	Day 14 Post Challenge
		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 Ia Isolation from Nasal Swabs

Swab calf	grp	Day														CPE Summ	PCR Summ
		0	1	2	3	4	5	6	7	8	9	10	11	12	13		
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	grp	Day														CPE Summ	PCR Summ	
		0	1	2	3	4	5	6	7	8	9	10	11	12	13			14
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

<b>Study Type</b>	Comparative Serology
<b>Pertaining to</b>	Bovine Virus Diarrhea Virus Type 1a
<b>Study Purpose</b>	Comparative serology for Bovine Virus Diarrhea Virus Type 1a to show that combining fractions with satisfactory efficacy studies does not reduce the immune response. Refer to the summaries of the original efficacy studies under Product Code 1181.21 and in the Product Compilation Summary for this Product Code.
<b>Product Administration</b>	Subcutaneous injection twice, 21 days apart
<b>Study Animals</b>	Weaning age calves
<b>Challenge Description</b>	Serological response prior to vaccination and 35 days after first vaccination
<b>Interval observed after challenge</b>	
<b>Results</b>	<p>Serological response to vaccination after 35 days showed a Geometric Mean Titer (GMT) for the Product Group, Reference Group, and Control group.</p> <p>Please see following pages for treatment groups, vaccination schedule and individual animal antibody titers.</p>
<b>USDA Approval Date</b>	May 16, 2017

Allocation BVDV1a naïve calves to Treatment Group

Group	Number of Calves (n)	Product	Animal ID
A	20	Reference Product Establishment 290, Product Code 1181.22 Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3- Respiratory Syncytial Virus Vaccine, Modified Live Virus	2,5,8,12,15,19,23,24,31,32,43,55,57,59,61, 64,67,68,72,74
B	21	Product	3,6,7,9,10,11,14,17,21,22,25,26,27,28,34,38, 41,42,53,56,76
D	6	Sterile H2O Diluent	1,4,16,20,54,60

**Individual Antibody titers to BVD Type 1a**

Tag #	Group	Day 0	Day 35
2	A	<2	64
5	A	<2	256
8	A	<2	512
12	A	<2	128
15	A	<2	2048
19	A	<2	256
23	A	<2	2048
24	A	<2	512
31	A	<2	1024
32	A	<2	1024
43	A	<2	1024
55	A	<2	1024
57	A	<2	512
59	A	<2	256
61	A	<2	1024
64	A	<2	1024
67	A	<2	2048
68	A	<2	1024
72	A	<2	2048
74	A	<2	1024
3	B	<2	1024
6	B	<2	2048
7	B	<2	128
9	B	<2	1024
10	B	<2	2048
11	B	<2	512
14	B	<2	2048
17	B	<2	1024
21	B	<2	256
22	B	<2	512
25	B	<2	1024
26	B	<2	1024
27	B	<2	1024
28	B	<2	256
34	B	<2	2048
38	B	<2	2048
41	B	<2	1024
42	B	<2	2048
53	B	<2	1024
56	B	<2	2048
76	B	<2	2048
1	D	<2	<2
4	D	<2	<2
16	D	<2	<2
20	D	<2	<2
54	D	<2	<2
60	D	<2	<2



<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bovine Viral Diarrhea Virus - Type 2 (BVD 2)
<b>Study Purpose</b>	Pivotal Efficacy against BVD 2
<b>Product Administration</b>	Single Dose administered subcutaneously
<b>Study Animals</b>	30 mixed breed beef calves, 4 to 5 months of age randomly divided into 20 vaccinates and 10 controls
<b>Challenge Description</b>	BVDV Type 2a strain 1373 administered intranasally 21 days following vaccination
<b>Interval observed after challenge</b>	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
<b>Results</b>	<p>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 &lt;2) to BVDV type 2.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The results are compliant with 9 CFR 113.311.</p>
<b>USDA Approval Date</b>	February 17, 2012

### Virus-neutralizing Antibody Titer

Calf	Grp	Prevaccination			Day of Challenge	Day 14 Post-Challenge
		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

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	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

BVDV2 Isolation from Nasal Swabs

2523	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	Dead	Dead	Dead	Dead	Dead	Dead
2544	C	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+
2565	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	Dead	Dead	Dead	Dead	Dead	Dead
2570	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+
2589	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	Dead	Dead	Dead	Dead	Dead	Dead
2598	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+
2600	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2606	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+
2609	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+
2614	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+

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	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+
2544	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
2565	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+
2570	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+
2589	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+
2598	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+
2600	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+
2606	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+
2609	C	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+
2614	C	-/-	-/-	-/-	-/-	-/+	-/-	-/-	-/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+	+/+

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

### Leukocyte Counts

Chf	BP	2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
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	5.1	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	9.3	9.1	8.9	7.7	5.4	4.5	5.1	6.7	7.3	8.1	7.2	8.1	9	8.5	9.5
2562	V	7.0	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	11.5	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	10.4	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	9.2	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	6.5	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	11.5	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	7.9	8.8	8.9	9.7	8.5	7.7	7.8	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	11.9	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	10.5	9.7	8.5	6.2	7.8	8.5	11.3	12.5	14	11.5	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	8.5	7.6	7.8	6.8	7.6

