



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	12X1.21
True Name	Canine Adenovirus Type 2-Parainfluenza-Bordetella Bronchiseptica Vaccine, Modified Live Virus & Avirulent Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vanguard CC 3 Intranasal - Zoetis New Zealand Ltd Vanguard Intranasal Rapid RESP 3 - No distributor specified Vanguard Intranasal Rapid RESP 3 SF - No distributor specified
Date of Compilation Summary	April 10, 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>	Canine Adenovirus Type 2 (CAV-2)																																																																						
<b>Study Purpose</b>	To demonstrate effectiveness against Canine Adenovirus Type 2 respiratory disease one year after vaccination																																																																						
<b>Product Administration</b>	One dose, administered intranasally																																																																						
<b>Study Animals</b>	Study involved 20 vaccinated and 10 control puppies, 8 weeks of age																																																																						
<b>Challenge Description</b>	Challenged with CAV-2, one year after vaccination																																																																						
<b>Interval observed after challenge</b>	After challenge, dogs were observed for 14 days for clinical signs of respiratory disease and sampled for nasal secretions to measure challenge virus shedding.																																																																						
<b>Results</b>	<p><b>Table 1:</b> Frequency Distribution of Coughing</p> <table border="1"> <thead> <tr> <th rowspan="3">Treatment</th> <th colspan="4">Coughing</th> <th rowspan="3">Total No. of Animals</th> </tr> <tr> <th colspan="2">No</th> <th colspan="2">Yes</th> </tr> <tr> <th>No. of Animals</th> <th>%</th> <th>No. of Animals</th> <th>%</th> </tr> </thead> <tbody> <tr> <td>Control</td> <td>0</td> <td>0%</td> <td>10</td> <td>100%</td> <td>10</td> </tr> <tr> <td>Vaccinated</td> <td>10</td> <td>50%</td> <td>10</td> <td>50%</td> <td>20</td> </tr> </tbody> </table> <p>No indicates coughing never observed, yes indicates coughing observed at least once.</p> <p><b>Table 2:</b> Five Number Summary of Duration of Cough (Days) by Treatment Group (<math>Q_1 = 25^{\text{th}}</math> percentile; <math>Q_3 = 75^{\text{th}}</math> percentile)</p> <table border="1"> <thead> <tr> <th>Treatment Number</th> <th>Minimum</th> <th>25th Percentile</th> <th>Median</th> <th>75th Percentile</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td>Control</td> <td>1</td> <td>3</td> <td>5.0</td> <td>8</td> <td>9</td> </tr> <tr> <td>Vaccinated</td> <td>0</td> <td>0</td> <td>0.5</td> <td>4</td> <td>14</td> </tr> </tbody> </table> <p><b>Table 3:</b> Frequency Distribution of Disease by Treatment Group</p> <table border="1"> <thead> <tr> <th rowspan="3">Treatment</th> <th colspan="4">Disease</th> <th rowspan="3">Total No. of Animals</th> </tr> <tr> <th colspan="2">No</th> <th colspan="2">Yes</th> </tr> <tr> <th>No. of Animals</th> <th>%</th> <th>No. of Animals</th> <th>%</th> </tr> </thead> <tbody> <tr> <td>Control</td> <td>0</td> <td>0.00</td> <td>10</td> <td>100.00</td> <td>10</td> </tr> <tr> <td>Vaccinated</td> <td>7</td> <td>35.00</td> <td>13</td> <td>65.00</td> <td>20</td> </tr> </tbody> </table> <p>For an animal to be considered diseased, one or more clinical signs were required to be present at least once.</p> <p>The raw data are shown on attached page</p>	Treatment	Coughing				Total No. of Animals	No		Yes		No. of Animals	%	No. of Animals	%	Control	0	0%	10	100%	10	Vaccinated	10	50%	10	50%	20	Treatment Number	Minimum	25th Percentile	Median	75th Percentile	Maximum	Control	1	3	5.0	8	9	Vaccinated	0	0	0.5	4	14	Treatment	Disease				Total No. of Animals	No		Yes		No. of Animals	%	No. of Animals	%	Control	0	0.00	10	100.00	10	Vaccinated	7	35.00	13	65.00	20
Treatment	Coughing				Total No. of Animals																																																																		
	No		Yes																																																																				
	No. of Animals	%	No. of Animals	%																																																																			
Control	0	0%	10	100%	10																																																																		
Vaccinated	10	50%	10	50%	20																																																																		
Treatment Number	Minimum	25th Percentile	Median	75th Percentile	Maximum																																																																		
Control	1	3	5.0	8	9																																																																		
Vaccinated	0	0	0.5	4	14																																																																		
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Control	0	0.00	10	100.00	10																																																																		
Vaccinated	7	35.00	13	65.00	20																																																																		
<b>USDA Approval Date</b>	June 1, 2017																																																																						

