



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
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)	Bovilis Vista 5 SQ - MSD Salud Animal Columbia S.A.S. Bovilis Vista 5 SQ - Merck Sharpe and Dohme (MSD) Bovilis Vista 5 SQ - No distributor specified Vista 5 SQ - Merck Animal Health Vista 5 SQ - No distributor specified
Date of Compilation Summary	May 26, 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 Virus Diarrhea Virus (BVDV) Type 1
Study Purpose	Demonstration of Efficacy of the BVDV1 fraction
Product Administration	Single dose administered subcutaneously
Study Animals	Twenty-eight calves, seronegative to BVDV1, 11-12 weeks of age, 14 vaccinates and 14 placebo controls
Challenge Description	BVDV1 strain T1186a administered intranasally 28 days after vaccination
Interval observed after challenge	Calves were observed daily for up to 14 days after challenge.
Results	<p>Calves monitored as per 9CFR 113.311.</p> <p>Serology at 28 days following vaccination. Neutralizing antibodies to BVDV $\geq 1:8$ are considered positive.</p>

Table 1. BVDV1 Serum Neutralization Antibody Titers

Group	Calf ID	Day Post-Challenge	
		28	Titer > 1:8
Vaccinate	142	1	
	144	23	Yes
	146	45	Yes
	147	512	Yes
	149	3	
	150	1	
	152	256	Yes
	153	1	
	154	91	Yes
	160	1448	Yes
	164	2896	Yes
	165	512	Yes
	166	512	Yes
	167	256	Yes
Control	143	1	
	145	1	
	148	1	
	151	1	
	155	1	
	156	1	
	157	1	
	158	1	
	159	1	
	161	1	
	162	1	
	163	1	
168	1		
169	1		

Note: Titer values < 1:2 are assigned a value of 1

Neutralizing Antibodies to BVDV ≥ 1:8

Vaccinates 10/14
 Controls 0/14

Rectal temperature $\geq 103.5^{\circ}\text{F}$ is considered fever. If any day during the observation period a fever was detected by rectal temperature, the calf is positive for fever.

Rectal Temperatures

Treatment	Calf ID	Rectal Temperature at Days Post-Challenge																
		1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Vaccinate	142	100.5	102.8	101.1	102.2	101.0	101.0	102.3	101.4	101.6	102.1	102.3	102.5	102.1	101.6	100.6	101.3	
	144	100.2	103.0	101.6	101.6	101.5	101.2	101.8	102.2	101.7	101.6	101.9	102.6	101.6	101.2	101.5	102.3	
	146	100.9	102.2	99.0	102.0	100.6	101.0	101.6	100.7	101.0	102.0	102.1	101.6	100.5	101.0	100.6	101.3	
	147	102.0	102.5	100.9	101.7	101.7	101.4	102.1	101.2	101.8	103.6	103.4	102.4	102.1	101.8	101.9	101.1	
	149	100.9	102.3	102.0	102.6	102.0	101.3	101.9	101.5	101.5	102.0	101.8	102.1	102.1	100.9	101.8	101.4	
	150	99.9	102.6	100.5	102.8	101.1	101.0	102.4	101.0	100.9	101.7	102.0	102.3	102.3	102.9	101.4	103.2	
	152	100.9	103.3	101.1	102.5	102.3	101.7	102.9	101.4	101.0	102.8	102.7	102.4	101.9	102.2	101.1	100.2	
	153	99.4	102.4	101.2	102.0	101.7	101.1	103.2	103.1	101.4	102.4	101.5	101.5	100.4	101.1	100.8	100.7	
	154	101.0	102.9	101.5	102.5	102.5	100.5	102.5	102.3	101.7	102.3	102.1	102.1	101.3	100.5	101.7	100.7	
	160	101.4	102.6	100.1	102.0	101.3	100.1	102.2	101.6	101.9	102.3	102.7	103.3	104.5	102.5	103.5	102.3	
	164	100.1	101.4	100.4	102.4	100.9	100.8	101.6	100.5	100.5	102.1	101.0	101.6	100.8	101.1	100.1	101.6	
	165	100.8	102.5	101.2	102.0	101.3	102.0	102.1	101.1	100.9	102.2	102.1	102.1	102.3	101.9	101.4	100.5	
	166	101.2	102.7	101.1	101.9	102.2	101.2	102.0	101.2	101.2	102.0	101.5	101.6	101.8	101.7	101.6	101.6	
	167	101.6	102.2	100.7	102.4	102.2	102.3	102.3	100.6	101.6	102.1	101.8	101.8	101.5	102.0	101.2	101.0	
	Control	143	99.1	102.5	100.4	101.9	101.8	100.9	101.5	100.8	103.2	101.8	104.0	101.8	102.2	102.1	101.7	101.0
		145	100.7	102.8	101.1	101.7	101.1	102.1	102.8	101.3	103.2	105.6	102.2	102.4	101.6	101.5	100.3	99.8
148		101.4	102.8	100.9	101.8	100.8	102.4	102.5	101.9	103.4	104.8	102.5	102.6	101.8	101.4	101.4	100.7	
151		102.0	102.2	101.2	103.1	102.0	102.0	103.2	100.6	103.7	104.1	104.2	103.8	102.2	103.2	99.3	102.1	
155		100.6	103.6	101.7	103.1	101.4	102.9	103.2	101.7	102.6	102.8	102.0	104.3	102.3	102.6	101.8	102.0	
156		101.3	101.6	100.9	102.0	102.2	101.0	102.0	101.5	101.6	102.6	105.0	104.0	101.4	103.0	101.0	102.8	
157		100.8	102.3	101.7	102.3	102.7	101.8	101.9	101.4	102.1	101.1	102.3	102.8	103.5	102.8	101.5	101.6	
158		101.4	102.4	100.6	102.3	100.7	101.9	102.6	101.2	102.8	102.8	105.2	102.7	101.2	102.7	101.3	101.5	
159		102.2	101.8	101.2	102.2	101.8	101.8	101.9	102.1	101.7	102.9	105.2	102.2	102.2	102.8	101.3	100.9	
161		99.6	102.4	100.2	102.3	101.0	101.0	102.4	101.7	102.7	105.6	102.2	102.4	101.6	102.7	100.5	101.5	
162		101.5	102.9	101.5	101.7	101.3	101.5	102.3	101.2	102.4	102.0	102.2	103.2	103.7	101.2	101.5	100.9	
163		100.4	103.0	100.3	102.3	101.7	102.3	102.5	102.4	103.6	103.5	103.8	103.0	103.0	102.1	100.1	101.2	
168		101.6	103.2	101.3	102.5	102.3	101.3	102.2	100.9	102.8	105.8	102.4	102.2	102.0	101.5	101.1	102.1	
169	101.7	102.8	101.3	101.8	101.6	102.3	102.0	101.9	102.4	106.0	102.2	103.8	100.6	102.1	101.8	101.4		

Note: Values are recorded as $^{\circ}\text{F}$

Temperature ($\geq 103.5^{\circ}\text{F}$)

Vaccinates
Controls

2/14
14/14

Clinical signs (diarrhea, nasal discharge) following challenge. Signs consistent with BVD infection are indicated by N2 on any day or D1,N1 on any day.

Clinical Observation Record

Treatment	Calf ID	Clinical Signs and Scores at Day Post-Challenge													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
Vaccinate	142	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	144	0	0	0	0	0	0	0	0	0	0	N,1	D,1	0	0
	146	0	0	0	0	0	0	C,1	0	0	0	C,1	0	0	0
	147	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	149	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	150	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	152	0	0	0	0	0	0	0	0	0	0	0	0	N,1	0
	153	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	154	0	0	0	0	0	0	0	0	0	0	0	D,1	0	0
	160	0	0	0	0	0	0	0	0	0	N,1	0	0	0	0
	164	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	165	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	166	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	167	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	143	0	0	0	0	0	0	0	0	0	0	N,1	N,1	N,2	0
	145	0	0	0	0	0	0	0	0	0	0	0	0	0	D,1
	148	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	151	0	0	0	0	0	0	0	N,1	0	0	N,2	0	N,2	0
	155	0	0	0	0	0	0	0	0	0	0	N,1	0	N,1	0
	156	0	0	0	0	0	0	0	0	0	0	N,1	0	0	0
	157	0	0	0	0	0	0	0	0	0	0	0	N,2	0	0
	158	0	0	0	0	0	0	0	0	0	0	0	N,2	N,2	0
	159	0	0	0	0	0	0	0	0	0	D,1	N,1	0	0	0
	161	0	0	0	0	0	0	0	0	0	0	D,1	0	0	N,2
	162	0	0	0	0	0	0	0	0	0	0	0	0	0	C,1
	163	0	0	0	0	0	0	0	N,2	0	N,1	0	0	0	0
168	0	0	0	0	0	0	0	0	0	0	N,2	N,2	0	0	
169	0	0	0	0	0	0	0	0	0	D,1	N,2	0	0	0	

D=Diarrhea, 1=Soft Feces, 2=Watery Diarrhea
 N=Nasal Discharge, 1=Mild, 2=Moderate
 C=Cough, 1= <3 episodes, 2= >3 episodes

Clinical Signs

Vaccinates 0/14
 Controls 9/14

Incidence of leukopenia following challenge. A drop of 40% from the baseline leukocyte count was the criterion for leukopenia.