2613	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	4.1	5.1	5.1	7
2565	C	7.6	7.4	7.6	9.8	9.7	5.8	4	3.5	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	3.3	1.8	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	11.5	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	8.5	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

Call	Group	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
2571	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	100.5	101.3
2560	V	100.3	102.1	101.7	101	101.5	101.5	101.4	101.4	101.2	101.3	101.1	102.6	101	101.4	101.4	101.1	101.1	100.6	100.5	101.2
2551	V	101.6	101.5	101.5	100.6	101.5	102.1	101.7	101.4	101.5	101.4	101.7	101.5	101.6	101.4	101.6	101.2	101.2	100.7	100.2	101.6
2562	V	102.0	101.5	101.4	102.1	102.4	102.2	102.1	102.4	102.1	101.2	102	101.8	101.8	101.3	101.4	101.2	101	100.7	100.7	101.4
2566	V	101.6	101.3	100.3	100.4	102.7	101.7	101.4	101.1	100.9	100.7	100.8	100.6	100.7	101.4	101.4	100.6	101.3	100.7	100.7	101.5
2589	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	100.5	100.9	101.1	101.3	100.5	100.5	101.6
2571	V	102.2	101.9	101.6	105	102.1	101.8	102.4	101.7	101.2	100.8	101.3	101.3	101.2	101.2	101.2	101.3	101	101.3	101.1	100.7
2574	V	101.5	102.1	100.6	100.3	101.2	101.6	101.9	101.4	101.2	101.3	101.8	101.2	100.5	100.8	101.2	101.2	101.3	101.1	101.2	100.3
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	101.6	102
2580	V	101.3	100.9	101.1	101.1	101.9	101.9	102	102	102	102	102	102	101.4	101.3	100.7	101.3	100.9	101.2	101.2	101.1
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	101.2	101.2
2591	V	101.4	101.9	101.4	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	101.4	101.1	101.8	101.6	101.3	101.4	100.5	101.3
2595	V	102.2	102.4	102	101.6	102.5	102.3	101.9	102	100.5	101.3	101.6	101.3	101.3	100.7	100.2	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	101.3	101.5	101.1	101.1	101	100.7	100.7	101.1	101.7	100.2	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	101.4	101.5	101.2	101.5	101.5	100.2	100.2
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
2619	V	102.5	102.8	101.7	100.6	100.7	101.8	102.3	101.2	100.2	100.2	100.2	100.2	101.3	101.1	101.6	100.7	101	100.5	100.5	100.3
2616	V	102.5	100.9	102.3	102	102.2	101.6	102.8	102	101.8	101.5	102.1	101.9	101.1	101.9	101.8	101.7	102.1	101.8	101.2	101.2

2613	C	101.9	101	101.5	100.5	101.1	102.4	101.8	102.8	102.4	105.1	105	103.7	104.1	102.3	Dead	Dead	Dead	Dead	Dead	Dead
2644	C	101.5	101.6	101.9	101.1	102.3	101.9	102.4	102.1	101.7	104.4	104.6	106	101.1	101.6	101	101.4	100.9	101.2	101.2	101.4
2655	C	100.8	101.1	102.4	100.6	101.4	101.4	101.5	102.1	102.1	104.3	106.4	106.2	106.8	101.8	Dead	Dead	Dead	Dead	Dead	Dead
2670	C	102.3	101.5	101.9	101.4	102.9	101.1	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
2689	C	102.5	100.2	101.2	100.3	101.5	101.7	102.4	102.9	101.7	104.3	105.2	104.6	104.9	100.4	Dead	Dead	Dead	Dead	Dead	Dead
2698	C	102.3	100.6	101.9	102.6	102.4	101.8	102.9	102.2	104.3	105.2	104.6	106	105.1	105.1	102	101.7	102.1	102.4	102.7	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	103.2	101.4	102.2	101.3	102.1
2606	C	102.5	101.6	101.9	100.5	102.6	101.7	104.1	104.2	104.9	104.7	105.1	105.4	104.6	105.6	105.4	104.8	104.6	104.6	104.6	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	104.8	104.8	104.8	104.4
2614	C	101.4	100.6	101.9	101.6	102.3	102.8	101.4	102.9	101.5	104.4	106	105.5	104.2	107.1	105.7	104.7	104.7	104.7	104.7	104.7

Day 0 is Day of Challenge

### Post Challenge Observations - Respiratory

Respiratory	Group	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
2541	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
2550	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
2578	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	0	0	0	0	0	0
2570	C	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
2589	C	0	0	0	0	0	0	0	0	0	0	0	0	1	2	Dead	Dead	Dead	Dead	Dead	Dead
2588	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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 – Nasal Discharge

Cat	Group	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
2521	V	0	1	0	0	1	1	0	0	0	0	1	0	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	1	2	1	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	1	0	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	1	0	1	0	1	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	1	0	1
2590	V	0	0	0	0	0	0	0	1	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	1	0	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	0	1	0	0	0	0	0	0	0	1	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	1	0	0	0	0	0	3	2	2	1	0