**Table 4: Cough Score Post-Challenge**

Animal	Trt	SD 367		SD 368		SD 369		SD 370		SD 371		SD 372		SD 373		SD 374		SD 375		SD 376		SD 377		SD 378		SD 379		SD 380		SD 381		SD 382			
		am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm		
1564001	Controls	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	2	2	0	2	0	0	0	0	0	0	2	0	0	2	0	0		
1564002		0	0	0	0	0	0	0	0	0	0	0	2	2	2	3	0	2	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0		
1564105		0	0	0	0	0	0	0	0	0	0	0	2	0	0	2	1	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564204		0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2	0	0	0	0	0	0	0	2	0	0	0	2	0	0		
1564301		0	0	0	0	0	0	0	0	0	0	0	1	2	0	2	0	3	3	3	0	2	2	2	2	2	0	0	0	2	0	0	0		
1564302		0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1564305		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0		
1564401		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	2	2	2	0	2	0	0	0	0	0	0	0	0	0	0	0	0	
1564403		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	2	0	
1564501		0	0	0	0	0	0	0	0	0	0	0	1	0	2	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1563901	Vaccinated	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1563902		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1563905		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564003		0	2	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	2	0	0	0	1	0	2	0	0	2	0	
1564101		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564102		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564103		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	0	
1564104		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564201		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564203		0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
1564303		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	2	0	0	
1564304		0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
1564402		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564502		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2	0	0	2	0	0	0	0	0	0	0	0	0	0
1564503		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564506		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564507	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	2	0	0	0	0	0	
1564601	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564602	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564605	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

0 – Absent

1 – Mild: Animal coughed once during clinical observation

2 – Moderate: Spontaneous/frequent coughing. Animal coughed 2X or more during clinical observation.

3 – Severe: Spontaneous with retching/Frequent coughing with retching. Animal had persistent and prolonged cough.

**Table 5: Nasal Discharge Score Post-Challenge**

Animal	Trt	SD 367		SD 368		SD 369		SD 370		SD 371		SD 372		SD 373		SD 374		SD 375		SD 376		SD 377		SD 378		SD 379		SD 380		SD 381		SD 382			
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM					
1564001	Controls	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
1564002		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
1564105		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	0	0	1	0	0	0	0	0	0	0	0	1	0	0		
1564204		0	0	0	0	0	0	0	1	0	1	0	1	0	1	1	0	0	2	1	2	1	2	0	2	1	0	1	1	0	2	0	0		
1564301		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	1	0	0	0		
1564302		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1564305		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1564401		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564403		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1	0	0	0	0	0	0	0	1	0	0	0	0	0	
1564501		0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	
1563901	Vaccinated	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0		
1563902		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	
1563905		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564003		0	0	1	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564101		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	
1564102		1	0	0	0	0	0	0	0	0	2	0	0	0	2	0	1	0	2	0	2	0	2	0	2	0	0	0	0	0	0	0	1	0	0
1564103		0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564104		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	
1564201		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564203		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
1564303		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564304		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564402		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564502		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564503		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564506		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564507		1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564601		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564602	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
1564605	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

**Nasal Discharge:**

- 0 – Absent (includes normal, moist nose)
- 1 – Mild: Serous (clear, watery) discharge, must be extending approximately ½ way down the nasal philtrum
- 2 – Moderate: Serous extending more than ½ way down the nasal philtrum, or evidence of mucopurulent discharge
- 3 – Severe: Mucopurulent discharge extending more than ½ way down the nasal philtrum, or bloody, or a combination of mucopurulent and bloody discharge