Table 2: White Blood Cell Counts

Group	Calf ID	Day Post-Challenge								Leukopenia
		-2	-1	0	2	4	6	8	10	
Vaccinate	142	10.0	9.1	7.8	8.7	10.1	8.5	8.4	7.1	
	144	18.7	18.1	16.1	17.3	18.8	16.6	15.7	15.5	
	146	10.7	9.4	9.9	12.4	11.4	10.5	11.2	8.8	
	147	13.2	10.5	8.6	9.3	NT	10.5	4.3	4.5	Yes
	149	9.2	8.3	7.5	7.4	9.0	6.8	7.4	7.1	
	150	10.7	9.2	7.6	9.3	10.6	10.0	8.1	8.5	
	152	10.7	10.7	9.4	9.9	9.3	8.9	7.5	7.5	
	153	13.6	13.3	12.2	13.4	10.2	5.5	9.5	9.3	Yes
	154	15.1	14.1	12.4	12.2	13.0	11.8	13.2	11.2	
	160	15.0	14.6	13.8	13.9	13.2	14.5	16.3	14.1	
	164	11.3	8.7	9.9	10.0	9.2	10.0	9.2	9.1	
	165	17.4	17.1	13.6	14.7	12.1	12.0	12.0	11.3	
	166	NT	29.7	25.4	23.5	23.6	23.7	20.7	20.5	
	167	15.1	15.3	11.8	14.5	13.5	12.2	11.4	13.1	
Control	143	9.7	6.2	7.0	8.9	6.4	5.8	5.5	5.7	Yes
	145	10.2	9.6	11.0	9.5	6.2	5.5	17.2	6.1	Yes
	148	7.8	8.2	7.1	8.4	5.0	5.4	6.9	7.0	Yes
	151	8.7	7.8	7.5	6.8	4.9	4.4	3.5	4.1	Yes
	155	8.2	9.3	7.7	5.4	6.5	7.0	6.5	6.5	
	156	7.3	6.2	5.9	7.3	7.7	6.0	5.8	10.8	
	157	10.9	10.2	8.4	6.2	7.0	9.7	8.3	6.2	Yes
	158	10.7	10.0	8.6	8.9	7.4	6.4	6.2	11.0	
	159	12.7	13.2	12.4	12.4	8.9	7.1	6.7	14.0	
	161	18.0	16.3	15.0	14.5	9.6	7.6	18.8	8.4	Yes
	162	18.1	17.0	15.2	15.2	12.9	11.7	11.3	8.8	
	163	15.8	17.2	13.7	12.9	8.4	8.2	6.7	7.2	Yes
	168	13.4	13.1	11.1	13.4	9.1	6.2	14.1	8.4	
169	11.9	11.4	12.2	10.4	8.1	5.5	11.0	6.7	Yes	

NT = Not Tested

Note: Values are recorded as $\times 10^3 / \text{mm}^3$

Number of calves

Vaccinates 2/14
 Controls 8/14

Nasal shedding of BVDV following challenge. Any number greater than zero is considered positive for nasal shedding of BVDV.

Table 2 Virus Shedding Measured by Virus Isolation from Nasal Swabs

Group	Calf ID	Virus Titer* at Days Post-Challenge												
		-28	-1	0	1	2	3	4	5	6	7	8	9	10
Vaccinate	142	0	0	0	0	0	0	0	0	0	0	0	0	0
	144	0	0	0	0	0	0	0	0	0	0	0	0	0
	146	0	0	0	0	0	0	0	0	0	0	0	0	0
	147	0	0	0	0	0	0	0	0	0	0	0	0	0
	149	0	0	0	0	0	0	0	0	0	0	0	0	0
	150	0	0	0	0	0	0	0	0	0	0	0	0	0
	152	0	0	0	0	0	0	0	0	0	0	0	0	0
	153	0	0	0	0	0	0	0	0	0	0	0	0	0
	154	0	0	0	0	0	0	0	0	0	0	0	0	0
	160	0	0	0	0	0	0	0	0	0	0	0	0	0
	164	0	0	0	0	0	0	0	0	0	0	0	0	0
	165	0	0	0	0	0	0	0	0	0	0	0	0	0
	166	0	0	0	0	0	0	0	0	0	0	0	0	0
	167	0	0	0	0	0	0	0	0	0	0	0	2.9	0
Control	143	0	0	0	0	0	0	1.7	0	0	2.5	2.1	2.5	0
	145	0	0	0	0	0	0	0	1.7	0	2.5	0	0	0
	148	0	0	0	0	0	0	0	0	0	3.3	2.3	1.9	0
	151	0	0	0	0	0	0	0	1.9	2.9	3.9	4.1	3.5	2.7
	155	0	0	0	0	0	0	0	0	1.7	2.7	2.5	2.9	3.9
	156	0	0	0	0	0	0	0	0	2.9	3.3	3.1	2.7	1.9
	157	0	0	0	0	0	0	0	0	0	2.9	0	3.5	3.9
	158	0	0	0	0	0	0	0	0	0	2.1	2.1	2.1	0
	159	0	0	0	0	0	1.9	0	1.7	1.7	2.7	2.3	1.7	1.7
	161	0	0	0	0	0	0	0	0	0	2.1	2.3	0	0
	162	0	0	0	0	0	0	0	0	0	0	0	0	0
	163	0	0	0	0	0	0	0	0	2.1	3.5	3.5	3.3	1.9
168	0	0	0	0	0	0	0	0	0	0	1.7	0	0	
169	0	0	0	0	0	0	0	0	0	0	2.5	0	0	0

*Values are recorded as Log₁₀ FAID₅₀/mL

	Number of calves shedding	Duration
Vaccinates	1/14	1 day
Controls	13/14	1-6 days

Viremia of BVDV1 following challenge. A positive isolation (P) is considered positive for viremia. A negative isolation (N) is considered negative for viremia.

Table 3. BVDV1 Isolation from Buffy Coat

Vaccinate		Control	
Calf No.	Isolation	Calf No.	Isolation
142	N	143	N
144	N	145	P
146	N	148	P
147	N	151	P
149	P	155	P
150	N	156	P
152	N	157	P
153	N	158	P
154	P	159	P
160	P	161	P
164	P	162	P
165	P	163	P
166	P	168	P
167	N	169	P

P = Positive; N = Negative

Number of calves viremic

Vaccinates 6/14
 Controls 13/14

**USDA
 Approval
 Date**

June 27, 2013

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 1 (BVDV1)
Study Purpose	To demonstrate efficacy against respiratory disease caused by BVDV1.
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV Type 1b NY-1 strain
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	February 20, 2004

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 1 (BVDV1)
Study Purpose	To demonstrate efficacy against persistent infection of calves caused by BVDV1.
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV Type 1b, strain SD02 BVD09
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 23, 2005

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 1 (BVDV1)
Study Purpose	To demonstrate efficacy against fetal infection caused by BVDV1 206 days after vaccination.
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV Type 1b strain SD02 BVD09
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	October 6, 2005

Study Type	Efficacy																																				
Pertaining to	Bovine Viral Diarrhea Virus Type 1 (BVDV1)																																				
Study Purpose	To demonstrate efficacy against respiratory disease caused by BVDV1 1 year after vaccination.																																				
Product Administration	1 dose administered by the subcutaneous route																																				
Study Animals	34 seronegative calves, 3 – 4 weeks of age; 22 vaccinates, 12 controls																																				
Challenge Description	All calves were challenged with BVDV1b strain T1186a at 1 year (365 days) after vaccination.																																				
Interval observed after challenge	All calves were monitored daily for 14 days post-challenge for clinical signs of disease. White Blood Cell (WBC) count and nasal shedding were determined daily for 10 days post-challenge.																																				
Results	<p><u>Leukopenia:</u> An affected calf was one that showed a > 40% decrease in white blood cell counts during the observation period.</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th># Affected</th> <th>Percent (%)</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>22</td> <td>2</td> <td>9</td> </tr> <tr> <td>Controls</td> <td>12</td> <td>12</td> <td>100</td> </tr> </tbody> </table> <p><u>Virus Shedding:</u> An affected calf was one in which nasal virus shedding was detected on any day post-challenge.</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th># Affected</th> <th>Percent (%)</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>22</td> <td>0</td> <td>0</td> </tr> <tr> <td>Controls</td> <td>12</td> <td>11</td> <td>92</td> </tr> </tbody> </table> <p><u>Clinical Observations:</u> An affected calf showed signs of acute BVDV1 (i.e. moderate to severe diarrhea, nasal discharge, and/or depression) during the observation period.</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th># Affected*</th> <th>Percent (%)</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>22</td> <td>1</td> <td>4.5</td> </tr> <tr> <td>Controls</td> <td>12</td> <td>6</td> <td>50</td> </tr> </tbody> </table> <p>Requirements per 9 CFR 113.311 were met.</p> <p>Raw data shown on attached pages.</p>	Group	# of Animals	# Affected	Percent (%)	Vaccinates	22	2	9	Controls	12	12	100	Group	# of Animals	# Affected	Percent (%)	Vaccinates	22	0	0	Controls	12	11	92	Group	# of Animals	# Affected*	Percent (%)	Vaccinates	22	1	4.5	Controls	12	6	50
Group	# of Animals	# Affected	Percent (%)																																		
Vaccinates	22	2	9																																		
Controls	12	12	100																																		
Group	# of Animals	# Affected	Percent (%)																																		
Vaccinates	22	0	0																																		
Controls	12	11	92																																		
Group	# of Animals	# Affected*	Percent (%)																																		
Vaccinates	22	1	4.5																																		
Controls	12	6	50																																		
USDA Approval Date	July 11, 2014																																				