2513	C	0	0	0	0	0	0	1	0	1	2	2	2	1	2	2	2	2	2	2	2
2544	C	0	0	0	0	0	0	2	0	0	2	2	2	2	3	3	3	3	3	3	3
2545	C	0	0	0	0	0	0	0	0	0	0	0	0	2	2	2	2	2	2	2	2
2570	C	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0
2580	C	1	0	0	0	0	0	0	0	0	0	0	0	2	2	3	3	3	3	3	3
2588	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	2	2
2600	C	0	0	0	0	0	0	0	0	0	0	1	2	3	3	3	3	3	2	2	2
2606	C	0	0	0	0	0	0	0	0	0	0	0	1	0	1	1	1	1	2	2	2
2609	C	0	0	0	0	0	0	0	1	0	0	0	0	0	2	2	2	2	2	2	2
2614	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	2	2	2	2

Day 0 is Day of Challenge  
 0 = No/slight, 1 = Mucous, 2 = Mucopurulent, 3 = Purulent, 1 = Blood-tinged





### Post Challenge Observations – Attitude

Attitude	Group	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
2121	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2143	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2160	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2161	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2162	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2166	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2169	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2171	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2176	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2188	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2190	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2191	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2192	V	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2199	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	0	0	0	0	0	0	0
2544	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2545	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2570	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2585	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2198	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	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	0	0	0	0
2614	C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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

Day 0 is Day of Challenge



<b>Study Type</b>	Comparative Serology
<b>Pertaining to</b>	Bovine Virus Diarrhea Virus Type 2
<b>Study Purpose</b>	Comparative serology for Bovine Virus Diarrhea Virus Type 2 to show that combining fractions with satisfactory efficacy studies does not reduce the immune response. Refer to the summaries of the original efficacy studies under Product Code 1181.21 and in the Product Compilation Summary for this Product Code.
<b>Product Administration</b>	Subcutaneous injection twice, 21 days apart
<b>Study Animals</b>	Weaning age calves
<b>Challenge Description</b>	Serological response prior to vaccination and 35 days after first vaccination
<b>Interval observed after challenge</b>	
<b>Results</b>	<p>Serological response to vaccination after 35 days showed a Geometric Mean Titer (GMT) for the Product Group, Reference Group, and Control group.</p> <p>Please see following pages for treatment groups, vaccination schedule and individual animal antibody titers.</p>
<b>USDA Approval Date</b>	May 16, 2017

Allocation BVDV 2 naïve calves to Treatment Group

Group	Number of Calves (n)	Product	Animal ID
A	20	Reference Product Establishment 290, Product Code 1181.22 Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3- Respiratory Syncytial Virus Vaccine, Modified Live Virus	2,5,8,12,15,19,23,24,31,32,43,55,57,59,61, 64,67,68,72,74
B	21	Product	3,6,7,9,10,11,14,17,21,22,25,26,27,28,34,38, 41,42,53,56,76
D	6	Sterile H2O Diluent	1,4,16,20,54,60

**Individual Antibody titers to BVD Type 2**

Tag #	Group	Day 0	Day 35
2	A	<2	256
5	A	<2	256
8	A	<2	128
12	A	<2	32
15	A	<2	256
19	A	<2	128
23	A	<2	2048
24	A	<2	512
31	A	<2	512
32	A	<2	1024
43	A	<2	512
55	A	<2	128
57	A	<2	128
59	A	<2	64
61	A	<2	512
64	A	<2	256
67	A	<2	2048
68	A	<2	1024
72	A	<2	1024
74	A	<2	64
3	B	<2	256
6	B	<2	1024
7	B	<2	512
9	B	<2	512
10	B	<2	2048
11	B	<2	128
14	B	<2	256
17	B	<2	512
21	B	<2	1024
22	B	<2	512
25	B	<2	512
26	B	<2	512
27	B	<2	512
28	B	<2	64
34	B	<2	1024
38	B	<2	256
41	B	<2	256
42	B	<2	256
53	B	<2	512
56	B	<2	512
76	B	<2	1024
1	D	<2	<2
4	D	<2	<2
16	D	<2	<2
20	D	<2	<2
54	D	<2	<2
60	D	<2	<2