**Table 6: Ocular Discharge Score Post-Challenge**

Animal	Trt	SD 367		SD 368		SD 369		SD 370		SD 371		SD 372		SD 373		SD 374		SD 375		SD 376		SD 377		SD 378		SD 379		SD 380		SD 381		SD 382			
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM			
1564001	Controls	1	2	1	0	1	2	0	2	2	1	2	0	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	2			
1564002		0	0	1	0	0	0	2	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
1564105		0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
1564204		0	0	0	0	0	0	2	1	0	0	0	0	0	2	0	0	0	1	1	1	1	0	0	0	0	0	0	1	0	0	0	0		
1564301		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1564302		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1564305		1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
1564401		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1564403		0	0	1	0	1	0	0	0	0	1	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
1564501		0	1	0	0	0	0	1	1	2	1	0	2	2	2	2	2	2	2	2	2	2	0	2	0	2	0	0	0	0	0	0	2		
1563901	Vaccinated	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
1563902		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1563905		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1564003		1	2	1	0	1	1	2	2	1	2	2	2	2	2	0	1	2	1	2	2	1	2	2	2	2	2	2	2	2	1	1	2	2	2
1564101		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564102		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564103		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564104		2	2	2	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	1	1	2	2	2	2	2	2	2	2	2	2	2	2	
1564201		0	0	0	0	1	2	1	0	2	0	2	1	0	2	1	1	0	0	1	1	1	1	0	1	0	0	0	0	0	2	1	2	0	
1564203		2	2	0	0	1	1	2	2	2	0	2	2	2	1	2	0	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
1564303		0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564304		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564402		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	
1564502		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564503		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564506	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
1564507	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1564601	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1564602	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2		
1564605	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		

Ocular Discharge: must be brimming and/or flowing out of the eye

0 – Absent

1 – Mild: evidence of excessive tear production, such as some secretion the corner of the eye or brimming with tears

2 – Moderate: thin and clear, serous (clear, watery) flowing out of the eye

3 – Severe: Mucopurulent discharge flowing out of the eye

**Table 7: Respiration Score Post-Challenge**

Animal	Trt	SD 367		SD 368		SD 369		SD 370		SD 371		SD 372		SD 373		SD 374		SD 375		SD 376		SD 377		SD 378		SD 379		SD 380		SD 381		SD 382	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	
1564001	Controls	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564002		0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564105		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564204		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564301		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	0	0	0	0	0	0	0	0	0	0	0
1564302		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564305		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564401		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564403		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564501		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1563901	Vaccinated	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1563902		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1563905		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564003		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564101		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564102		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564103		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564104		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564201		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564203		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564303		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564304		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564402		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564502		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564503		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564506		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564507		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564601		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564602	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564605	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

Respiration:

0 – Absent

2 – Moderate: Small clicking, bubbling, or rattling sounds in the lung (Rales)

3 – Severe: Difficult or labored breathing; shortness of breath (Dyspnea)

**Table 8: Retch Score Post-Challenge**

Animal	Trt	SD 367		SD 368		SD 369		SD 370		SD 371		SD 372		SD 373		SD 374		SD 375		SD 376		SD 377		SD 378		SD 379		SD 380		SD 381		SD 382						
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM					
1564001	Controls	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
1564002		0	0	0	0	0	0	0	0	0	0	0	0	3	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
1564105		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
1564204		0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
1564301		0	0	0	0	0	0	0	0	0	0	0	1	2	0	2	0	2	2	2	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0			
1564302		0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
1564305		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
1564401		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1564403		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1564501		0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1563901	Vaccinated	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
1563902		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1563905		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564003		0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564101		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564102		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564103		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564104		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564201		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564203		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564303		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564304		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564402		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564502		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564503		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564506		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564507		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564601		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564602	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564605	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

Retch: incoercible and unsuccessful attempts to vomit

0 – Absent

1 – Mild: Animal retches or vomits once briefly or occasionally

2 – Moderate: Animal retches or vomits for a prolonged period

3 – Severe: Animal retches or vomits multiple times for a prolonged period

**Table 9: Sneeze Score Post-Challenge**

Animal	Trt	SD 367		SD 368		SD 369		SD 370		SD 371		SD 372		SD 373		SD 374		SD 375		SD 376		SD 377		SD 378		SD 379		SD 380		SD 381		SD 382	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	
1564001	Controls	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
1564002		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564105		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564204		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564301		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564302		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564305		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564401		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564403		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564501		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1563901	Vaccinated	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1563902		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1563905		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564003		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564101		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564102		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564103		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564104		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564201		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564203		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564303		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564304		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564402		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564502		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564503		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564506		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564507		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1564601	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564602	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1564605	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

Sneeze:

- 0 – Absent
- 1 – Mild: Animal sneezed once or twice during observation
- 2 – Moderate: Animal sneezed repeatedly during clinical observation
- 3 – Severe: Animal presented paroxysmal sneeze