White Blood Cell (WBC) Counts

Group	ID	WBC Counts (x 10 ³ /mL) Day Post-Challenge										
		-2	-1	0	2	3	4	5	6	7	8	10
Controls	308	16.7	13.2	10.5	11.1	5.1	4.9	6.1	5.5	8.2	8.2	9.3
	315	10.9	7.1	7.9	6.2	4.8	3.7	4.6	4.4	5.2	7.9	6.4
	319	11.6	9.5	8.7	9.5	5.2	5.4	6.5	6.5	6.5	8.9	7.0
	320	10.6	8.4	6.2	6.8	3.9	3.3	4.4	3.7	5.3	6.0	6.4
	322	12.5	11.0	9.1	11.5	5.3	3.7	5.9	5.6	7.6	11.6	7.8
	325	11.4	9.3	8.0	7.3	4.1	3.9	4.7	4.1	4.8	1.9	6.1
	327	14.7	12.7	9.8	11.6	7.1	5.3	8.3	6.7	7.9	9.2	9.7
	330	12.6	10.4	9.2	7.8	4.8	4.6	7.1	5.4	5.9	7.8	6.8
	334	10.0	10.1	9.4	10.7	6.7	5.6	6.8	5.9	7.0	9.5	7.7
	336	11.3	8.8	7.9	7.4	4.8	3.9	4.7	3.7	4.3	6.2	6.1
	337	11.4	8.8	7.5	9.3	4.6	4.1	5.1	4.5	4.5	6.9	9.1
	338	13.7	11.3	10.4	10.2	6.2	5.6	5.0	5.2	5.6	7.7	8.8
	Ave.:	12.3	10.1	8.7	9.1	5.2	4.5	5.8	5.1	6.1	7.7	7.6
Vaccinates	309	13.4	6.5	8.0	8.1	8.4	7.7	8.5	7.8	7.3	8.0	8.7
	310	13.6	10.7	9.6	9.9	8.9	8.7	11.0	9.8	11.1	8.0	9.9
	311	13.4	10.5	7.7	8.2	2.2	8.7	8.5	7.1	9.3	10.3	7.7
	312	12.5	11.3	8.7	9.1	9.1	8.0	6.5	7.3	9.2	8.0	10.3
	313	10.2	9.4	7.4	6.8	6.4	6.3	7.6	8.4	8.8	8.3	8.6
	314	9.6	10.6	8.8	9.9	7.0	8.5	9.0	7.8	7.3	7.4	8.7
	316	11.2	11.0	8.2	9.9	9.8	9.3	8.8	8.5	8.3	8.0	9.3
	317	13.3	8.3	9.6	10.6	8.9	10.5	9.2	9.5	10.1	10.9	12.1
	318	13.4	9.4	8.2	9.3	7.7	7.8	9.0	7.2	8.7	9.2	10.1
	321	11.7	11.2	7.3	11.1	8.7	7.3	6.9	7.4	9.3	9.6	12.0
	323	14.7	13.6	12.3	12.7	11.0	10.9	9.8	9.4	8.9	8.1	10.9
	324	15.5	13.7	11.6	10.1	11.1	10.1	11.2	10.6	10.1	10.1	10.2
	326	12.9	9.8	7.3	8.6	8.0	8.1	9.1	8.1	7.5	8.1	11.3
	328	14.4	14.0	10.6	11.4	10.1	10.0	9.5	9.6	9.5	10.4	9.8
	329	11.9	11.4	11.4	12.1	9.4	10.4	9.4	8.7	8.2	10.4	10.4
	331	10.1	8.5	7.9	8.5	7.9	7.7	9.1	6.5	7.6	7.5	7.5
	332	11.2	11.0	10.2	9.5	9.4	9.3	9.0	8.5	9.5	9.0	8.7
	333	14.7	11.0	11.8	12.2	12.1	10.7	9.6	9.5	10.3	10.3	10.1
335	9.3	9.7	8.6	8.7	7.1	8.2	7.8	7.0	5.9	6.1	7.7	
339	11.8	9.6	8.7	9.1	8.4	6.7	7.9	6.8	7.2	7.6	8.4	
340	13.8	10.8	9.9	7.6	6.7	7.4	7.6	7.3	7.6	9.0	9.1	
341	8.4	11.3	11.4	13.5	10.2	11.2	10.8	8.6	8.1	9.5	8.4	
	Ave.:	12.3	10.6	9.3	9.9	8.6	8.8	8.9	8.2	8.6	8.8	9.5

Bold indicates leukopenia (>40% reduction in WBC count compared to baseline count)

Nasal Swab Virus Shedding Results

Group	ID	Nasal Virus Titer (Log ₁₀ TCID ₅₀ /mL)													
		Vac ¹	Day Post-Challenge												
		-1	0	1	2	3	4	5	6	7	8	9	10		
Controls	308	0	0	0	0	0	0	0	0	1.7	0	0	0		
	315	0	0	0	0	0	0	1.9	0	1.9	1.7	0	1.9		
	319	0	0	0	0	0	0	0	0	1.7	2.1	1.7	0	0	
	320	0	0	0	0	0	0	0	0	0	1.7	0	0	0	
	322	0	0	0	0	0	0	0	0	0	0	1.7	0	0	
	325	0	0	0	0	0	0	0	0	1.7	2.1	1.7	1.7	2.1	
	327	0	0	0	0	0	0	0	0	0	0	1.7	0	0	
	330	0	0	0	0	0	0	0	0	0	1.9	1.9	2.1	1.9	
	334	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	336	0	0	0	0	0	0	0	0	1.9	2.3	2.3	1.7	0	0
	337	0	0	0	0	0	0	0	0	1.7	1.7	1.7	0	0	0
	338	0	0	0	0	0	0	0	0	0	3.1	1.7	1.7	1.9	0
		Ave.:	0	0	0	0	0	0	0	0.6	1.5	1.3	0.6	0.7	0
Vaccinates	309	0	0	0	0	0	0	0	0	0	0	0	0	0	
	310	0	0	0	0	0	0	0	0	0	0	0	0	0	
	311	0	0	0	0	0	0	0	0	0	0	0	0	0	
	312	0	0	0	0	0	0	0	0	0	0	0	0	0	
	313	0	0	0	0	0	0	0	0	0	0	0	0	0	
	314	0	0	0	0	0	0	0	0	0	0	0	0	0	
	316	0	0	0	0	0	0	0	0	0	0	0	0	0	
	317	0	0	0	0	0	0	0	0	0	0	0	0	0	
	318	0	0	0	0	0	0	0	0	0	0	0	0	0	
	321	0	0	0	0	0	0	0	0	0	0	0	0	0	
	323	0	0	0	0	0	0	0	0	0	0	0	0	0	
	324	0	0	0	0	0	0	0	0	0	0	0	0	0	
	326	0	0	0	0	0	0	0	0	0	0	0	0	0	
	328	0	0	0	0	0	0	0	0	0	0	0	0	0	
	329	0	0	0	0	0	0	0	0	0	0	0	0	0	
	331	0	0	0	0	0	0	0	0	0	0	0	0	0	
	332	0	0	0	0	0	0	0	0	0	0	0	0	0	
	333	0	0	0	0	0	0	0	0	0	0	0	0	0	
	335	0	0	0	0	0	0	0	0	0	0	0	0	0	
	339	0	0	0	0	0	0	0	0	0	0	0	0	0	
340	0	0	0	0	0	0	0	0	0	0	0	0	0		
341	0	0	0	0	0	0	0	0	0	0	0	0	0		
	Ave.:	0	0	0	0	0	0	0	0	0	0	0	0	0	

¹ Prior to vaccination, Study day 0

Clinical Observations Post-Challenge

Group	ID	Day Post-Challenge														Affected*		
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12		13	14
Controls	308	0	0	0	0	0	0	0	C1	0	N2	0	D2	D2,N1	0	0	0	Yes
	315	0	C1	0	0	0	0	C1	C1	C2	C2	C2	N2,C1	N2,C2	0	0	C2	Yes
	319	0	0	0	0	0	0	0	0	N2	N2	0	N1,C1	N1	N1	0	0	Yes
	320	0	0	0	0	0	0	0	0	0	0	0	N1	0	0	0	0	No
	322	0	0	0	0	0	0	0	0	0	0	N1	0	0	0	0	0	No
	325	0	0	0	0	0	0	0	0	0	0	0	N1	N1	N1	0	C1	No
	327	0	0	0	0	0	N1	N1	N1	0	N2	0	N1	N1	N2	0	0	Yes
	330	0	0	0	0	0	0	0	0	0	0	0	0	D2,N1	D1	0	0	Yes
	334	0	0	0	0	0	0	C1	0	0	C2	0	0	0	N1	0	0	No
	336	0	0	0	0	0	0	0	0	0	N1,C1	0	0	0	0	0	0	No
	337	0	0	0	0	0	0	0	0	0	0	0	C1	0	0	0	0	No
	338	0	0	0	0	0	0	0	0	0	0	0	N1	D2,N1	0	0	0	Yes
	Vaccinates	309	0	0	0	0	0	0	0	0	0	0	0	D1	0	0	0	No
310		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
311		0	0	0	0	0	0	0	0	0	0	0	0	D1	0	0	0	No
312		0	0	0	0	0	0	0	0	0	0	0	0	C1	0	0	0	No
313		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
314		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
316		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
317		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
318		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
321		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
323		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
324		0	0	0	0	0	N1	0	0	0	N1	N1	0	C1	0	0	0	No
326		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
328		0	0	0	0	0	0	0	0	0	0	0	0	D1	C1	0	0	No
329		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
331		0	0	0	0	0	0	0	N1	N1	D1,N1	D2	0	0	0	0	0	Yes
332		0	0	0	0	0	0	0	0	0	0	0	D1	0	0	0	0	No
333		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
335		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No
339		0	0	0	0	0	0	0	0	0	0	0	0	D1	0	0	0	No
340	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No	
341	0	0	0	0	0	0	0	C1	0	0	0	0	0	0	0	0	No	

