



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1071.20
True Name	Bovine Rhinotracheitis-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bovilis Nasalgen 3 - Merck Animal Health Bovilis Nasalgen 3 - No distributor specified
Date of Compilation Summary	April 13, 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	Infectious bovine rhinotracheitis (IBR)																		
Study Purpose	Demonstrate Duration of Immunity (effectiveness) of the infectious bovine rhinotracheitis (IBR) fraction against respiratory disease caused by IBR																		
Product Administration	One dose administered intranasally																		
Study Animals	Forty-six colostrum deprived calves, less than 1 week of age, divided into two groups: 21 vaccinates and 20 controls																		
Challenge Description	Challenged intranasally with virulent Cooper strain of IBR 195 days after vaccination																		
Interval observed after challenge	Calves observed daily for 16 days after challenge																		
Results	<p>Animals were considered affected by the challenge if they moderate to severe (severity score of 2) clinical signs (nasal or ocular discharge, nasal lesions, dyspnea, depression, anorexia, and/or cough) on any day during the post-challenge period, or a rectal temperature $\geq 104.0^{\circ}\text{F}$ for two or more consecutive days post-challenge. Nasal virus shedding was evaluated.</p> <p>For fever, an affected calf was one with a rectal temperature $\geq 104.0^{\circ}\text{F}$ for two or more consecutive post-challenge days.</p> <p>Totals: Affected: 9/21 vaccinates with IBR Morbidity 20/20 controls with IBR Morbidity</p> <p>Fever: 9/21 vaccinates 20/20 controls</p> <p>Duration of Nasal Shedding</p> <table border="1"> <thead> <tr> <th>Treatment</th> <th>Min.</th> <th>1st Qu.</th> <th>Median</th> <th>3rd Qu.</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>Control</td> <td>6</td> <td>6</td> <td>7</td> <td>8</td> <td>10</td> </tr> <tr> <td>Vaccinate</td> <td>8</td> <td>9</td> <td>10</td> <td>10</td> <td>12</td> </tr> </tbody> </table> <p>Raw data: See attached.</p>	Treatment	Min.	1 st Qu.	Median	3 rd Qu.	Max	Control	6	6	7	8	10	Vaccinate	8	9	10	10	12
Treatment	Min.	1 st Qu.	Median	3 rd Qu.	Max														
Control	6	6	7	8	10														
Vaccinate	8	9	10	10	12														
USDA Approval Date	September 9, 2019																		

TABLE 1: Clinical Observations

Group	Calf ID	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	Affected ¹	Duration ¹	Duration w/Fever ²	
Controls	2	0	0	0	0	0	0	N1,L1,R1	N2,L1,R1	N2,L1,R2	N2,L1,R1	N2,L1,R1	L2	0	0	0	0	0	0	Yes	5	8	
	4	0	0	0	0	0	0	N1,R1	N1,L1	N2,L2,R2	N1,L1	N1,L2	N1	0	0	0	0	0	0	Yes	3	6	
	7	0	0	0	0	0	0	N2,L2,R1	N2,L2,R1	N2,L2,R2	N2,L2,R2	N2,L2,R2	N2,L2,R2	N2,L2,R2	N2,L2,R1	L2	N2,L2	L2	L2	0	Yes	11	12
	9	O1	0	0	0	0	0	N1,L1,R1	N2,L1,R2	N2,O1,L1,R2	N2,O1,L2,R2	N2,L2,R2	N2,L2,R2	N2,L2,R1	N2,L2,R1	N2,L2	L2	L2	0	Yes	10	13	
	10	0	0	0	0	0	0	N1	L1	N2,L1	N2,L1	N2,L2	N2,L2	N2,L2	N1,L2	L2	L2	0	0	Yes	8	12	
	12	0	0	0	0	O1	0	N1,R1	N1,L1	N1,L1,R1	N2,L1,R1	0	0	0	0	0	0	0	0	0	Yes	1	7
	13	0	0	0	0	0	0	0	L1	N1,L1	N2,L2,R2	N1,L1	0	0	0	0	0	0	0	0	Yes	1	6
	17	0	0	0	0	0	0	N2,L1,R1	N2,L2,R1	N2,L1,R1	N2,L1,R2	N2,L2,R2	N2,L1	N2	0	0	0	0	0	0	Yes	7	8
	19	0	0	0	0	0	0	N1	N2,L1	N1,L1	N2,L1,R2	0	0	0	0	0	0	0	0	0	Yes	3	5
	20	0	0	0	0	0	0	N1,L1	N1,L1	N2,L2,R1	N2,L2,R2	N2,L2,R2	L2	L2	0	0	0	0	0	0	Yes	5	9
	21	0	0	0	0	0	0	N2,R1	N2,L2,R1	N2,L2,R2	N2,O1,L1,R2	N2,O2,L2,R2	N2,O2,R2	N2,O2,L2,R	0	N1	0	0	0	0	Yes	7	10
	27	0	0	0	0	0	0	N2,L1,R1	N2,L1,R1	N2,L2,R2	N2,L2,R2	N2,L2,R2	N2,L2,R2	0	L2	L2	0	0	0	0	Yes	9	11
	28	0	0	0	0	0	0	N2,L2,R1	N2,L1	N2,L2,R2	N2,L2,R2	N2,L2,R2	0	0	0	0	0	0	0	0	Yes	5	7
	32	0	0	0	0	0	0	0	N2,D1,R1	N2,L1,R2	N2,L2,R2	N2,L2,R2	0	0	0	0	0	0	0	0	Yes	3	6
	37	0	0	0	0	0	0	N2,L2,R1	N2,L2,R1	N2,L2,R2	N2,L2,R2	N2,L2,R2	L2	L2	0	L2	0	0	0	0	Yes	9	10
	38	0	0	0	0	0	0	N2,L1,R1	N2,L1,R1	N2,L1,R2	N2,L1,R2	N2,L1,R2	N1,O1,R1	N1	0	0	0	0	0	0	Yes	5	7
	39	0	0	0	0	0	0	N1	0	N2,L1	N2,L2,R2	N2,L2,R2	N2,L2,R2	N2,L2	N2,L2	N1,L2	N2,L2	N2,L2	0	0	Yes	9	11
	42	0	0	0	0	0	0	N1	N1	N1,L1,R2	N1	N2,L1,R2	N1	N1	0	0	0	0	0	0	Yes	3	9
	45	0	0	0	0	0	0	L1	N1,D1	L1	N1,L1	N1,L1	N2,R1	N1	0	0	0	0	0	0	Yes	1	6
	46	0	0	0	0	0	0	0	N2,L1,R2	N2,L2,D1,R2	N2,L2,D1,R2	N2,O1,D1,R2	N2,L2,R2	N2,L2,R2	N2,R2	N2,L2,R2	N2	0	0	0	Yes	9	11
Vaccinates	1	0	0	0	0	0	0	N1,L1	N1,L1	N1,L1	N2,L2,R2	N1,L1,R1	0	0	0	0	0	0	0	Yes	1	4	
	3	0	0	0	0	0	0	N1	0	0	N1	N2,L2,R1	0	0	0	0	0	0	0	Yes	1	7	
	5	0	0	0	0	0	0	N1,R1	L1	0	N2,L1,R1	N1,L1	0	0	0	0	0	0	0	Yes	1	5	
	6	0	0	0	0	0	0	R1	N1	0	0	N1	0	0	0	0	0	0	0	No	0	0	
	8	0	0	0	0	0	0	0	0	O1	0	0	0	0	0	0	0	0	0	0	No	0	0
	11	0	0	0	0	0	0	0	0	0	N1	0	0	0	0	0	0	0	0	0	No	0	8
	14	0	0	0	0	0	0	0	0	N1,L1	0	0	0	0	0	0	0	0	0	0	No	0	0
	15	0	0	0	0	0	0	N1	N2,L1	0	0	N1	0	0	0	0	0	0	0	0	Yes	1	10
	16	0	0	0	0	0	0	N1,R1	N1	N1	N1	0	0	0	0	0	0	0	0	0	No	0	2
	18	0	0	0	0	0	0	R1	0	N1,L1	0	0	0	0	0	0	0	0	0	0	No	0	0
	22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No	0	0
	23	0	0	0	0	0	0	N1,L1	N2,L2	L1	N1	0	0	0	0	0	0	0	0	0	Yes	1	1
	25	0	0	0	0	0	0	N1	0	N1,L1	N1	N1	0	0	0	0	0	0	0	0	No	0	0
	29	0	0	0	0	0	0	N2,L2,R1	N2,L2,R2	N2,L2,R2	N2,L2,R2	N2,L2,R2	N2,L2,R1	0	0	0	0	0	0	0	Yes	5	7
	30	0	0	0	0	0	0	N1	N1,R1	N1,L1	0	N1,L2,R1	N1,L2	L2	L2	L2	L2	0	0	0	Yes	6	11
	34	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	No	0	0
35	0	0	0	0	0	0	R1	D1	0	0	0	0	0	0	0	0	0	0	0	No	0	0	
40	0	0	0	0	0	0	0	N1,R1	N1,L1	N1	0	0	0	0	0	0	0	0	0	No	0	1	
41	0	0	0	0	0	0	R1	N2,L1,R1	N2,L2,R2	N2,L2,R2	N2,L2,R2	0	0	0	0	0	0	0	0	Yes	4	8	
43	0	0	0	0	0	0	0	N1,L1	N2,L2	N1,L2	N1	0	0	0	0	0	0	0	0	Yes	2	6	
44	0	0	0	0	0	0	0	N1,L1	0	N1	0	0	0	0	0	0	0	0	0	No	0	3	