<b>Study Type</b>	Efficacy																														
<b>Pertaining to</b>	Bovine Rhinotracheitis (IBR)																														
<b>Study Purpose</b>	Demonstrate efficacy against respiratory disease																														
<b>Product Administration</b>	Single dose administered subcutaneously																														
<b>Study Animals</b>	33 mixed-breed beef calves, 4 to 5 months of age, randomly divided into 22 vaccinates and 11 controls																														
<b>Challenge Description</b>	IBR virus administered 28 days following vaccination																														
<b>Interval observed after challenge</b>	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).																														
<b>Results</b>	<p>Presence of nasal lesions:  11/11 Controls  4/22 Vaccinates</p> <p>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</p> <p>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.</p> <p>Duration of nasal shedding of virus, in days:</p> <table border="1"> <thead> <tr> <th></th> <th>Min</th> <th>1<sup>st</sup> Quartile</th> <th>Median</th> <th>3<sup>rd</sup> Quartile</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td><b>Control (CPE*)</b></td> <td>9</td> <td>10</td> <td>11</td> <td>12</td> <td>13</td> </tr> <tr> <td><b>Vaccinate (CPE)</b></td> <td>6</td> <td>8</td> <td>9</td> <td>10</td> <td>14</td> </tr> <tr> <td><b>Control (PCR)</b></td> <td>10</td> <td>10</td> <td>11</td> <td>12</td> <td>13</td> </tr> <tr> <td><b>Vaccinate (PCR)</b></td> <td>6</td> <td>8</td> <td>9</td> <td>10</td> <td>14</td> </tr> </tbody> </table> <p>*CPE= cytopathic effect in cell culture</p> <p>See Next Page for Raw Data.</p>		Min	1 <sup>st</sup> Quartile	Median	3 <sup>rd</sup> Quartile	Max	<b>Control (CPE*)</b>	9	10	11	12	13	<b>Vaccinate (CPE)</b>	6	8	9	10	14	<b>Control (PCR)</b>	10	10	11	12	13	<b>Vaccinate (PCR)</b>	6	8	9	10	14
	Min	1 <sup>st</sup> Quartile	Median	3 <sup>rd</sup> Quartile	Max																										
<b>Control (CPE*)</b>	9	10	11	12	13																										
<b>Vaccinate (CPE)</b>	6	8	9	10	14																										
<b>Control (PCR)</b>	10	10	11	12	13																										
<b>Vaccinate (PCR)</b>	6	8	9	10	14																										
<b>USDA Approval Date</b>	September 25, 2012																														

Bovine Nasal Lesion Scores

Calf ID	Group	Observation Day (Challenge administered on Day 0)																	
		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	0
7	Vaccinate	0	0	0	0	0	1	1	1	1	0	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	0
12	Vaccinate	0	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	0
14	Vaccinate	0	0	0	0	0	0	1	1	1	1	1	1	1	1	0	0	0	0
15	Vaccinate	0	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	0
19	Vaccinate	0	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	0
25	Vaccinate	0	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	0
28	Vaccinate	0	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	0
31	Vaccinate	0	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	0
103	Vaccinate	0	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	0
111	Vaccinate	0	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	0
115	Vaccinate	0	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	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
4	Control	0	0	0	0	0	1	2	4	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	0
17	Control	0	0	0	0	0	1	2	3	4	4	4	4	4	4	4	2	1	1
21	Control	0	0	0	0	0	1	1	3	4	4	4	4	4	4	3	3	3	3
22	Control	0	0	0	0	0	1	3	3	4	4	4	4	3	3	3	2	2	2
23	Control	0	0	0	0	0	1	3	4	4	4	4	4	4	4	4	4	3	3
30	Control	0	0	0	0	0	1	2	3	4	4	4	4	4	4	4	4	4	2
116	Control	0	0	0	0	0	1	3	4	4	4	4	4	3	3	3	3	3	2
118	Control	0	0	0	0	0	0	1	3	4	4	4	4	4	4	4	2	2	2
124	Control	0	0	0	0	0	0	1	2	3	4	4	4	4	4	3	2	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

<b>Study Type</b>	Comparative Serology
<b>Pertaining to</b>	Infectious Bovine Rhinotracheitis
<b>Study Purpose</b>	Comparative serology for Infectious Bovine Rhinotracheitis to show that combining fractions with satisfactory efficacy studies does not reduce the immune response. Refer to the summaries of the original efficacy studies under Product Code 1181.21 and in the Product Compilation Summary for this Product Code.
<b>Product Administration</b>	Subcutaneous injection twice, 21 days apart – See Table 2
<b>Study Animals</b>	28 Day old calves – See Table 1
<b>Challenge Description</b>	Serological response prior to vaccination and 35 days after first vaccination
<b>Interval observed after challenge</b>	
<b>Results</b>	<p>Serological response to vaccination after 35 days showed a Geometric Mean Titer (GMT) for the Product Group, Reference Group, and Control group.</p> <p>Please see following pages for treatment groups, vaccination schedule and individual animal antibody titers.</p>
<b>USDA Approval Date</b>	May 16, 2017

**Table 1: Allocation of Animal ID Numbers By Treatment Group.**

<b>Group</b>	<b>Number of Animals</b>	<b>Product</b>	<b>Animal IDs</b>
<b>A</b>	16	Product	302, 306, 308, 324, 334, 338, 340, 365, 366, 372, 375, 377, 390, 397, 404, 405
<b>B</b>	16	Reference Product Establishment 290, Product Code 1181.22 Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	304, 313, 322, 326, 330, 357, 368, 370, 371, 374, 385, 387, 388, 391, 400, 403
<b>C</b>	15	Reference Product Establishment 315 Product Code 7935.04 Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid	310, 315, 325, 328, 341, 351, 364, 373, 376, 379, 380, 384, 389, 393, 401
<b>D</b>	5	Sterile H <sub>2</sub> O Diluent	320, 343, 360, 361, 402