Clinical Description: 0 = Normal, C = Cough, D = Diarrhea, N = Nasal Discharge

*An affected calf is one with a moderate to severe clinical sign of diarrhea, nasal discharge or depression on any post-challenge day

Clinical Score	Diarrhea	Nasal Discharge	Depression	Dyspnea	Cough
0	None	None	None	None	None
1	Soft feces	Serous discharge	Moves slowly, head down	Short and rapid	< 3 episodes
2	Watery diarrhea	Mucopurulent discharge	Tends to lie down, staggers	Labored, noticeable abdominal	> 3 episodes
3	Watery and bloody diarrhea	Severe mucopurulent discharge	Stands with difficulty	Very labored, grunting	NA

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 2 (BVDV2)
Study Purpose	To demonstrate efficacy against respiratory disease caused by BVDV2.
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV2a strain 1373
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	December 10, 2003

Study Type	Efficacy
Pertaining to	Bovine Viral Diarrhea Virus Type 1 (BVDV2)
Study Purpose	To demonstrate efficacy against persistent infection of calves caused by BVDV2
Product Administration	
Study Animals	Bovine
Challenge Description	BVDV Type 2 strain SD02 BVD05
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	April 25, 2005

Study Type	Efficacy																																																
Pertaining to	Bovine Viral Diarrhea Virus Type 2 (BVDV2)																																																
Study Purpose	To demonstrate efficacy against respiratory disease caused by BVDV2 1 year after vaccination.																																																
Product Administration	1 dose administered by the subcutaneous route																																																
Study Animals	40 calves, 3 months of age; 20 vaccinates, 20 controls																																																
Challenge Description	All calves were challenged with BVDV2a strain 1373 384 days after vaccination.																																																
Interval observed after challenge	All calves were monitored daily for 14 days post-challenge for clinical signs of disease.																																																
Results	<p><u>Mortality:</u> An affected calf was one that died or was humanely euthanized due to severe BVDV2 disease during the post-challenge period.</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th># Affected</th> <th>Percent (%)</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>20</td> <td>0</td> <td>0</td> </tr> <tr> <td>Controls</td> <td>20</td> <td>11*</td> <td>55</td> </tr> </tbody> </table> <p>* An additional 7 control calves either died or were euthanized by day 16 post-challenge (2 days after the post-challenge observation period) due to severe BVDV2 clinical disease, bringing the mortality rate to 90% for control calves.</p> <p><u>Leukopenia:</u> An affected calf was one that showed a post-challenge WBC count $\leq 60\%$ of the baseline WBC count, and/or $\leq 4.0 \times 10^3$ WBC/μL.</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th># Affected</th> <th>Percent (%)</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>20</td> <td>3</td> <td>15</td> </tr> <tr> <td>Controls</td> <td>20</td> <td>19</td> <td>95</td> </tr> </tbody> </table> <p><u>Virus Shedding:</u> An affected calf was one in which nasal virus shedding was detected on any day post-challenge.</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th># Affected</th> <th>Percent (%)</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>20</td> <td>0</td> <td>0</td> </tr> <tr> <td>Controls</td> <td>20</td> <td>20</td> <td>100</td> </tr> </tbody> </table> <p><u>Clinical Observations:</u> An affected calf showed moderate to severe signs of acute BVD2 (i.e. moderate to severe diarrhea, nasal discharge, depression, dyspnea, oral lesions, or mortality) on any day during the observation period.</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th># Affected*</th> <th>Percent (%)</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>20</td> <td>2</td> <td>10</td> </tr> <tr> <td>Controls</td> <td>20</td> <td>20</td> <td>100</td> </tr> </tbody> </table> <p>Raw data shown on attached pages.</p>	Group	# of Animals	# Affected	Percent (%)	Vaccinates	20	0	0	Controls	20	11*	55	Group	# of Animals	# Affected	Percent (%)	Vaccinates	20	3	15	Controls	20	19	95	Group	# of Animals	# Affected	Percent (%)	Vaccinates	20	0	0	Controls	20	20	100	Group	# of Animals	# Affected*	Percent (%)	Vaccinates	20	2	10	Controls	20	20	100
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Vaccinates	20	2	10																																														
Controls	20	20	100																																														
USDA Approval Date	September 19, 2014																																																

White Blood Cell (WBC) Counts (x 10³/μL)

Group	ID	Day Post-Challenge														
		-2	-1	0	Baseline	2	3	4	5	6	7	8	9	10	12	14
Controls	195	11.1	11.0	11.1	11.1	11.4	6.7	6.6	6.1	6.3	7.1	6.7	4.9	4.3	4.4	3.9
	198	10.6	11.2	10.7	10.8	9.4	5.8	5.2	4.9	5.0	4.8	4.0	6.4	7.0	Dead	Dead
	199	8.4	8.4	9.8	8.9	8.6	5.2	5.3	5.5	5.8	4.9	3.9	4.0	2.7	3.1	Dead
	202	7.0	6.5	7.0	6.8	7.4	3.7	4.4	4.1	4.3	4.3	3.4	4.8	6.5	4.3	7.2
	204	11.1	8.8	16.7	12.2	14.7	8.0	8.5	8.8	8.4	10.0	7.4	5.8	4.0	4.4	Dead
	206	9.1	8.9	8.5	8.8	8.5	4.4	4.9	4.7	4.5	4.9	3.5	2.5	2.7	2.2	Dead
	207	9.9	10.5	9.9	10.1	9.8	5.3	6.7	7.5	6.6	6.2	5.5	3.9	3.6	5.2	Dead
	209	11.9	11.5	10.7	11.4	11.6	6.6	8.5	6.8	7.4	7.1	5.1	4.0	4.6	Dead	Dead
	211	8.1	8.5	8.1	8.2	7.8	4.9	6.6	5.5	5.1	4.9	3.8	3.2	2.4	1.9	Dead
	212	11.4	13.5	9.9	11.6	7.7	5.7	5.0	6.1	6.1	6.0	5.3	3.9	3.0	3.7	3.0
	213	10.5	8.6	8.4	9.2	9.8	6.5	6.8	6.3	6.3	5.0	5.3	2.8	2.1	2.2	1.4
	218	10.9	10.3	10.3	10.5	9.6	5.6	6.5	6.4	6.1	5.8	8.3	11.3	10.7	7.5	8.8
	219	14.5	15.0	14.1	14.5	14.5	10.7	11.5	10.2	10.8	8.4	8.9	5.6	5.0	6.6	Dead
	220	9.2	8.8	8.4	8.8	8.3	7.1	6.5	5.5	5.6	5.2	5.6	4.9	3.6	3.9	3.0
	221	9.3	10.0	10.3	9.9	8.1	6.5	6.0	6.9	6.1	4.7	3.2	2.8	2.6	1.6	Dead
	222	11.1	8.3	8.7	9.4	10.0	5.6	6.1	6.2	7.1	6.0	5.7	5.6	11.1	Dead	Dead
	223	16.2	14.7	15.9	15.6	13.6	12.0	12.3	11.4	11.2	9.7	9.4	6.8	5.3	4.2	Dead
	227	12.1	10.6	10.6	11.1	12.0	8.7	7.9	8.7	8.4	7.8	7.6	9.6	10.1	10.6	9.2
	230	11.6	11.2	11.3	11.4	11.9	9.3	8.6	8.5	8.4	8.4	6.2	6.4	7.5	8.2	13.0
	231	7.3	7.1	7.3	7.2	7.6	6.9	6.0	6.5	5.2	5.1	3.8	3.9	3.4	3.0	1.8
	Ave.:				10.4	10.1	6.8	7.0	6.8	6.7	6.3	5.6	5.2	5.1	4.5	5.7
Vaccinates	194	18.4	17.3	18.7	18.1	18.9	16.7	13.9	15.1	16.7	18.7	16.2	16.4	17.2	16.4	17.1
	196	8.1	7.5	8.4	8.0	9.4	10.5	7.6	5.9	7.3	6.9	7.7	7.6	8.3	8.8	8.1
	197	14.6	13.7	14.0	14.1	13.5	13.8	13.2	12.5	11.3	12.5	11.6	13.1	13.1	13.3	13.4
	200	8.1	8.7	10.4	9.1	12.5	9.3	9.0	8.4	8.0	7.7	9.6	8.5	7.9	7.4	7.2
	201	10.8	9.8	8.5	9.7	8.2	7.3	5.2	6.5	5.8	7.9	8.4	8.3	7.8	7.1	7.4
	203	9.8	10.7	10.5	10.3	8.4	5.1	5.4	5.6	6.7	6.6	10.6	10.7	8.0	8.8	6.6
	205	9.3	10.7	10.9	10.3	9.3	8.0	6.8	5.5	6.4	9.6	10.5	10.6	9.8	9.5	9.9
	208	8.6	9.9	8.5	9.0	8.3	9.0	9.7	7.1	7.7	7.0	8.9	9.2	9.8	6.9	7.6
	210	11.1	11.0	11.1	11.1	11.9	9.7	8.9	9.1	10.4	10.0	11.1	9.5	9.1	9.7	9.0
	214	15.5	18.2	15.7	16.5	22.6	16.4	15.1	13.1	13.0	15.4	15.8	15.4	18.6	14.1	14.2
	215	8.4	9.5	8.8	8.9	8.3	8.0	6.9	6.5	6.6	8.4	8.7	9.1	8.9	8.9	8.9
	216	10.1	10.5	11.0	10.5	12.1	9.8	7.0	6.7	6.8	8.2	10.3	9.1	9.1	8.2	8.6
	217	12.1	13.6	13.2	13.0	13.4	13.7	12.5	11.2	12.4	14.7	14.1	12.8	10.2	10.9	12.3
	224	10.4	9.0	8.6	9.3	10.7	9.5	7.7	7.5	7.2	9.3	7.7	8.1	10.5	8.8	10.5
	225	10.7	11.5	10.5	10.9	10.3	11.3	10.5	8.0	7.8	7.5	10.8	10.6	12.5	10.7	10.4
	226	9.2	8.3	9.7	9.1	10.4	9.9	9.1	9.1	8.4	8.4	8.7	9.3	10.2	8.7	9.0
	228	8.3	8.0	7.4	7.9	8.4	7.7	6.4	5.4	6.4	7.1	9.4	7.9	8.6	7.2	7.1
	229	7.4	7.6	7.0	7.3	7.2	7.3	7.0	7.3	6.8	6.6	6.9	6.3	5.5	7.1	7.5
232	11.1	10.7	11.3	11.0	10.7	10.0	8.7	8.5	8.2	12.0	10.3	9.3	9.4	7.6	8.0	
233	15.3	16.2	14.0	15.2	14.1	13.8	11.6	11.6	11.2	13.9	13.4	14.2	14.1	14.8	12.9	
	Ave.:				11.0	11.4	10.3	9.1	8.5	8.8	9.9	10.5	10.3	10.4	9.7	9.8