Clinical Descriptions: N=Nasal Discharge, O=Ocular Discharge, C=Cough, L=Nasal Lesions, D=Depression, R=Dyspnea; Severity: 0=Normal, 1=Mild, 2=Moderate to Severe

Bold indicates an affected calf with moderate to severe clinical signs

¹An affected calf is one with moderate to severe clinical signs of disease on any post-challenge day (score of 2)

²An affected calf is one with moderate to severe clinical signs of disease or rectal temperature $\geq 104.0^{\circ}\text{F}$ on any post-challenge day

TABLE 3: Nasal Swab Virus Shedding

	Calf ID	-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Controls	2	0	3.5	6.5	7.3	7.5	7.1	7.3	5.7	4.5	2.5	1.9	0	0	0	0
	4	0	4.7	6.1	7.3	7.3	6.5	5.9	5.5	3.1	0	0	0	0	0	0
	7	0	5.1	8.1	8.9	7.7	6.9	6.9	6.5	5.5	4.3	3.1	1.9	0	0	0
	9	0	6.1	8.1	7.3	6.9	7.1	7.1	5.5	4.5	2.3	1.9	1.7	0	0	0
	10	0	5.1	7.1	8.1	7.1	5.9	6.5	5.3	3.7	2.7	0	0	0	0	0
	12	0	3.9	6.7	7.7	7.5	6.5	6.9	5.5	4.3	2.9	1.9	0	0	0	0
	13	0	4.7	6.1	7.7	7.3	6.5	6.7	4.5	3.9	1.7	0	0	0	0	0
	17	0	5.9	7.3	7.7	8.1	7.5	7.5	5.9	4.7	2.5	0	0	0	0	0
	19	0	4.7	6.7	8.5	7.7	6.9	7.3	5.9	4.5	3.7	2.3	0	0	0	0
	20	0	6.5	7.5	8.3	6.3	5.7	6.1	4.7	3.7	2.3	0	0	0	0	0
	21	0	3.7	7.1	8.5	7.7	7.3	6.5	5.9	3.9	2.7	2.1	0	0	0	0
	27	0	4.7	7.1	7.3	8.7	7.3	6.7	4.5	3.7	1.7	0	0	0	0	0
	28	0	4.5	6.7	7.5	7.7	7.5	7.1	5.3	4.3	3.7	2.7	0	0	0	0
	32	0	5.7	7.1	7.7	8.1	7.3	7.3	5.7	4.3	2.7	1.7	0	0	0	0
	37	0	4.9	6.7	6.9	7.9	6.7	7.1	5.9	4.7	3.1	2.3	0	0	0	0
	38	0	3.9	5.7	7.7	6.9	6.5	7.1	5.9	3.5	2.5	1.7	0	0	0	0
	39	0	4.1	7.1	8.5	8.3	7.1	6.9	5.9	4.5	3.7	2.1	1.7	1.7	0	0
	42	0	3.5	6.3	7.3	7.7	6.7	6.7	5.5	4.7	4.5	2.1	1.9	0	0	0
45	0	4.7	6.5	8.3	7.7	6.7	7.3	5.5	3.7	3.3	1.9	0	0	0	0	
46	0	4.9	7.1	8.1	7.7	5.7	6.7	6.3	5.5	3.5	1.9	0	0	0	0	
Vaccinates	1	0	3.7	6.3	7.9	7.5	6.9	6.7	5.3	3.9	2.5	1.9	0	0	0	0
	3	0	4.9	8.3	7.9	7.5	6.5	5.3	0	0	0	0	0	0	0	0
	5	0	3.5	7.1	7.1	6.9	7.1	6.3	3.1	0	0	0	0	0	0	0
	6	0	4.9	6.5	6.3	6.7	5.5	3.3	1.7	0	0	0	0	0	0	0
	8	0	3.9	5.9	5.1	4.5	4.1	2.5	0	0	0	0	0	0	0	0
	11	0	5.1	6.5	6.9	7.1	6.3	3.5	1.7	0	0	0	0	0	0	0
	14	0	4.7	5.9	7.3	6.3	7.3	4.7	1.9	1.7	0	0	0	0	0	0
	15	0	4.9	7.1	7.9	7.9	5.5	4.7	3.1	0	0	0	0	0	0	0
	16	0	4.7	6.3	7.5	6.5	6.5	5.3	2.3	0	0	0	0	0	0	0
	18	0	4.5	5.7	5.3	5.7	4.3	3.3	0	0	0	0	0	0	0	0
	22	0	2.5	3.5	1.9	3.3	2.1	1.9	0	0	0	0	0	0	0	0
	23	0	5.3	6.7	6.9	6.9	6.5	4.1	0	0	0	0	0	0	0	0
	25	0	5.1	6.9	6.7	5.9	5.5	3.7	0	0	0	0	0	0	0	0
	29	0	4.3	6.9	7.9	8.3	7.5	6.5	0	2.3	0	0	0	0	0	0
	30	0	4.5	7.3	7.5	7.5	6.7	5.7	4.1	2.1	0	0	0	0	0	0
	34	0	4.5	3.5	3.5	4.7	3.9	2.9	3.7	0	0	0	0	0	0	0
	35	0	4.9	7.3	6.9	4.7	5.7	4.1	1.9	0	0	0	0	0	0	0
	40	0	5.9	7.3	7.5	7.3	7.1	6.9	4.7	2.7	0	0	0	0	0	0
41	0	5.1	6.9	7.9	7.7	6.9	6.5	3.9	3.1	0	0	0	0	0	0	
43	0	4.5	7.3	6.9	7.3	6.7	5.7	3.5	0	0	0	0	0	0	0	
44	0	3.1	4.3	4.7	3.7	2.1	3.7	0	0	0	0	0	0	0	0	