**Table 2: Vaccination Schedule.**

<b>Group</b>	<b>Day 0</b>	<b>Day 21</b>
<b>A</b>	Product	Reference Product Code 7935.04
<b>B</b>	Reference Product Code 1181.22	Sterile H <sub>2</sub> O Diluent
<b>C</b>	Reference Product Code 7935.04	Reference Product Code 7935.04
<b>D</b>	Sterile H <sub>2</sub> O Diluent	Sterile H <sub>2</sub> O Diluent

**Individual Calf Antibody Titer for Infectious Bovine Rhinotracheitis**

Tag #	Group	Day 0	Day 35
302	A	<2	64
306	A	<2	32
308	A	<2	64
324	A	<2	128
334	A	<2	16
338	A	<2	128
340	A	<2	128
365	A	<2	32
366	A	<2	32
372	A	<2	64
375	A	<2	64
377	A	<2	128
390	A	<2	8
397	A	<2	32
404	A	<2	128
405	A	<2	128
304	B	<2	128
313	B	<2	32
322	B	<2	64
326	B	<2	128
330	B	<2	8
357	B	<2	128
368	B	<2	64
370	B	<2	16
371	B	<2	128
374	B	<2	16
385	B	<2	64
387	B	<2	128
388	B	<2	32
391	B	<2	8
400	B	<2	16
403	B	<2	32

Tag #	Group	Day 0	Day 35
310	C	<2	<2
315	C	<2	<2
325	C	<2	<2
328	C	<2	<2
341	C	<2	<2
351	C	<2	<2
364	C	<2	<2
373	C	<2	<2
376	C	<2	<2
379	C	<2	<2
380	C	<2	<2
384	C	<2	<2
389	C	<2	<2
393	C	<2	<2
401	C	<2	<2
320	D	<2	<2
343	D	<2	<2
360	D	<2	<2
361	D	<2	<2
402	D	<2	<2

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Mannheimia haemolytica</i>
<b>Study Purpose</b>	Efficacy against respiratory disease caused by <i>M. haemolytica</i>
<b>Product Administration</b>	Two doses, given subcutaneously, three weeks apart
<b>Study Animals</b>	Calves, 2.5 months of age, 20 vaccinates and 10 placebo controls and 4 environmental controls (non-vaccinated, non-challenged)
<b>Challenge Description</b>	<i>M. haemolytica</i> given 14 days after second vaccination
<b>Interval observed after challenge</b>	Observed daily for 4 days for clinical signs
<b>Results</b>	<p>A calf was considered positive if mortality was due to <i>M. haemolytica</i>.</p> <p>Mortality after Challenge</p> <p>Vaccinates 7/20 (35%)  Controls 10/10 (100%)</p> <p>Raw data in following table.</p>
<b>USDA Approval Date</b>	January 9, 2012

<u>Animal ID</u>	<u>Treatment</u>	<u>Clinical Observation</u>	<u>Organism Isolated</u>
P10	V		MH
P18	P	Died 1 dpc	MH
P26	P	Died 1 dpc	MH
P27	V		
P28	P	Died 1 dpc	MH
P35	V		MH
P39	P	Died 1 dpc	MH
P42	V		MH
P45	V		MH
B46	V	Died 2 dpc	MH
G54	V		MH
G55	P	Died 4 dpc	MH
G59	V	Died 2 dpc	MH
Y61	V	Died 2 dpc	MH
Y63	V		MH
P5	EC		
P41	EC		
351	P	Died 1 dpc	MH
352	V		
353	EC		
354	V		
355	V	Died 1 dpc	MH
357	P	Died 1 dpc	MH
358	V	Died 1 dpc	MH
359	P	Died 1 dpc	MH
361	V		
362	V	Died 1 dpc	MH
363	V		
364	V		
366	EC		
367	P	Died 1 dpc	MH
368	V		
369	V	Died 1 dpc	MH
371	P	Died 1 dpc	MH

V=vaccinate  
P=placebo control  
EC=environmental control  
dpc = day post challenge



<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Mannheimia Haemolytica ( <i>M. haemolytica</i> )
<b>Study Purpose</b>	Efficacy against Mannheimia Haemolytica
<b>Product Administration</b>	Subcutaneous Injection repeated in 21 days – See Table 1
<b>Study Animals</b>	Calves 2.5 to 4 months of age 11 calves in Product Group 11 calves in Placebo Group
<b>Challenge Description</b>	Challenge with Mannheimia Haemolytica 14 days after second vaccination
<b>Interval observed after challenge</b>	Calves were monitored daily for 5 days then lung tissues were examined
<b>Results</b>	<p>The primary outcome was lung lesions as described in 9 CFR 113.68.</p> <p>Placebo Group Calf #23 died post-challenge due to <i>M. haemolytica</i>.</p> <p>Please next pages for animal grouping and lesion scores.</p>
<b>USDA Approval Date</b>	December 7, 2018