Bold indicates leukopenia (WBC count ≤ 60% of baseline count, and/or WBC count ≤ 4.0 x 10³/μL)

Nasal Swab Virus Shedding Results

Group	ID	Nasal Virus Titer (Log ₁₀ FAID ₅₀ /mL) Day Post-Challenge														
		Vac. ¹	-1	0	1	2	3	4	5	6	7	8	9	10	12	14
Controls	195	0	0	0	0	0	0	0	0	0	0	1.7	2.3	2.5	1.7	C ²
	198	0	0	0	0	0	0	0	0	1.7	2.5	2.5	2.5	1.7	Dead	Dead
	199	0	0	0	0	0	0	0	0	0	0	1.9	2.5	2.5	0	Dead
	202	0	0	0	0	0	0	1.7	0	1.9	2.3	1.7	2.3	2.1	0	0
	204	0	0	0	0	0	0	0	0	0	0	1.9	2.9	3.9	2.5	Dead
	206	0	0	0	0	0	0	0	0	0	2.1	0	2.1	3.1	0	Dead
	207	0	0	0	0	0	0	0	0	1.9	0	2.5	2.7	2.9	2.7	Dead
	209	0	0	0	0	0	0	0	0	0	1.7	2.3	2.5	2.9	Dead	Dead
	211	0	0	0	0	0	0	0	1.7	1.9	0	2.1	3.5	3.5	3.9	Dead
	212	0	0	0	0	0	0	0	0	0	0	1.7	2.7	2.3	0	0
	213	0	0	0	0	0	0	0	0	0	1.9	2.3	3.5	3.5	3.3	2.1
	218	0	0	0	0	0	0	0	0	0	0	0	1.7	0	0	0
	219	0	0	0	0	0	0	0	0	0	1.9	2.1	0	2.7	1.7	Dead
	220	0	0	0	0	0	0	0	0	0	0	2.3	2.7	3.5	3.5	3.9
	221	0	0	0	0	0	0	0	1.7	0	2.3	2.1	3.9	3.5	4.1	Dead
	222	0	0	0	0	0	0	0	0	0	1.9	2.5	2.9	2.5	Dead	Dead
	223	0	0	0	0	0	0	0	0	0	0	1.9	2.3	2.5	0	Dead
227	0	0	0	0	0	0	0	0	0	0	0	0	1.9	0	0	
230	0	0	0	0	0	0	0	0	0	1.9	1.7	3.1	1.9	0	0	
231	0	0	0	0	0	0	0	0	0	0	0	3.1	2.3	1.9	1.7	
	Ave.:	0	0	0	0	0	0	0.1	0.2	0.4	0.9	1.7	2.5	2.6	1.5	1.0
Vaccinates	194	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	196	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	197	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	200	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	201	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	203	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	205	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	208	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	210	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	214	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	215	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	216	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	217	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	224	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	225	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	226	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	228	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
229	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
232	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
233	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	Ave.:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

¹Prior to vaccination, Study day 0

²Contaminated sample

Clinical Observation Post-Challenge

Group	ID	Day Post-Challenge														Affected	Died/Euthanized		
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12			13	14
Controls	195	0	0	0	0	0	0	0	N1	N1	N1	N1,OL1	N2,D2,A1,OL3	NA	N2,D3,A1,R1,OL3	D3,A2,R2,OL3	Yes	No ¹	
	198	0	0	0	0	0	0	0	N1,C1	N1	N1	N1,OL1	Died	NA	NA	NA	Yes	Yes	
	199	0	0	0	0	0	0	0	N1	N1	N1	N3,OL1	N3,D2,A3,R2,OL3,Euth.	NA	NA	NA	Yes	Yes	
	202	0	0	0	0	0	0	0	0	0	N2,D1	N3,A1,OL1	N3,D2,OL2	N1,A1	N2,A1,OL2		Yes	No ¹	
	204	N1	0	0	0	0	0	0	N1	N1	N1,D1	N2,OL2	N1,D1,A1,OL2	Died	NA	NA	Yes	Yes	
	206	0	0	0	0	0	0	0	N1	0	N1	N3,OL2	N3,D1,A2,R2,OL2	Died	NA	NA	Yes	Yes	
	207	N1	0	0	0	0	0	0	N1	N1,D1	N1	N1,D2,A1	N3,D3,R2,A3,Euth.	NA	NA	NA	Yes	Yes	
	209	0	0	0	0	0	0	0	0	0	N1	N1,D2	N1,D2,A1,R2,OL1	Died	NA	NA	Yes	Yes	
	211	0	0	0	0	0	0	0	N1	N1,D1	N1	N1,D2,A1	N3,A1,OL2	N2,D2,A2,OL3,Euth.	NA	NA	Yes	Yes	
	212	N1	0	0	0	0	0	0	N1	N1	N1	N3,D1	N1	N2,D1,A1	N1,A1,OL1	NA	Yes	No ¹	
	213	N1	0	0	0	0	0	0	N1	N1	N1	N2,OL2	N1,OL2	A1,OL3,Bleeding	N1,A2,R2,OL3		Yes	No ¹	
	218	N1	0	0	0	0	0	0	N1	N1	N2	N2	N1	N1	N1	N1	Yes	No	
	219	0	0	0	0	0	0	0	N1	0	N1	N3,OL2	N2,A1,OL2	N2,D2,A3,R2,OL2,Euth.	NA	NA	Yes	Yes	
	220	N1	0	0	0	0	0	0	N1	N1	N1	N1	N1	N2,A1	N3,A1	N2,A1,OL2	Yes	No ¹	
	221	0	0	0	0	0	0	0	N1	N2	N1	N1	N2,D1,A1,OL3	N2,OL3	Died	NA	Yes	Yes	
	222	N1	0	0	0	0	0	0	N1	N1	N2	N1,OL1	N1	Died	NA	NA	Yes	Yes	
	223	N1	0	0	0	0	0	0	N1	N1	N1	N1	N1,A2,R2	N1,A3,R3,Euthanized	NA	NA	Yes	Yes	
	227	0	0	0	0	0	0	0	N1	N1	N1	N2,D2,A1,OL1	N1,D2,A1	0	N1,A1		Yes	No ¹	
	230	0	0	0	0	0	0	0	N1	N2	N1	N2	N2,A1,R1,OL1	N1,OL1	N2,A2,OL1,Bleeding	A2,OL2	Yes	No ¹	
	231	0	0	0	0	0	0	0	N1	N1	N1	N1	N1,D1	N2,OL3	N3,D2,A1	N1,D2,A1	Yes	No ¹	
	Vaccinates	194	0	0	0	0	0	0	0	0	0	N1	0	0	0	N1	0	No	No
		196	0	0	0	0	0	0	0	N1	0	N1	N1	N1	N1	N1	N1	No	No
		197	0	0	0	0	0	0	0	N1	0	N1	N1	N1	N1	N1	0	No	No
200		0	0	0	0	0	0	0	0	0	N1	0	N1	N1	N1	0	No	No	
201		N1	0	0	0	0	0	0	0	0	N1	0	N1	N1	0	0	0	No	No
203		0	0	0	0	0	0	0	N1	N1,D1	D1	N1,D1	N1,D1	0	0	0	0	No	No
205		N1	0	0	0	0	0	0	N1	N1	N1	N1	0	N2	N1	N1	N1	Yes	No
208		0	0	0	0	0	0	0	N1	0	N1	N1	N1	N1	N1	0	0	No	No
210		0	0	0	0	0	0	0	N1	0	0	N1	N1	N1	N1	N1	0	No	No
214		0	0	0	0	0	0	0	N1	0	N1	N1	N1	N1	N1	N1	0	No	No
215		0	0	0	0	0	0	0	N1	N1	N1	N1	N1,D1	N1,D1	N1,D1	N1	N1	No	No
216		0	0	0	0	0	0	0	N1	N1	N1	N1	N1,D1	0	N1	0	0	No	No
217		0	0	0	0	0	0	0	N1	D1	N1,D1	N1	N1	N1	N1	N1	N1	No	No
224	0	0	0	0	0	0	0	N1	0	N1	N1	N1,D1	0	N1,D1	N1	N1	No	No	
225	0	0	0	0	0	0	0	0	0	0	N1	N1	N1	N1	N1	0	No	No	
226	0	0	0	0	0	0	0	0	0	0	N1	N1,D1	0	N1	0	0	No	No	
228	N1	0	0	0	0	0	0	N1	0	0	N1,D1	0	N1	0	0	0	No	No	
229	0	0	0	0	0	0	0	N1,D1	0	0	N2	N1	N1	N2	N1	N1	Yes	No	
232	0	0	0	0	0	0	0	N1	0	0	N1	0	N1	0	0	0	No	No	
233	N1	0	0	0	0	0	0	N1	0	N1	N1	N1	0	N1	N1	0	No	No	