Bold indicates positive nasal shedding (results are reported as Log₁₀ TCID₅₀/mL)

Study Type	Efficacy
Pertaining to	infectious bovine rhinotracheitis (IBR)
Study Purpose	Demonstrate effectiveness of the infectious bovine rhinotracheitis (IBR) fraction against respiratory disease caused by IBR
Product Administration	One dose administered intranasally
Study Animals	Forty-four colostrum deprived calves, less than 1 week of age, divided into two groups: 22 vaccinates and 22 controls
Challenge Description	Challenged intranasally with the virulent Cooper strain of IBR 29 days after vaccination
Interval observed after challenge	Calves observed daily for 17 days after challenge
Results	<p>Animals were considered affected by the challenge if they had moderate to severe (severity score of 2) clinical signs (nasal or ocular discharge, nasal lesions, dyspnea, depression, anorexia, and/or cough) on any day during the post-challenge period, or a rectal temperature $\geq 104.0^{\circ}\text{F}$ on any post-challenge day.</p> <p>For fever, an affected calf was one with a rectal temperature $\geq 104.0^{\circ}\text{F}$ for two or more consecutive post-challenge days.</p> <p>Totals: 22/22 controls affected 5/22 vaccinates affected</p> <p>Raw data: See attached.</p>
USDA Approval Date	January 3, 2018

TABLE 1: Clinical Observations

Group	Calf ID	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Affected ¹	Duration ²	
Controls	445	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	11
	446	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	9
	450	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	10
	451	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	12
	456	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	11
	458	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	9
	459	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8
	460	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	9
	461	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	9
	464	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5
	465	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5
	466	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8
	467	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	12
	470	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	9
	472	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8
	475	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	6
	476	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	6
479	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	13	
481	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8	
482	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	9	
485	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	10	
486	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	10	
Vaccinates	443	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	444	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	447	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	448	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
	452	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	453	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	454	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	455	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	10
	457	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	462	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	463	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8
	468	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	469	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8
	471	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	473	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	474	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	477	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
478	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
480	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
483	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
484	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	10	
486	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

Clinical Descriptions: N=Nasal Discharge, O=Ocular Discharge, C=Cough, L=Nasal Lesions, D=Depression, R=Dyspnea, Severity: 0=Normal, 1=Mild, 2=Moderate to Severe, * =Fever
¹ An affected calf is one with moderate to severe clinical signs of disease on any post-challenge day (score of 2)
² For determining duration, an affected calf is one with moderate to severe clinical signs of disease or rectal temperature $\geq 104.0^{\circ}\text{F}$ on any post-challenge day