Animal grouping and vaccination scheme

Group	Purpose	# of Animals	1 <sup>st</sup> vaccination	2 <sup>nd</sup> vaccination
1	Product Group	11	Product	Reference Product Establishment 315 Product Code 7935.04 Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid
2	Placebo Group	11	Placebo matched to Product vaccine without <i>M. haemolytica</i> and <i>Pasteurella multocida</i> antigenic fractions	Placebo matched to Reference Product without <i>M. haemolytica</i> and <i>Pasteurella multocida</i> antigenic fractions

Percentages of Affected Pneumonic Tissue of Individual Lobes  
 Calculated amount each lobe contributes to total lung lesion (percentage × weight)

<b>Animal ID</b>	<b>Left Cranial (5%)</b>	<b>Left Posterior Cranial (6%)</b>	<b>Left Caudal (32%)</b>	<b>Inter-mediate (4%)</b>	<b>Right Cranial (6%)</b>	<b>Right Posterior Cranial (5%)</b>	<b>Right Middle (7%)</b>	<b>Right Caudal (35%)</b>
1	0	0	5	5	0	0	5	5
2	0	0	35	0	0	0	0	30
3	0	0	10	0	0	0	15	15
6	100	100	50	0	100	0	80	20
7	0	0	5	0	0	0	0	10
10	0	0	5	0	50	0	5	5
11	5	10	20	30	80	5	100	20
12	0	0	10	0	0	0	5	15
16	0	0	20	0	0	0	20	10
19	5	0	70	30	90	40	30	50
20	0	0	5	0	0	0	0	5
22	5	0	15	5	100	0	5	15
23	NA	NA	NA	NA	NA	NA	NA	NA
25	0	0	20	0	0	0	0	15
26	90	100	20	30	15	0	90	15
28	0	40	25	80	30	0	100	30
29	5	30	30	0	10	0	50	40
30	5	100	40	20	100	0	90	50
31	0	0	5	0	0	0	0	1
33	70	100	15	100	100	0	10	5
34	0	5	5	0	0	0	0	5
36	0	0	30	80	100	20	5	40

Lung lesion scores of calves 5 days after *M. haemolytica* challenge

<b>Group</b>	<b>Animal ID</b>	<b>Lung Lesion Score</b>
Vaccinated	31	1.95
	20	3.35
	34	3.65
	1	3.9
	7	5.1
	10	6.7
	12	8.8
	3	9.5
	16	11.3
	25	11.65
	22	16.85
	Placebo	2
33		26.75
11		27.5
29		29.75
26		30.55
28		32.9
36		34.15
6		45.6
30		49.65
19		50.85
23		51

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

caif	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

<b>Study Type</b>	Comparative Serology
<b>Pertaining to</b>	Parainfluenza 3 Virus (PI3)
<b>Study Purpose</b>	Comparative serology for Parainfluenza 3 Virus to show that combining fractions with satisfactory efficacy studies does not reduce the immune response. Refer to the summaries of the original efficacy studies under Product Code 1181.21 and in the Product Compilation Summary for this Product Code.
<b>Product Administration</b>	Subcutaneous injection twice, 21 days apart
<b>Study Animals</b>	Weaning age calves
<b>Challenge Description</b>	Serological response prior to vaccination and 35 days after first vaccination
<b>Interval observed after challenge</b>	
<b>Results</b>	<p>Serological response to vaccination after 35 days showed a Geometric Mean Titer (GMT) for the Product Group, Reference Group, and Control group.</p> <p>Please see following pages for treatment groups, vaccination schedule and individual animal antibody titers.</p>
<b>USDA Approval Date</b>	May 16, 2017



### Allocation of PI3 naïve calves to treatment group

Group	Number of Calves (n)	Product	Animal ID
A	22	Reference Product Establishment 290, Product Code 1181.22 Bovine Rhinotracheitis- Virus Diarrhea- Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	5,23,24,32,36,43,49,57,64,67,68,113,116, 121,124,130,138,142,145,178,180,181
B	23	Product	3,6,7,9,14,21,26,29,34,38,41,42,53,66,76, 119,125,146,174,176,177,179,182
D	5	Sterile H2O Diluent	1,4,16,20,54

### Individual Antibody Titers to Parainfluenza 3

Tag#	Group	PI3	
		Day 0	Day 35
5	A	<2	8
23	A	<2	16
24	A	<2	32
32	A	<2	16
36	A	<2	16
43	A	<2	8
49	A	<2	64
57	A	<2	16
64	A	<2	16
67	A	<2	64
68	A	<2	32
113	A	<2	2
116	A	<2	32
121	A	<2	4
124	A	<2	8
130	A	<2	16
138	A	<2	2
142	A	<2	4
145	A	<2	2
178	A	<2	2
180	A	<2	32
181	A	<2	8
3	B	<2	16
6	B	<2	16
7	B	<2	16
9	B	<2	8
14	B	<2	32
21	B	<2	64
26	B	<2	16
29	B	<2	32
34	B	<2	32
38	B	<2	8
41	B	<2	64
42	B	<2	32
53	B	<2	16
66	B	<2	8
76	B	<2	16
119	B	<2	32
125	B	<2	32
146	B	<2	128
174	B	<2	128
176	B	<2	64
177	B	<2	16
179	B	<2	128
182	B	<2	16
1	D	<2	<2
4	D	<2	<2
16	D	<2	<2
20	D	<2	<2
54	D	<2	<2