Clinical Descriptions: 0 = Normal, N = Nasal Discharge, D = Diarrhea, A = Depression, R = Dyspnea, OL = Oral Lesion, NA = Not observed, Severity: 1 = mild, 2 = moderate, 3 = severe
¹Animal died or was euthanized by 16 days post-challenge (20-Dec-13)

Clinical Score	Diarrhea	Nasal Discharge	Depression (Attitude)	Dyspnea	Oral Lesions
0	None	None	Normal	None	None
1	Soft feces	Serous discharge	Moves slowly, head down	Short and rapid	Erosions on oral mucosa
2	Watery diarrhea	Mucopurulent discharge	Tends to lie down, staggers	Labored, abdominal breathing	Ulcerations on oral mucosa
3	Watery and bloody diarrhea	Severe mucopurulent	Stands with difficulty	Very labored, grunts or raspy breathing	Hemorrhages on oral mucosa

Study Type	Efficacy																								
Pertaining to	Bovine Viral Diarrhea Virus Type 2 (BVDV2)																								
Study Purpose	To demonstrate efficacy against fetal infection caused by BVDV2 206 days after vaccination.																								
Product Administration	1 dose administered by the subcutaneous route 28 days prior to breeding.																								
Study Animals	46 seronegative heifers, 28 vaccinates and 18 controls.																								
Challenge Description	All heifers were challenge with BVDV2 strain IV809-04 at 164-178 days of gestation.																								
Interval observed after challenge	Blood samples were collected on days 0, 5 through 10 post challenge for virus isolation. Fetuses were collected on day 60 after challenge.																								
Results	<p><u>Virus Isolation on heifers:</u></p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th># Affected</th> <th>Percent (%)</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>28</td> <td>2</td> <td>7</td> </tr> <tr> <td>Controls</td> <td>18</td> <td>18</td> <td>100</td> </tr> </tbody> </table> <p><u>Virus Isolation from fetal samples:</u> Calves (fetuses) were considered positive if virus was isolated from any fetal tissue (lung, spleen, thymus, kidney, buffy coat).</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th># Affected</th> <th>Percent (%)</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>28</td> <td>2</td> <td>4</td> </tr> <tr> <td>Controls</td> <td>18</td> <td>17</td> <td>94</td> </tr> </tbody> </table> <p>Raw data shown on attached pages.</p>	Group	# of Animals	# Affected	Percent (%)	Vaccinates	28	2	7	Controls	18	18	100	Group	# of Animals	# Affected	Percent (%)	Vaccinates	28	2	4	Controls	18	17	94
Group	# of Animals	# Affected	Percent (%)																						
Vaccinates	28	2	7																						
Controls	18	18	100																						
Group	# of Animals	# Affected	Percent (%)																						
Vaccinates	28	2	4																						
Controls	18	17	94																						
USDA Approval Date	October 4, 2007																								

Viremia of Challenged Heifers

(Vaccinate Group)

Heifer Number	Isolation of BVDV from Buffy-coats at Days post-challenge							
	0	5	6	7	8	9	10	
1536	0	0	0	0	0	0	0	
1538	0	0	0	0	0	0	0	
1541	0	0	0	0	0	0	0	
1544	0	0	1	0	0	0	0	
1545	0	0	0	0	0	0	0	
1556	0	0	0	0	0	0	0	
1558	0	0	0	0	0	0	0	
1562	0	0	0	0	0	0	0	
1566	0	0	0	0	0	0	0	
1567	0	0	0	0	0	0	0	
1569	0	0	0	0	0	0	0	
1570	0	0	0	0	0	0	0	
1575	0	0	0	0	0	0	0	
1581	0	0	0	0	0	0	0	
1582	0	0	0	0	0	0	0	
1585	0	0	1	0	0	0	0	
1594	0	0	0	0	0	0	0	
1596	0	0	0	0	0	0	0	
1597	0	0	0	0	0	0	0	
1598	0	0	0	0	0	0	0	
1599	0	0	0	0	0	0	0	
1601	0	0	0	0	0	0	0	
1605	0	0	0	0	0	0	0	
1606	0	0	0	0	0	0	0	
1607	0	0	0	0	0	0	0	
1608	0	0	0	0	0	0	0	
1609	0	0	0	0	0	0	0	
1614	0	0	0	0	0	0	0	

0=negative; 1=positive.

(Control Group)

Heifer Number	Isolation of BVDV from Buffy-coats at Days post-challenge							
	0	5	6	7	8	9	10	
1540	0	1	1	1	1	0	0	
1542	0	1	1	0	1	0	0	
1543	0	1	1	1	1	0	1	
1546	0	0	1	1	1	0	0	
1549	0	1	1	1	1	1	0	
1553	0	1	1	1	1	1	0	
1557	0	0	1	1	1	0	0	
1571	0	1	1	1	1	0	0	
1572	0	1	1	0	1	0	0	
1573	0	1	1	1	1	0	0	
1574	0	1	1	1	0	1	0	
1577	0	1	1	1	0	0	0	
1586	0	1	1	1	0	0	0	
1590	0	1	1	1	0	0	0	
1591	0	1	1	1	1	1	0	
1593	0	1	1	1	1	1	0	
1595	0	1	1	1	1	1	0	
1615	0	1	0	0	0	1	0	

0=negative; 1=positive.

Virus Isolation from Fetal Samples

Groups	Heifer ID	Virus isolations					VI Results
		Thymus	Spleen	Lung	Kidney	Buffy-coats	
Vaccinate	1536	0	0	0	0	0	0
	1538	0	0	0	0	0	0
	1541	0	0	0	0	0	0
	1544	0	0	0	0	0	0
	1545	1	1	1	0	1	1
	1556	0	0	0	0	0	0
	1558	0	0	0	0	0	0
	1562	0	0	0	0	0	0
	1566	0	0	0	0	0	0
	1567	0	0	0	0	0	0
	1569	0	0	0	0	0	0
	1570	0	0	0	0	0	0
	1575	0	0	0	0	0	0
	1581	0	0	0	0	0	0
	1582	0	0	0	0	0	0
	1585	0	0	0	0	0	0
	1594	0	0	0	0	0	0
	1596	0	0	0	0	0	0
	1597	0	0	0	0	0	0
	1598	0	0	0	0	0	0
	1599	0	0	0	0	0	0
1601	0	0	0	0	1	1	
1605	0	0	0	0	0	0	
1606	0	0	0	0	0	0	
1607	0	0	0	0	0	0	
1608	0	0	0	0	0	0	
1609	0	0	0	0	0	0	
1614	0	0	0	0	0	0	

Groups	Heifer ID	Virus isolations					VI Results
		Thymus	Spleen	Lung	Kidney	Buffy-coats	
Controls	1540	1	1	1	1	1	1
	1542	1	1	1	1	0	1
	1543	0	0	0	0	1	1
	1546	0	0	0	0	1	1
	1549	1	1	1	1	1	1
	1553	1	1	1	1	1	1
	1557	1	1	1	1	1	1
	1571	0	0	0	0	0	0
	1572	0	0	0	0	1	1
	1573	0	0	0	0	1	1
	1574	1	1	1	1	0	1
	1577	0	0	0	0	1	1
	1586	1	1	1	1	0	1
	1590	1	1	1	1	0	1
	1591	1	1	1	1	0	1
	1593	0	1	0	1	1	1
	1595	1	1	1	1	1	1
1615	0	0	0	0	1	1	