TABLE 2: Rectal Temperatures

Call ID	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Affected	Duration ¹	
Controls	445	101.6	101.7	101.3	104.1	105.1	104.4	105.0	104.6	103.7	103.3	101.9	100.4	101.2	100.9	101.4	Yes	5	
	446	102.1	101.2	101.1	103.2	104.3	104.0	103.9	103.5	102.9	102.0	101.8	100.6	101.2	101.2	101.0	Yes	2	
	450	101.9	102.2	102.3	102.4	104.0	105.6	106.1	104.8	103.6	102.7	102.1	102.3	101.4	101.9	101.6	101.2	Yes	4
	451	102.8	101.7	101.8	102.3	103.1	104.3	102.5	104.0	103.8	103.7	103.0	101.5	101.5	102.6	101.6	101.7	No	3
	456	101.7	102.4	101.1	101.8	104.5	104.9	104.2	104.2	103.8	106.0	104.9	104.9	101.9	101.2	101.1	102.3	Yes	8
	458	101.7	101.1	101.3	101.0	104.5	104.4	103.5	104.8	102.8	102.7	102.5	101.7	100.2	101.1	100.8	101.6	Yes	4
	459	102.0	102.0	101.1	101.6	103.6	103.6	104.0	103.3	102.1	101.1	101.5	100.4	101.6	100.4	101.0	101.0	No	1
	460	102.5	101.2	101.6	101.4	102.5	104.7	104.0	103.8	102.2	101.1	101.0	101.4	100.0	101.3	101.0	101.2	Yes	2
	461	102.2	101.6	101.3	101.9	104.8	105.0	104.2	104.0	103.3	101.6	101.3	101.1	101.1	101.3	101.4	101.4	Yes	4
	464	101.3	101.3	100.9	101.0	103.2	105.0	104.2	104.8	103.0	103.0	101.6	102.0	99.8	101.1	101.0	101.1	Yes	4
	465	102.2	101.0	101.0	101.1	102.4	104.0	104.0	101.5	101.3	101.5	101.2	101.1	100.6	101.5	100.0	101.0	Yes	2
	466	101.3	102.0	101.4	101.0	103.9	104.3	104.0	102.8	102.4	101.0	101.4	101.4	100.6	101.5	101.7	101.4	Yes	2
	467	102.2	100.8	101.8	101.3	103.7	104.4	102.7	102.9	103.1	103.4	102.4	101.7	101.1	101.3	100.9	101.6	No	1
	470	102.8	101.4	101.8	101.5	103.0	104.6	104.2	104.3	104.1	104.6	104.6	104.1	101.0	101.3	100.8	101.1	Yes	7
	472	102.1	101.0	100.5	101.6	105.0	105.2	103.9	104.3	103.6	102.7	101.6	102.0	100.1	101.6	101.2	101.5	Yes	4
	473	102.4	101.3	101.8	102.2	105.1	105.2	103.5	103.6	102.6	102.0	101.6	101.7	100.2	102.0	101.1	102.0	Yes	2
	475	101.3	100.8	100.1	101.0	103.2	104.3	103.3	103.9	103.0	102.1	103.0	100.2	100.6	100.6	100.5	100.3	No	1
	479	101.4	101.1	102.3	101.6	103.0	104.4	104.8	103.6	104.4	102.0	101.9	101.9	100.7	100.2	101.5	101.1	Yes	4
	481	101.7	101.1	100.9	101.3	104.0	104.3	104.0	104.5	104.1	102.2	101.6	101.5	100.3	101.2	100.6	100.5	Yes	5
	482	101.7	101.1	100.4	100.9	104.0	105.2	103.6	104.3	102.4	101.1	101.5	101.1	100.8	102.1	100.8	100.9	Yes	4
485	101.7	101.3	101.0	101.7	104.5	104.4	106.1	104.3	104.5	103.1	102.3	102.6	100.5	101.0	100.7	101.0	Yes	5	
488	101.0	101.9	101.0	101.6	101.5	103.8	101.2	102.7	102.7	102.4	101.3	101.7	100.2	101.1	101.1	101.0	No	0	
Vaccinates	443	101.4	101.0	100.8	101.3	101.3	101.5	100.4	102.2	101.4	101.6	101.5	100.2	101.7	101.1	101.4	No	0	
	444	101.1	101.7	101.9	102.0	102.4	102.3	101.4	102.0	102.5	102.4	101.7	100.9	101.0	102.1	101.7	101.6	No	0
	447	101.8	101.6	101.1	101.0	101.4	101.3	100.8	101.2	101.2	101.0	101.3	101.0	100.1	100.9	101.3	101.0	No	0
	448	101.6	101.0	100.6	101.7	104.2	105.1	103.0	102.1	101.7	101.4	101.0	101.0	100.3	101.1	101.3	101.6	Yes	2
	452	102.0	101.2	101.6	101.4	102.4	102.8	100.8	101.6	101.4	102.0	101.4	101.9	100.2	101.8	100.6	101.6	No	0
	453	101.8	101.1	101.2	101.3	101.6	101.5	99.5	101.1	101.0	102.0	102.0	100.4	101.7	101.4	101.3	101.3	No	0
	454	101.7	101.5	101.1	101.5	102.8	102.5	102.5	104.0	103.5	103.7	101.5	102.7	101.6	102.3	101.1	101.1	No	1
	456	101.8	101.2	101.0	101.1	102.5	102.2	100.4	101.3	101.0	101.0	101.0	102.4	100.9	100.2	102.9	100.8	No	0
	457	102.0	100.9	101.6	101.6	101.8	101.7	101.2	102.0	102.1	101.6	101.7	101.6	100.6	101.8	101.5	100.8	No	0
	462	100.9	101.7	101.1	101.5	102.1	104.4	104.0	104.6	103.0	103.6	102.5	101.2	99.7	101.0	100.8	101.0	Yes	3
	463	102.1	101.8	101.0	101.3	102.0	101.3	101.0	102.0	102.0	102.2	101.6	101.3	101.3	101.3	101.4	101.6	No	0
	468	101.3	101.4	101.0	101.4	101.5	104.8	106.1	104.3	103.1	101.8	101.1	101.3	100.2	101.1	101.1	101.2	Yes	3
	469	101.6	101.6	101.4	101.5	103.5	103.7	102.1	102.8	100.9	101.9	101.1	101.6	101.1	101.9	101.6	101.2	No	0
	471	102.0	101.4	101.1	100.9	102.2	102.7	100.5	102.0	101.6	102.0	102.1	101.7	100.4	101.2	101.3	101.7	No	0
	473	102.0	100.6	101.2	101.3	102.2	102.4	100.8	101.4	101.1	101.3	101.4	101.3	101.3	100.5	100.7	100.9	No	0
	474	102.2	102.0	101.0	102.0	102.1	102.6	101.1	101.3	101.8	101.8	101.0	102.0	101.0	102.4	100.8	101.6	No	0
	477	102.9	102.0	102.4	102.2	103.0	101.7	101.2	101.5	102.0	101.8	101.5	101.8	101.4	102.2	101.0	101.5	No	0
	478	101.5	101.3	100.9	101.4	102.0	101.4	101.2	101.4	101.0	101.0	101.4	101.4	99.9	101.0	100.9	101.2	No	0
	480	101.9	101.8	101.3	101.7	102.2	102.2	101.9	102.0	101.9	101.8	102.0	102.5	100.3	102.0	101.1	101.8	No	0
	483	102.4	101.2	101.9	101.7	103.6	104.5	104.2	104.4	104.3	103.6	102.5	102.0	100.4	101.4	100.8	100.6	Yes	4
484	101.2	101.4	101.3	101.3	101.3	101.1	100.0	101.6	101.3	101.5	101.6	102.9	103.4	102.6	100.2	100.7	No	0	
486	101.5	101.0	100.8	100.2	101.1	101.0	100.5	101.1	101.5	100.9	103.6	101.3	99.7	101.2	100.8	101.1	No	0	

Bold indicates fever $\geq 104.0^\circ F$

¹An affected calf is one with a rectal temperature $\geq 104.0^\circ F$ for two or more consecutive days