<b>Study Type</b>	Efficacy																																							
<b>Pertaining to</b>	<i>Pasteurella multocida</i>																																							
<b>Study Purpose</b>	Demonstration of efficacy against <i>Pasteurella multocida</i>																																							
<b>Product Administration</b>	Two doses, administered intraperitoneally, 14 days apart																																							
<b>Study Animals</b>	Mice																																							
<b>Challenge Description</b>	0.2 ml containing 100-10000 mouse LD <sub>50</sub> of <i>P. multocida</i> P1062, administered intraperitoneally 10-12 days after second vaccination.																																							
<b>Interval observed after challenge</b>	Observe daily for 10 days to record mortalities.																																							
<b>Results</b>	<p>Vaccines were evaluated using the standard reference Pasteurella Multocida P1062 Bacterin (PMSRB2) supplied by APHIS per the criteria in 9 CFR 113.121(c) and the results were satisfactory (S).</p> <table border="1"> <thead> <tr> <th rowspan="2">Serials/Ref</th> <th colspan="4">Protection at Different Dilutions</th> <th rowspan="2">PD<sub>50</sub></th> <th rowspan="2">Results</th> </tr> <tr> <th>1</th> <th>5</th> <th>25</th> <th>125</th> </tr> </thead> <tbody> <tr> <td>#28001</td> <td>15/20*</td> <td>13/20</td> <td>15/20</td> <td>12/20</td> <td>NA</td> <td>S</td> </tr> <tr> <td>#28002</td> <td>15/20</td> <td>14/20</td> <td>13/20</td> <td>2/20</td> <td>5<sup>1.83</sup></td> <td>S</td> </tr> <tr> <td>#28003</td> <td>14/20</td> <td>14/20</td> <td>6/20</td> <td>8/20</td> <td>5<sup>1.57</sup></td> <td>S</td> </tr> <tr> <td>PMSRB2</td> <td>18/20</td> <td>9/20</td> <td>1/20</td> <td>0/20</td> <td>5<sup>0.87</sup></td> <td></td> </tr> </tbody> </table> <p>* live/total mice number  Challenge dose: 120 mouse LD<sub>50</sub> of <i>P. multocida</i> P1062.</p>	Serials/Ref	Protection at Different Dilutions				PD <sub>50</sub>	Results	1	5	25	125	#28001	15/20*	13/20	15/20	12/20	NA	S	#28002	15/20	14/20	13/20	2/20	5 <sup>1.83</sup>	S	#28003	14/20	14/20	6/20	8/20	5 <sup>1.57</sup>	S	PMSRB2	18/20	9/20	1/20	0/20	5 <sup>0.87</sup>	
Serials/Ref	Protection at Different Dilutions				PD <sub>50</sub>	Results																																		
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#28003	14/20	14/20	6/20	8/20	5 <sup>1.57</sup>	S																																		
PMSRB2	18/20	9/20	1/20	0/20	5 <sup>0.87</sup>																																			
<b>USDA Approval Date</b>	January 29, 2013																																							

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Pasteurella Multocida
<b>Study Purpose</b>	Efficacy of Pasteurella Multocida
<b>Product Administration</b>	Mouse Potency Test
<b>Study Animals</b>	Mice
<b>Challenge Description</b>	Test conducted according to 9 CFR 113.121
<b>Interval observed after challenge</b>	
<b>Results</b>	<p>The potency test was conducted in triplicate (three sets of mice for each vaccine). Each test was initiated on a different day and fresh preparations of the vaccines were used in each test.</p> <p>See next page for test results</p>
<b>USDA Approval Date</b>	May 16, 2017

***Pasteurella multocida* mouse potency PD<sub>50</sub> values**

Observation	Test	Treatment	Number Live / Dead				PD <sub>50</sub>
			Undilute	1:5	1:25	1:125	
1	1	Product	11 / 20	8 / 20	5 / 20	1 / 20	3.09
2	1	Reference Product Establishment 315 Product Code 7935.04 Mannheimia Haemolytica- Pasteurella Multocida Bacterin-Toxoid	12 / 20	6 / 20	2 / 20	0 / 20	2.16
3	2	Product	11 / 20	8 / 20	2 / 20	1 / 20	2.51
4	2	Reference Product Establishment 315 Product Code 7935.04 Mannheimia Haemolytica- Pasteurella Multocida Bacterin-Toxoid	12 / 20	9 / 20	3 / 20	2 / 20	3.49
5	3	Product	12 / 20	8 / 20	3 / 20	1 / 20	2.92
6	3	Reference Product Establishment 315 Product Code 7935.04 Mannheimia Haemolytica- Pasteurella Multocida Bacterin-Toxoid	11 / 20	8 / 20	3 / 20	0 / 20	2.51