Study Type	Efficacy
Pertaining to	Infectious Bovine Rhinotracheitis (IBR)
Study Purpose	To demonstrate effectiveness against disease caused by IBR
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 29, 2004

Study Type	Efficacy
Pertaining to	Infectious Bovine Rhinotracheitis (IBR)
Study Purpose	To demonstrate effectiveness against abortions caused by IBR
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 27, 2005

Study Type	Efficacy																		
Pertaining to	Bovine Rhinotracheitis Virus (IBR)																		
Study Purpose	To demonstrate efficacy against infectious bovine rhinotracheitis 1 year after vaccination.																		
Product Administration	1 dose administered by the subcutaneous route																		
Study Animals	39 three-month-old male calves; 20 controls, 19 vaccinates																		
Challenge Description	All calves were challenged with IBR 1 year (364 days) after vaccination.																		
Interval observed after challenge	All calves were monitored daily for 14 days post-challenge for clinical signs of acute IBR. Nasal swabs were evaluated daily for 10 days post-challenge.																		
Results	<p><u>Clinical Signs:</u> An affected calf was defined as displaying severe nasal or ocular discharge, cough, depressions, dyspnea, and/or nasal lesions on any post-challenge day.</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th># Affected</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>19</td> <td>1 (5%)</td> </tr> <tr> <td>Controls</td> <td>20</td> <td>18 (90%)</td> </tr> </tbody> </table> <p><u>Nasal Virus Shedding:</u> An affected calf was one in which nasal virus shedding was detected on any day post-challenge to evaluated duration of shedding</p> <table border="1"> <thead> <tr> <th>Group</th> <th># of Animals</th> <th># Affected</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>19</td> <td>19</td> </tr> <tr> <td>Controls</td> <td>20</td> <td>20</td> </tr> </tbody> </table> <p>* All control calves were still shedding virus on day 10 post-challenge.</p> <p>Raw data shown on attached pages.</p>	Group	# of Animals	# Affected	Vaccinates	19	1 (5%)	Controls	20	18 (90%)	Group	# of Animals	# Affected	Vaccinates	19	19	Controls	20	20
Group	# of Animals	# Affected																	
Vaccinates	19	1 (5%)																	
Controls	20	18 (90%)																	
Group	# of Animals	# Affected																	
Vaccinates	19	19																	
Controls	20	20																	
USDA Approval Date	August 20, 2014																		

Clinical Observations Scoring

Nasal / Ocular Discharge

- 0 = Normal – dry and clean nose or eyes
- 1 = Mild – serous discharge
- 3 = Severe – mucopurulent discharge

Cough

- 0 = Normal – no cough
- 1 = Mild – occasional cough
- 3 = Severe – repeated cough

Attitude / Depression

- 0 = Normal – normal in activities
- 1 = Mild – head down, moves slowly, nearly normal appetite
- 3 = Severe – stands with difficulty, moves or responds to stimuli reluctantly, little interest in surroundings

Dyspnea

- 0 = Normal – breathing normally
- 1 = Mild – slight difficulty breathing, short and rapid breathing
- 3 = Severe – labored abdominal breathing, audible grunts or raspy breathing

Nasal Lesions

- 0 = Normal – no lesions on nasal mucosa
- 1 = Mild – white-colored lesions
- 3 = Severe – bloody or red colored lesions

Clinical Observations Post-Challenge

Group	ID	Day Post-Challenge														Affected*			
		-1	0	1	2	3	4	5	6	7	8	9	10	11	12		13	14	
Vaccinates	505	ND1	0	ND1	0	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1	ND1	ND1	ND1	ND1	No	
	507	0	0	0	0	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	0	ND1	ND1	No	
	508	0	0	0	0	NL1	NL1	NL1	NL1	NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	0	ND1	0	No	
	510	0	0	0	0	NL1	NL1	NL1	NL1	NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	0	ND1	0	No	
	512	0	0	0	0	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1	ND1	0	No
	513	0	0	0	0	NL1	ND1,NL1	ND1	ND1	0	No								
	516	0	0	ND1	0	NL1	NL1	NL1	NL1	NL1	NL1	0	NL1	0	0	0	0	0	No
	520	0	0	ND1	ND1	NL1	ND1,NL1	0	ND1	ND1	0	No							
	522	0	0	0	0	NL1	ND1,NL1	0	ND1	ND1	0	No							
	523	0	0	0	0	ND1,NL1	0	ND1	ND1	0	No								
	524	0	0	0	0	ND1,NL1	ND1,NL1	ND1	No										
	527	0	0	0	0	NL1	NL1	NL1	NL1	NL1	NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	0	0	0	No
	532	0	0	0	0	ND1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1	ND1	0	0	0	0	No
	533	0	0	0	0	ND1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	ND1,NL1	NL1	NL1	NL1	0	0	0	No
	536	0	0	0	0	NL1	ND1,NL1	ND3	ND3	ND1	ND1	Yes							
	540	0	0	0	0	NL1	NL1	NL1	NL1	NL1	NL1	0	0	0	0	0	0	0	No
	541	0	0	0	0	NL1	ND1,NL1	ND1	ND1	ND1	No								
542	0	0	0	0	NL1	ND1,NL1	ND1,NL1	ND1,NL1	NL1	ND1,NL1	0	ND1	ND1	0	0	0	0	No	
543	0	0	0	0	NL1	ND1,NL1	ND1,NL1	NL1	ND1,NL1	ND1,NL1	NL1	ND1	ND1	NL1	NL1	0	0	No	
Controls	504	0	0	0	0	NL1	ND1,NL1	ND1,NL1	Yes										
	506	0	0	0	0	NL1	ND1,NL1	ND1,NL1	Yes										
	509	0	0	ND1	0	NL1	ND1,NL1	ND1,NL1	Yes										
	511	0	0	0	0	NL1	ND1,NL1	ND1,NL1	Yes										
	514	0	0	0	0	NL1	ND1,NL1	ND1,NL1	Yes										
	515	0	0	0	0	NL1	ND1,NL1	ND1,NL1	Yes										
	517	0	0	0	0	NL1	ND1,NL1	ND1,NL1	No										
	518	0	0	0	0	NL1	NL1	NL1	NL1	NL1	NL1	ND3,NL1	ND3,NL1	ND3,NL1	ND3,NL1	ND3,NL1	ND3,NL1	Yes	
	519	0	0	0	0	NL1	ND1,NL1	ND1,NL1	Yes										
	521	0	0	0	0	NL1	ND1,NL1	ND1,NL1	Yes										
	525	0	0	0	0	NL1	ND1,NL1	ND1,NL1	Yes										
	526	0	0	0	0	NL1	ND1,NL1	ND1,NL1	Yes										
	528	ND1	0	0	0	NL1	ND1,NL1	ND1,NL1	Yes										
	529	0	0	0	0	NL1	ND1,NL1	ND1,NL1	Yes										
	530	0	0	0	0	NL1	ND1,NL1	ND1,NL1	Yes										
	531	ND1	0	0	0	NL1	ND1,NL1	ND1,NL1	Yes										
	534	0	0	0	0	NL1	ND1,NL1	ND1,NL1	Yes										
535	0	0	0	0	NL1	ND1,NL1	No												
538	0	0	0	0	NL1	ND1,NL1	Yes												
539	0	0	0	0	NL1	ND1,NL1	Yes												

000026

*An affected calf is one with a severe clinical sign on any post-challenge day
 0 = Normal, ND = Nasal Discharge, C = Cough, A = Attitude (Depression), D = Dyspnea, NL = Nasal Lesions, Severity: 1 = Mild, 3 = Severe