²For determining duration, an affected calf is one with a rectal temperature $\geq 104.0^\circ F$ on any post-challenge day

Study Type	Efficacy																		
Pertaining to	<i>Parainfluenza 3 (PI3)</i>																		
Study Purpose	Demonstrate effectiveness of the <i>Parainfluenza 3</i> fraction against respiratory disease caused by <i>Parainfluenza 3</i>																		
Product Administration	One dose administered intranasally at 6 or 7 days of age																		
Study Animals	Colostrum deprived calves, 6 or 7 days of age, divided into two groups: Group A vaccinates, 22 calves, test vaccine with <i>Parainfluenza 3</i> antigen at the minimum protective dose (MPD) and the other seven antigen fractions at or above release levels Group B controls, 13 calves, placebo vaccine with the seven antigen fractions at or above release levels and without the <i>Parainfluenza 3</i> fraction																		
Challenge Description	Challenged with a virulent <i>Parainfluenza 3</i> at either 39 (1 st shipment) or 32 (2 nd shipment) days post vaccination																		
Interval observed after challenge	Observed for clinical signs of the disease for 14 days post challenge																		
Results	Vaccinates and controls were evaluated for viral shedding as virus shedding is the primary criteria related to <i>Parainfluenza 3</i> infection. Number of calves with viral shedding and days duration during post-challenge period: Group A Vaccinates: 13/22 shed PI3 post-challenge Group B Controls: 13/13 shed PI3 post-challenge <i>Duration (days) of shedding, five number summary</i> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th><i>Group</i></th> <th><i>Min</i></th> <th><i>Q₁</i></th> <th><i>Median</i></th> <th><i>Q₃</i></th> <th><i>Max</i></th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>0</td> <td>0</td> <td>1</td> <td>4</td> <td>8</td> </tr> <tr> <td>Controls</td> <td>5</td> <td>7</td> <td>9</td> <td>9</td> <td>10</td> </tr> </tbody> </table> Raw data attached	<i>Group</i>	<i>Min</i>	<i>Q₁</i>	<i>Median</i>	<i>Q₃</i>	<i>Max</i>	Vaccinates	0	0	1	4	8	Controls	5	7	9	9	10
<i>Group</i>	<i>Min</i>	<i>Q₁</i>	<i>Median</i>	<i>Q₃</i>	<i>Max</i>														
Vaccinates	0	0	1	4	8														
Controls	5	7	9	9	10														
USDA Approval Date	September 24, 2014																		

Table 1: Nasal Swab Virus Shedding Results

Group	ID	Nasal PI3 Virus Titer (Log ₁₀ TCID ₅₀ /mL) Day Post-Challenge												
		Vac. ¹	-1	0	1	2	3	4	5	6	7	8	9	10
Controls	202	0	0	0	0	1.7	2.5	2.7	3.5	3.5	2.3	1.9	3.9	2.9
	206	0	0	0	3.1	4.3	5.3	5.5	5.9	4.1	2.1	0	0	0
	207	0	0	0	0	1.7	3.9	4.9	4.5	3.7	2.3	0	0	1.7
	212	0	0	0	0	0	3.7	3.1	4.7	5.9	3.3	3.1	3.3	0
	213	0	0	0	1.7	2.5	3.7	3.9	4.5	5.5	4.5	2.9	2.3	0
	220	0	0	0	0	3.1	3.9	4.5	5.7	6.3	3.1	2.5	3.9	1.7
	222	0	0	0	0	1.9	2.5	3.7	5.7	4.9	3.3	2.3	2.7	3.7
	223	0	0	0	0	2.1	2.7	2.7	3.1	3.5	2.5	1.9	2.1	2.1
	230	0	0	0	0	1.9	3.9	4.7	5.3	4.5	2.9	2.5	3.5	2.7
	231	0	0	0	0	1.7	1.7	1.7	2.3	2.5	0	0	0	0
	234	0	0	0	0	0	1.7	3.7	4.9	3.9	2.1	0	0	0
	236	0	0	0	3.3	4.3	4.5	5.7	5.7	4.9	2.7	3.5	2.5	2.1
	242	0	0	0	0	0	1.9	3.7	4.7	5.1	3.7	2.7	0	0
	Average:	0	0	0	0.6	1.9	3.2	3.9	4.7	4.5	2.7	1.8	1.9	1.3
Vaccinates	201	0	0	0	0	0	0	0	0	0	0	0	0	0
	203	0	0	0	0	0	1.9	0	0	0	0	0	0	0
	204	0	0	0	0	0	0	0	0	0	0	0	0	0
	205	0	0	0	0	3.5	4.3	4.7	3.9	0	0	0	0	0
	208	0	0	0	0	0	0	1.7	0	0	0	0	0	0
	211	0	0	0	1.7	2.7	5.7	3.7	1.7	0	0	0	0	0
	215	0	0	0	0	1.7	0	0	0	0	0	0	0	0
	217	0	0	0	0	0	0	1.7	0	0	0	0	0	0
	218	0	0	0	0	0	0	0	0	0	0	0	0	0
	224	0	0	0	1.7	2.9	2.7	3.7	3.3	0	0	0	0	0
	225	0	0	0	0	0	1.7	2.1	2.3	3.3	3.1	0	1.7	0
	226	0	0	0	0	0	0	0	0	0	0	0	0	0
	227	0	0	0	0	0	2.3	3.5	2.5	0	0	0	0	0
	228	0	0	0	0	1.7	1.7	1.7	0	0	0	0	0	0
	229	0	0	0	0	1.7	2.9	3.3	2.7	0	0	0	0	0
	232	0	0	0	0	0	2.7	3.5	3.7	3.9	2.7	1.9	2.5	1.9
	233	0	0	0	0	1.9	2.5	0	0	0	0	0	0	0
	235	0	0	0	0	0	0	0	0	0	0	0	0	0
237	0	0	0	0	0	0	0	0	0	0	0	0	0	
239	0	0	0	0	0	0	0	0	0	0	0	0	0	
240	0	0	0	0	0	0	0	0	0	0	0	0	0	
241	0	0	0	0	0	0	0	0	0	0	0	0	0	
	Average:	0	0	0	0.2	0.7	1.3	1.3	0.9	0.3	0.3	0.1	0.2	0.1

¹Prior to vaccination (study day 0 or 7)