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



<b>Study Type</b>	Comparative Serology
<b>Pertaining to</b>	Bovine Respiratory Syncytial Virus
<b>Study Purpose</b>	Comparative serology for Bovine Respiratory Syncytial Virus to show that combining fractions with satisfactory efficacy studies does not reduce the immune response. Refer to the summaries of the original efficacy studies under Product Code 1181.21 and in the Product Compilation Summary for this Product Code.
<b>Product Administration</b>	Subcutaneous injection twice, 21 days apart – See Table 2
<b>Study Animals</b>	28 Day old calves – See Table 1
<b>Challenge Description</b>	Serological response prior to vaccination and 35 days after first vaccination
<b>Interval observed after challenge</b>	
<b>Results</b>	<p>Serological response to vaccination after 35 days showed a Geometric Mean Titer (GMT) for the Product Group, Reference Group, and Control group.</p> <p>Please see following pages for treatment groups, vaccination schedule and individual animal antibody titers.</p>
<b>USDA Approval Date</b>	May 16, 2017

**Table 1: Allocation of Animal ID Numbers By Treatment Group**

<b>Group</b>	<b>Number of Animals</b>	<b>Product</b>	<b>Animal IDs</b>
<b>A</b>	16	Product	302, 306, 308, 324, 334, 338, 340, 365, 366, 372, 375, 377, 390, 397, 404, 405
<b>B</b>	16	Reference Product Establishment 290, Product Code 1181.22 Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus	304, 313, 322, 326, 330, 357, 368, 370, 371, 374, 385, 387, 388, 391, 400, 403
<b>C</b>	15	Reference Product Establishment 315 Product Code 7935.04 Mannheimia Haemolytica-Pasteurella Multocida Bacterin-Toxoid	310, 315, 325, 328, 341, 351, 364, 373, 376, 379, 380, 384, 389, 393, 401
<b>D</b>	5	Sterile H <sub>2</sub> O Diluent	320, 343, 360, 361, 402

**Table 2: Vaccination Schedule.**

<b>Group</b>	<b>Day 0</b>	<b>Day 21</b>
<b>A</b>	Product	Reference Product Code 7935.04
<b>B</b>	Reference Product Code 1181.22	Sterile H <sub>2</sub> O Diluent
<b>C</b>	Reference Product Code 7935.04	Reference Product Code 7935.04
<b>D</b>	Sterile H <sub>2</sub> O Diluent	Sterile H <sub>2</sub> O Diluent

**Individual Calf Antibody Titer for Bovine Respiratory Syncytial Virus**

Tag #	Group	Day 0	Day 35
302	A	<2	4
306	A	<2	2
308	A	<2	4
324	A	<2	4
334	A	<2	4
338	A	<2	8
340	A	<2	4
365	A	<2	2
366	A	<2	4
372	A	<2	4
375	A	<2	16
377	A	<2	8
390	A	<2	8
397	A	<2	4
404	A	<2	16
405	A	<2	8
304	B	<2	4
313	B	<2	4
322	B	<2	2
326	B	<2	16
330	B	<2	8
357	B	<2	2
368	B	<2	2
370	B	<2	8
371	B	<2	2
374	B	<2	8
385	B	<2	16
387	B	<2	8
388	B	<2	8
391	B	<2	2
400	B	<2	8
403	B	<2	2

Tag #	Group	Day 0	Day 35
310	C	<2	<2
315	C	<2	<2
325	C	<2	<2
328	C	<2	<2
341	C	<2	<2
351	C	<2	<2
364	C	<2	<2
373	C	<2	<2
376	C	<2	<2
379	C	<2	<2
380	C	<2	<2
384	C	<2	<2
389	C	<2	<2
393	C	<2	<2
401	C	<2	<2
320	D	<2	<2
343	D	<2	<2
360	D	<2	<2
361	D	<2	<2
402	D	<2	<2

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All
<b>Study Purpose</b>	Demonstrate safety in cattle 5 months of age or older
<b>Product Administration</b>	One dose subcutaneously
<b>Study Animals</b>	638 head of cattle ranging in age of 4 to 12 months with 69% at or below the minimum age of 5 months.
<b>Challenge Description</b>	NA
<b>Interval observed after challenge</b>	Observed daily for 24 days after vaccination
<b>Results</b>	The only recorded adverse events were 43 head of cattle that were treated for and recovered from pneumonia. These events were not associated with the use of the product by the attending veterinarians.
<b>USDA Approval Date</b>	June 5, 2019

### Summary of Field Safety Test

Group	No. Head	Adverse Events	Adverse Events Attributed to Product	Mortality
1	87	0	0	0
2	86	1	0	0
3	79	3	0	0
4	95	12	0	0
5	95	9	0	0
6	98	6	0	0
7	98	12	0	0
Total	638	43	0	0

\*Calves treated for pneumonia and recovered without event. Cause of pneumonia was undetermined.