Nasal Swab Virus Shedding Results

Group	Calf ID	Vac. ¹	Nasal Virus Titer (Log ₁₀ TCID ₅₀ /mL) Day Post-Challenge											
			-1	0	1	2	3	4	5	6	7	8	9	10
Vaccinates	505	0	0	0	4.3	6.5	6.7	6.5	6.5	5.9	2.1	0	0	0
	507	0	0	0	4.7	7.3	7.7	6.7	6.7	6.5	2.1	0	0	0
	508	0	0	0	4.9	7.7	7.1	6.7	6.7	6.5	1.7	1.7	0	0
	510	0	0	0	4.9	7.1	6.7	6.3	6.9	5.7	0	0	0	0
	512	0	0	0	4.5	6.9	6.5	6.7	6.5	3.5	0	0	0	0
	513	0	0	0	4.5	5.7	6.9	6.5	6.9	6.9	4.9	2.5	0	0
	516	0	0	0	3.7	6.3	5.3	4.5	5.3	2.7	0	0	0	0
	520	0	0	0	4.5	6.3	6.3	5.7	5.7	5.1	3.5	0	0	0
	522	0	0	0	4.7	6.7	7.1	5.1	6.3	4.9	1.7	0	0	0
	523	0	0	0	5.1	7.7	8.1	6.3	6.7	5.7	1.7	0	0	0
	524	0	0	0	4.9	7.5	6.7	6.3	5.7	5.7	2.1	0	0	0
	527	0	0	0	4.9	7.1	7.3	6.7	6.1	5.7	3.5	0	0	0
	532	0	0	0	5.1	5.9	5.7	4.9	4.1	3.1	2.1	2.3	0	0
	533	0	0	0	5.3	7.9	7.1	6.1	6.7	5.9	2.1	0	0	0
	536	0	0	0	5.3	7.1	6.9	5.7	6.7	6.5	4.9	0	0	0
	537	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	540	0	0	0	6.1	6.7	6.7	4.7	5.7	3.5	0	0	0	0
541	0	0	0	5.7	7.1	6.9	6.3	6.5	6.3	3.9	2.5	0	0	
542	0	0	0	5.1	5.9	5.9	4.9	5.9	4.3	2.7	0	0	0	
543	0	0	0	5.5	7.5	6.7	6.3	6.7	6.1	3.9	1.7	0	0	
Controls	504	0	0	0	4.7	7.7	6.9	7.9	6.9	6.1	5.9	5.1	3.9	2.5
	506	0	0	0	4.7	7.5	6.9	6.7	7.1	5.9	6.7	4.7	4.1	2.9
	509	0	0	0	6.1	7.5	6.9	6.3	6.5	6.3	5.1	4.7	3.3	1.9
	511	0	0	0	4.7	7.3	7.7	6.5	6.1	6.1	5.5	4.5	4.3	2.5
	514	0	0	0	5.9	7.1	7.7	7.3	6.5	6.5	5.5	4.7	3.5	2.5
	515	0	0	0	5.1	7.3	7.3	7.5	7.3	6.5	5.3	4.1	3.1	1.9
	517	0	0	0	4.3	6.7	7.9	7.3	7.1	6.7	6.7	4.5	3.3	2.5
	518	0	0	0	4.9	7.7	7.3	7.3	6.7	6.1	6.3	5.3	3.5	2.3
	519	0	0	0	5.3	7.3	7.7	7.7	6.7	7.9	6.7	5.5	4.5	2.9
	521	0	0	0	5.3	7.7	7.9	6.9	6.5	6.3	6.5	5.9	3.7	2.9
	525	0	0	0	5.3	5.5	6.7	7.1	7.5	6.5	5.5	4.7	3.7	2.5
	526	0	0	0	5.1	6.9	7.3	6.9	6.3	7.3	5.9	5.1	4.3	2.5
	528	0	0	0	5.1	7.9	7.5	7.7	6.9	6.9	7.5	4.9	3.9	1.9
	529	0	0	0	5.3	7.3	6.9	7.1	6.3	5.5	6.3	5.1	3.9	2.1
	530	0	0	0	5.1	7.5	8.1	6.9	7.7	6.3	6.1	5.3	3.9	2.9
	531	0	0	0	5.1	6.9	7.3	7.9	7.9	6.9	6.5	4.5	3.5	2.1
	534	0	0	0	5.9	7.1	8.1	6.5	6.1	5.9	7.1	4.7	4.3	2.5
535	0	0	0	5.1	7.5	7.9	7.7	7.1	6.7	5.9	5.1	3.1	1.9	
538	0	0	0	5.3	6.7	6.5	5.5	6.3	6.9	6.7	4.5	2.7	1.9	
539	0	0	0	6.3	7.3	7.9	6.3	7.1	6.3	5.3	3.5	2.5	1.7	

¹Prior to vaccination, Study day 0

Study Type	Efficacy
Pertaining to	Infectious Bovine Rhinotracheitis (IBR)
Study Purpose	To demonstrate efficacy against abortions caused by IBR at 217 days post vaccination.
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 16, 2006

Study Type	Efficacy
Pertaining to	Parainfluenza ₃ Virus (PI3)
Study Purpose	To demonstrate effectiveness against shedding caused by PI3
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	April 12, 2005

Study Type	Efficacy
Pertaining to	Bovine Respiratory Syncytial Virus (BRSV)
Study Purpose	To demonstrate effectiveness against BRSV
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 3, 2004

Study Type	Safety																																																																												
Pertaining to	NA																																																																												
Study Purpose	Demonstrate safety in pregnant cows or in calves nursing pregnant cows if previously vaccinated pre-breeding with same product																																																																												
Product Administration	<p>One dose of test product was administered subcutaneously 30-60 days before breeding to all study animals. Then the test or control product was given during the targeted trimester of gestation.</p> <ul style="list-style-type: none"> • <u>Test product</u>: Contains modified live virus fractions • <u>Control product</u>: Product of similar composition except virus fraction(s) are killed 																																																																												
Study Animals	Pregnant cows: separate groups vaccinated at each trimester of gestation. Similar sized groups in each trimester were maintained as controls.																																																																												
Challenge Description	NA																																																																												
Interval observed after challenge	No challenge. After vaccination, observed daily through birth of calves. Calves monitored for 48 hours (bull calves) or 4 weeks (heifer calves).																																																																												
Results	<table border="1"> <thead> <tr> <th rowspan="2">Trimester</th> <th rowspan="2">Vaccinated During Gestation With</th> <th colspan="4">Number Pregnant Cows</th> </tr> <tr> <th>Vaccinated</th> <th>Removed from study^a</th> <th>Unrelated Abortions^b</th> <th>Abortions^c</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Control Product</td> <td>233</td> <td>7</td> <td>2</td> <td>2</td> </tr> <tr> <td>1</td> <td>Test Product</td> <td>235</td> <td>4</td> <td>3</td> <td>1</td> </tr> <tr> <td>2</td> <td>Control Product</td> <td>230</td> <td>0</td> <td>2</td> <td>1</td> </tr> <tr> <td>2</td> <td>Test Product</td> <td>231</td> <td>2</td> <td>6</td> <td>1</td> </tr> <tr> <td>3</td> <td>Control Product</td> <td>224</td> <td>2</td> <td>5</td> <td>1</td> </tr> <tr> <td>3</td> <td>Test Product</td> <td>216</td> <td>1</td> <td>8</td> <td>0</td> </tr> </tbody> </table> <p>^aRemovals affirmed by study cooperator to be unrelated to vaccination. ^bAbortions affirmed by study cooperator to have known cause, unrelated to infectious bovine rhinotracheitis or bovine virus diarrhea viruses ^cAbortions with unknown causes OR related to infectious bovine rhinotracheitis or bovine virus diarrhea viruses</p> <table border="1"> <thead> <tr> <th rowspan="2">Trimester</th> <th rowspan="2">Vaccinated During Gestation With</th> <th colspan="2">Number of Calves</th> </tr> <tr> <th>Live Births^a</th> <th>Mortality Prior to End of Observation Period</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Control Product</td> <td>224</td> <td>4</td> </tr> <tr> <td>1</td> <td>Test Product</td> <td>229</td> <td>6</td> </tr> <tr> <td>2</td> <td>Control Product</td> <td>233</td> <td>5</td> </tr> <tr> <td>2</td> <td>Test Product</td> <td>230</td> <td>2</td> </tr> <tr> <td>3</td> <td>Control Product</td> <td>223</td> <td>14</td> </tr> <tr> <td>3</td> <td>Test Product</td> <td>221</td> <td>5</td> </tr> </tbody> </table> <p>^aLive births include twins</p>	Trimester	Vaccinated During Gestation With	Number Pregnant Cows				Vaccinated	Removed from study ^a	Unrelated Abortions ^b	Abortions ^c	1	Control Product	233	7	2	2	1	Test Product	235	4	3	1	2	Control Product	230	0	2	1	2	Test Product	231	2	6	1	3	Control Product	224	2	5	1	3	Test Product	216	1	8	0	Trimester	Vaccinated During Gestation With	Number of Calves		Live Births ^a	Mortality Prior to End of Observation Period	1	Control Product	224	4	1	Test Product	229	6	2	Control Product	233	5	2	Test Product	230	2	3	Control Product	223	14	3	Test Product	221	5
Trimester	Vaccinated During Gestation With			Number Pregnant Cows																																																																									
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USDA Approval Date	May 9, 2013																																																																												

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions.
Product Administration	
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 16, 2004

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety in pregnant animals under field conditions when cows or heifers are vaccinated prior to breeding, within the previous 12 months, with a modified live Infectious Bovine Rhinotracheitis Virus (IBRV) and Bovine Viral Diarrhea Virus (BVDV) product
Product Administration	Two doses, administered subcutaneously. First vaccination given 14 to 60 days prior to breeding. Second vaccination given during a specified trimester of pregnancy.
Study Animals	1 st Trimester Study: 468 pregnant heifers (52 – 86 days pregnant) 2 years of age and older. 2 nd Trimester Study: 461 pregnant heifers (100 – 180 days pregnant) 2 – 14 years of age. 3 rd Trimester Study: 440 pregnant heifers (≥190 days pregnant) 2 years of age and older.
Challenge Description	Not applicable
Interval observed after challenge	All cows were observed from pre-breeding vaccination through calving.
Results	Summary of the results listed in the table below
USDA Approval Date	May 9, 2013

Summary of the results as follows:

Trimester	Group	No. of Cows		Fetal Loss (%) related to vaccination	Fetal Loss (%) unrelated to vaccination as affirmed by licensee
		Entered	Removed*		
1 st	Vaccinates	235	4	1 (0.4 %)	3 (1.3%)
	Controls	233	7	2 (0.9%)	2 (0.9%)
2 nd	Vaccinates	231	2	1 (0.4%)	6 (2.5%)
	Controls	230	0	1 (0.4%)	2 (0.8%)
3 rd	Vaccinates	216	1	0 (0%)	8 (3.7%)
	Controls	224	2	1 (0.5%)	5 (2.2%)

*Number of cows removed from the study results due to death serious illness considered unrelated to vaccination as affirmed by licensee