Study Type	Efficacy																		
Pertaining to	<i>Parainfluenza 3</i>																		
Study Purpose	Demonstrate Duration of Immunity (effectiveness) of the <i>Parainfluenza 3</i> fraction against respiratory disease caused by <i>Parainfluenza 3</i>																		
Product Administration	One dose administered intranasally at 3 to 5 days of age																		
Study Animals	44 Colostrum deprived calves, 3 to 5 days of age, divided into two groups: Group A vaccinates, 22 calves, test vaccine Group B controls, 22 calves, placebo vaccine																		
Challenge Description	Challenged with virulent <i>Parainfluenza 3</i> at 95 days post vaccination																		
Interval observed after challenge	Observed for clinical signs of the disease for 14 days post challenge																		
Results	<p>Number of calves with viral shedding during post-challenge period: Group A Vaccinates: 18/20 shed PI3 post-challenge Group B Controls: 20/20 shed PI3 post-challenge</p> <p>Duration of shedding in days:</p> <table border="1"> <thead> <tr> <th><i>Group</i></th> <th><i>Minimum</i></th> <th><i>Q1</i></th> <th><i>Median</i></th> <th><i>Q3</i></th> <th><i>Maximum</i></th> </tr> </thead> <tbody> <tr> <td><i>Vaccinate</i></td> <td>0</td> <td>2</td> <td>3.5</td> <td>5</td> <td>7</td> </tr> <tr> <td><i>Control</i></td> <td>6</td> <td>6</td> <td>6.0</td> <td>7</td> <td>8</td> </tr> </tbody> </table> <p><i>Q=quartile</i></p> <p>NOTE: 1 control animal was removed from the study prior to vaccination. Two vaccinates and 1 control animal were removed or humanely euthanized, for reasons unrelated to vaccination, prior to challenge.</p> <p>Raw data attached</p>	<i>Group</i>	<i>Minimum</i>	<i>Q1</i>	<i>Median</i>	<i>Q3</i>	<i>Maximum</i>	<i>Vaccinate</i>	0	2	3.5	5	7	<i>Control</i>	6	6	6.0	7	8
<i>Group</i>	<i>Minimum</i>	<i>Q1</i>	<i>Median</i>	<i>Q3</i>	<i>Maximum</i>														
<i>Vaccinate</i>	0	2	3.5	5	7														
<i>Control</i>	6	6	6.0	7	8														
USDA Approval Date	February 21, 2019																		

Table 1: Nasal Swab Virus Shedding Results

CalfID	0 PV	-1 PC	1 PC	2 PC	3 PC	4 PC	5 PC	6 PC	7 PC	8 PC	9 PC	10 PC	Duration (days)	
Controls	214	0	0	2.7	3.7	4.5	5.3	6.1	2.9	0	0	0	6	
	215	0	0	2.5	4.1	4.7	5.7	6.1	4.9	0	0	0	6	
	217	0	0	3.3	3.1	3.7	4.5	4.5	2.5	1.7	0	0	8	
	218	0	0	3.9	3.3	4.5	4.7	5.1	4.7	0	0	0	6	
	219	0	0	3.5	3.5	4.5	5.7	6.1	4.9	0	0	0	6	
	222	0	0	2.7	4.3	5.5	6.7	5.9	3.5	1.7	0	0	7	
	227	0	0	3.7	4.1	3.9	5.1	5.1	1.9	0	0	0	6	
	230	0	0	4.3	5.9	4.5	5.1	6.3	2.9	1.7	0	0	7	
	231	0	0	4.1	4.9	4.7	6.1	6.3	5.7	2.7	1.7	0	8	
	233	0	0	2.9	4.3	5.9	4.9	6.7	4.5	2.1	0	0	7	
	236	0	0	2.9	4.9	6.7	5.3	4.9	2.9	0	0	0	6	
	237	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
	239	0	0	3.7	4.7	4.9	4.9	5.9	4.3	2.1	0	0	7	
	241	0	0	3.9	4.1	4.1	5.5	5.5	3.5	0	0	0	6	
	243	0	0	2.9	4.9	5.1	5.7	5.1	3.5	0	0	0	6	
	245	0	0	3.1	4.3	4.3	4.7	4.5	3.9	0	0	0	6	
	247	0	0	3.1	3.3	3.3	4.7	4.7	3.1	0	0	0	6	
	248	0	0	3.3	4.5	4.7	5.3	6.1	2.7	0	0	0	6	
	250	0	0	4.3	5.5	6.1	6.7	6.5	2.9	0	0	0	6	
	252	0	0	3.7	4.9	5.9	6.7	7.1	4.5	2.1	1.7	0	8	
255	0	0	3.7	4.9	5.9	6.7	7.1	4.5	2.1	1.7	0	8		
Vaccinates	212	0	3.3	2.5	3.5	2.9	2.7	2.7	0	0	0	0	5	
	213	0	0	0	0	1.7	1.9	0	0	0	0	0	2	
	216	0	NA	2.3	NA	NA	0	0	0	0	0	0	1	
	220	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
	221	0	0	2.5	2.9	3.5	4.5	3.1	0	0	0	0	5	
	223	0	0	1.9	0	1.7	1.7	0	0	0	0	0	4	
	225	0	0	2.3	1.7	0	0	1.7	0	0	0	0	5	
	226	0	0	0	0	0	0	0	0	0	0	0	0	
	228	0	0	0	0	0	0	2.3	0	0	0	0	0	1
	229	0	0	0	0	0	0	0	0	0	0	0	0	
	232	0	0	2.5	1.7	0	1.7	0	0	0	0	0	0	4
	234	0	0	2.1	3.3	2.1	0	0	0	0	0	0	0	3
	235	0	0	1.7	0	0	1.7	0	0	0	0	0	0	4
	238	0	0	1.9	1.7	0	0	0	0	0	0	0	0	2
	240	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	242	0	0	3.5	3.3	4.5	5.5	5.5	5.1	1.9	0	0	0	7
	244	0	0	1.9	0	0	2.3	0	0	0	0	0	0	4
	246	0	0	2.3	2.1	1.7	0	0	0	0	0	0	0	3
	249	0	0	3.3	2.7	4.1	4.9	4.5	0	0	0	0	0	5
	251	0	0	4.1	2.9	2.5	2.9	2.9	0	0	0	0	0	5
253	0	0	2.7	2.1	2.9	0	0	0	0	0	0	0	3	
254	0	0	1.7	1.9	0	0	0	0	0	0	0	0	2	

PV=post-vaccination, PC=post-challenge; **Bold** indicates positive nasal shedding

Study Type	Efficacy																		
Pertaining to	Bovine Respiratory Syncytial Virus (BRSV)																		
Study Purpose	To demonstrate efficacy of the BRSV fraction																		
Product Administration	One dose administered intranasally at 1 week of age																		
Study Animals	<p>Forty-four calves, less than one week-of-age, divided into two groups:</p> <p>Group 1, 22 calves, vaccine with BRSV antigen at the minimum protective dose (MPD) and the other four antigen fractions at or above proposed release levels.</p> <p>Group 2, 22 calves, placebo vaccine containing all antigens at or above proposed release levels but without BRSV</p>																		
Challenge Description	Challenged with aerosolized virulent BRSV virus (two mL of challenge virus was administered per naris), at 30 days and again at 31 days after vaccination.																		
Interval observed after challenge	Observed daily for 8 days.																		
Results	<p>Three Group 2 calves died or were euthanized prior to challenge, therefore Group 2 is 19 calves.</p> <p>BRSV Nasal Virus Shedding: Group 1 Vaccinates: 7/22 Group 2 Controls: 16/19</p> <p>Lung Lesion Score (LLS):</p> <table border="1"> <thead> <tr> <th>Group</th> <th>Min</th> <th>Q1</th> <th>Med</th> <th>Q3</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>Vaccinate</td> <td>0</td> <td>0</td> <td>0</td> <td>0.1</td> <td>11.3</td> </tr> <tr> <td>Control</td> <td>0.2</td> <td>0.9</td> <td>2.1</td> <td>5.35</td> <td>13.7</td> </tr> </tbody> </table> <p>Min is minimum Q is quartile Med is median Max is maximum</p> <p>Raw data attached</p>	Group	Min	Q1	Med	Q3	Max	Vaccinate	0	0	0	0.1	11.3	Control	0.2	0.9	2.1	5.35	13.7
Group	Min	Q1	Med	Q3	Max														
Vaccinate	0	0	0	0.1	11.3														
Control	0.2	0.9	2.1	5.35	13.7														
USDA Approval Date	January 3, 2018																		

Nasal BRSV Titer (TCID₅₀/mL)

Group	ID	-1	2	3	4	5	6	7	8	Duration (days)
Controls	342	0	0	0	0	0	0	0	0	0
	343	0	0	0	0	0	1.21E+02	2.70E+01	0	2
	344	0	0	0	0	1.28E+01	2.56E+02	1.86E+01	2.70E+01	4
	346	0	0	0	0	3.93E+01	5.72E+01	1.86E+01	1.28E+01	4
	348	0	0	0	0	0	0	1.28E+01	0	1
	349	0	0	0	0	0	0	1.86E+01	1.28E+01	2
	352	0	0	0	0	1.86E+01	2.70E+01	0	0	2
	355	0	0	0	1.86E+01	1.28E+01	5.72E+01	2.70E+01	0	4
	360	0	0	0	0	0	3.93E+01	5.72E+01	0	2
	361	0	0	0	1.86E+01	2.70E+01	2.70E+01	0	0	3
	366	0	0	0	0	1.86E+01	1.86E+01	0	0	2
	367	0	0	0	2.70E+01	2.70E+01	2.70E+01	1.28E+01	0	4
	368	0	0	0	0	1.28E+01	0	1.21E+02	0	3
	371	0	0	0	1.28E+01	8.32E+01	2.70E+01	8.32E+01	1.28E+01	5
	373	0	0	0	1.28E+01	0	3.93E+01	2.70E+01	0	4
	375	0	0	0	0	0	0	0	0	0
	377	0	0	0	0	0	0	0	0	0
382	0	0	0	0	0	3.93E+01	3.93E+01	0	2	
384	0	0	0	0	0	2.70E+01	1.28E+01	1.28E+01	3	
Vaccinates	347	0	0	0	0	0	0	0	0	0
	350	0	0	0	1.28E+01	3.93E+01	1.76E+02	5.72E+01	0	4
	351	0	0	0	0	0	0	0	0	0
	353	0	0	0	0	1.28E+01	2.70E+01	1.28E+01	0	3
	354	0	0	0	0	0	0	0	0	0
	356	0	0	0	0	1.86E+01	1.28E+01	0	0	2
	357	0	0	0	0	0	0	0	0	0
	358	0	0	0	0	0	0	0	0	0
	359	0	0	0	0	0	0	0	0	0
	362	0	0	1.28E+01	0	1.86E+01	1.28E+01	0	0	4
	363	0	0	0	1.28E+01	1.86E+01	0	0	0	2
	364	0	0	0	0	0	0	0	0	0
	369	0	0	0	0	0	0	0	0	0
	370	0	0	0	0	0	0	1.28E+01	1.28E+01	2
	372	0	0	0	0	0	0	0	0	0
	374	0	0	0	0	0	0	0	0	0
	376	0	0	0	3.93E+01	1.76E+02	5.43E+02	1.86E+01	0	4
379	0	0	0	0	0	0	0	0	0	
380	0	0	0	0	0	0	0	0	0	
381	0	0	0	0	0	0	0	0	0	
383	0	0	0	0	0	0	0	0	0	
385	0	0	0	0	0	0	0	0	0	

Bold indicates presence of viral shedding

Lung Lesion Score by Lung Lobe

Group	Calf ID	L Cranial	L Middle	L Caudal	R Cranial	R Post Cranial	R Middle	R Caudal	Accessory	Total Lung Score
Controls	342	2	5	1	0	0	0	0	0	0.7
	343	0	0	0	5	0	0	0	0	0.3
	344	30	20	10	40	10	10	5	10	11.7
	346	0	5	0	5	5	0	0	0	0.9
	348	0	5	5	2	0	2	0	0	2.2
	349	0	0	2	10	0	0	0	5	1.4
	352	0	20	10	25	0	15	10	10	10.9
	355	0	0	2	5	5	15	5	5	4.2
	360	5	5	2	10	2	10	5	0	4.3
	361	1	50	15	60	2	30	0	2	13.7
	366	5	15	5	2	2	15	2	1	4.8
	367	0	0	0	20	0	2	0	0	1.3
	368	2	2	0	0	0	0	0	0	0.2
	371	5	10	2	20	0	15	5	10	5.9
	373	0	5	2	2	0	2	0	5	1.4
	375	0	10	0	5	2	15	0	0	2.1
377	0	0	2	2	0	2	0	0	0.9	
382	0	0	0	15	0	60	2	10	6.2	
384	0	0	0	0	0	10	0	0	0.7	
Vaccinates	347	0	0	0	0	0	0	0	0	0
	350	15	20	10	15	0	10	12	8	11.3
	351	0	0	0	0	0	0	0	0	0
	353	0	2	0	60	5	30	10	10	10.0
	354	0	0	0	0	2	0	0	0	0.1
	356	0	0	0	0	0	0	0	0	0
	357	0	0	0	0	0	0	0	0	0
	358	0	0	0	0	0	0	0	0	0
	359	0	0	0	0	0	0	0	0	0
	362	0	0	0	0	0	0	0	0	0
	363	0	0	0	0	0	0	0	0	0
	364	0	0	0	0	0	0	0	0	0
	369	0	0	0	0	0	0	0	0	0
	370	0	0	0	0	0	0	0	0	0
	372	0	0	0	0	0	0	0	0	0
	374	0	0	0	10	0	15	2	2	2.4
376	0	5	0	15	2	2	0	0	1.4	
379	0	0	0	0	0	0	0	0	0	
380	0	2	0	0	0	0	0	0	0.1	
381	0	0	0	0	0	0	0	0	0	
383	0	0	0	0	0	0	0	0	0	
385	0	0	0	0	0	0	0	0	0	

Bold indicates animal considered affected

L= Left; R= Right

Study Type	Efficacy																		
Pertaining to	Bovine Respiratory Syncytial Virus (BRSV)																		
Study Purpose	Demonstrate Duration of Immunity (effectiveness) of the BRSV fraction																		
Product Administration	One 2 mL dose administered intranasally (Study Day 0)																		
Study Animals	Forty-four colostrum deprived calves, 5-7 days of age, divided into two groups: 22 vaccinates and 22 controls																		
Challenge Description	Challenged with aerosolized virulent BRSV virus (2 mL of challenge virus per naris), on Study Days 78 and 79 post vaccination																		
Interval observed after challenge	Calves observed daily for 8 days after challenge then lung tissue was examined.																		
Results	<p>Lung Lesion Scores:</p> <p><i>Table 1: Total lung lesions (Percent)</i></p> <table border="1"> <thead> <tr> <th>Group</th> <th>Minimum</th> <th>Q1</th> <th>Median</th> <th>Q3</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td>Vaccinate</td> <td>0</td> <td>1</td> <td>2</td> <td>4</td> <td>7</td> </tr> <tr> <td>Control</td> <td>3</td> <td>4</td> <td>6</td> <td>9</td> <td>27</td> </tr> </tbody> </table> <p><i>Q=Quartile</i></p> <p>Raw Data is Attached</p>	Group	Minimum	Q1	Median	Q3	Maximum	Vaccinate	0	1	2	4	7	Control	3	4	6	9	27
Group	Minimum	Q1	Median	Q3	Maximum														
Vaccinate	0	1	2	4	7														
Control	3	4	6	9	27														
USDA Approval Date	June 18, 2019																		

AVERAGE LUNG LESION SCORES*

Group	Calf ID	Ave. LLS (Scorer 1 & 2)
Controls	445	3.52
	446	4.22
	451	2.89
	454	16.72
	456	4.86
	457	6.45
	459	14.70
	460	9.31
	461	8.26
	464	3.59
	466	11.98
	467	5.36
	469	7.96
	471	9.95
	472	3.53
	473	27.30
	476	4.22
	479	4.83
480	6.11	
483	9.08	
484	5.74	
487	3.86	
Vaccinates	444	4.24
	447	1.54
	448	4.02
	449	0.39
	450	1.52
	452	4.97
	453	0.59
	455	1.15
	458	0.35
	462	1.63
	463	6.03
	465	3.65
	468	6.85
	470	1.11
	474	2.13
	475	1.57
	477	3.43
	478	5.47
481	0.83	
482	2.15	
485	2.63	
486	0.36	

* Lung Lesion Score average is based on the mean of two independent scorers.

Study Type	Safety																														
Pertaining to	ALL																														
Study Purpose	Demonstrate safety of product under typical use conditions																														
Product Administration	A single 2 mL dose administered by the intranasal (IN) route																														
Study Animals	998 calves, 0 to 63 days of age, at 3 different geographical locations consisting of 665 vaccinates and 333 controls																														
Challenge Description	NA																														
Interval observed after challenge	Animals were observed daily for 14 days post vaccination.																														
Results	<p><u>Clinical Observations</u>: Numbers of animals with specific clinical observations post-vaccination:</p> <table border="1"> <thead> <tr> <th>Adverse Events (AE): VeDDRA Preferred Term (Total 998 animals in study)</th> <th>Number* Vaccinates</th> <th>Number* Control</th> </tr> </thead> <tbody> <tr> <td>NORMAL</td> <td>556</td> <td>290</td> </tr> <tr> <td>RESPIRATORY TRACT DISORDER NOS</td> <td>64</td> <td>23</td> </tr> <tr> <td>DIARRHOEA</td> <td>54</td> <td>22</td> </tr> <tr> <td>DEATH</td> <td>10</td> <td>4</td> </tr> <tr> <td>LETHARGY</td> <td>7</td> <td>4</td> </tr> <tr> <td>LAMENESS</td> <td>2</td> <td>1</td> </tr> <tr> <td>PNEUMONIA</td> <td>3</td> <td>0</td> </tr> <tr> <td>DIGESTIVE TRACT HAEMORRHAGE NOS</td> <td>1</td> <td>0</td> </tr> <tr> <td>SEPTICAEMIA</td> <td>1</td> <td>0</td> </tr> </tbody> </table> <p>NOS = Not otherwise specified</p> <p>* Subjects may have had AE in more than one VeDDRA Preferred Term and are counted once in each appropriate class. VeDDRA is the Veterinary Dictionary for Drug Regulatory Activities.</p> <p>All deaths were considered not vaccine product related as affirmed by licensee.</p>	Adverse Events (AE): VeDDRA Preferred Term (Total 998 animals in study)	Number* Vaccinates	Number* Control	NORMAL	556	290	RESPIRATORY TRACT DISORDER NOS	64	23	DIARRHOEA	54	22	DEATH	10	4	LETHARGY	7	4	LAMENESS	2	1	PNEUMONIA	3	0	DIGESTIVE TRACT HAEMORRHAGE NOS	1	0	SEPTICAEMIA	1	0
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LAMENESS	2	1																													
PNEUMONIA	3	0																													
DIGESTIVE TRACT HAEMORRHAGE NOS	1	0																													
SEPTICAEMIA	1	0																													
USDA Approval Date	July 5, 2019																														

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Safety by intranasal administration to pregnant cows and calves nursing pregnant cows
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Scientific data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.