<b>Study Type</b>	Efficacy																																		
<b>Pertaining to</b>	Canine Adenovirus Type 2 (CAV-2)																																		
<b>Study Purpose</b>	To demonstrate effectiveness against Canine Adenovirus Type 2 respiratory disease																																		
<b>Product Administration</b>	One dose, administered intranasally																																		
<b>Study Animals</b>	Study involved 20 vaccinated and 10 control puppies, 8 weeks of age																																		
<b>Challenge Description</b>	Challenged with CAV-2, twenty-one days after vaccination																																		
<b>Interval observed after challenge</b>	After challenge, dogs were observed for coughing for 14 days post-challenge.																																		
<b>Results</b>	<p><u>Table 1: Clinical Respiratory Sign (Coughing)</u></p> <table border="1"> <thead> <tr> <th rowspan="2">Treatment</th> <th rowspan="2">Total</th> <th colspan="2">At least 1 day</th> <th colspan="2">At least one occurrence of 2 consecutive days</th> <th colspan="3">Duration</th> </tr> <tr> <th>Positive</th> <th>Negative</th> <th>Positive</th> <th>Negative</th> <th>Q1</th> <th>Median</th> <th>Q3</th> </tr> </thead> <tbody> <tr> <td>Control</td> <td>10</td> <td>6/10 (60%)</td> <td>4/10 (40%)</td> <td>3/10 (30%)</td> <td>7/10 (70%)</td> <td>0</td> <td>1</td> <td>6</td> </tr> <tr> <td>Vaccinated</td> <td>20</td> <td>3/20 (15%)</td> <td>17/20 (85%)</td> <td>0/20 (0%)</td> <td>20/20 (100%)</td> <td>0</td> <td>0</td> <td>0</td> </tr> </tbody> </table> <p>For an animal to be considered diseased, a cough was required to be present at least once.</p> <p>Please see attached page for raw data.</p>	Treatment	Total	At least 1 day		At least one occurrence of 2 consecutive days		Duration			Positive	Negative	Positive	Negative	Q1	Median	Q3	Control	10	6/10 (60%)	4/10 (40%)	3/10 (30%)	7/10 (70%)	0	1	6	Vaccinated	20	3/20 (15%)	17/20 (85%)	0/20 (0%)	20/20 (100%)	0	0	0
Treatment	Total			At least 1 day		At least one occurrence of 2 consecutive days		Duration																											
		Positive	Negative	Positive	Negative	Q1	Median	Q3																											
Control	10	6/10 (60%)	4/10 (40%)	3/10 (30%)	7/10 (70%)	0	1	6																											
Vaccinated	20	3/20 (15%)	17/20 (85%)	0/20 (0%)	20/20 (100%)	0	0	0																											
<b>USDA Approval Date</b>	April 08, 2013																																		

**Table 2: Individual Animal Data of Coughing**

Animal	Trt	Day 21		Day 22		Day 23		Day 24		Day 25		Day 26		Day 27		Day 28		Day 29		Day 30		Day 31		Day 32		Day 33		Day 34		Day 35					
		Pre-Challenge	Post-Challenge	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM					
1117505	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
1117604		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
1117701		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1117704		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1117707		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1117801		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1117804		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1145102		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1145205		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1145301		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1117601		Vaccinated	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1117602			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1117603			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1117605			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1117702			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1117703	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1117705	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1117706	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1117802	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1117803	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1117805	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1117806	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1117807	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1145101	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1145103	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1145201	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1145202	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1145203	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1145204	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
1145302	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		

**Key**

- Trt = Treatment
- 1 = mild cough
- 2 = moderate coughing
- 3 = severe coughing

<b>Study Type</b>	Efficacy																							
<b>Pertaining to</b>	Bordetella bronchiseptica ( <i>B. bronchiseptica</i> )																							
<b>Study Purpose</b>	To demonstrate effectiveness against <i>B. bronchiseptica</i> infection one year after vaccination																							
<b>Product Administration</b>	One dose, administered intranasally																							
<b>Study Animals</b>	Study involved 16 vaccinated and 16 control puppies, 8 weeks of age																							
<b>Challenge Description</b>	Challenged with <i>B. bronchiseptica</i> , one year after vaccination																							
<b>Interval observed after challenge</b>	After challenge, dogs were observed daily 28 days post-challenge.																							
<b>Results</b>	<p>Number of days of coughing Five number summary (<i>Q</i>=quartile)</p> <table border="1"> <thead> <tr> <th rowspan="2">Treatment</th> <th colspan="5">Number of Days Animal Coughed</th> </tr> <tr> <th>Min</th> <th>Q1</th> <th>Median</th> <th>Q3</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>Control</td> <td>4.0</td> <td>10.0</td> <td>18.0</td> <td>25.5</td> <td>28.0</td> </tr> <tr> <td>Vaccine</td> <td>0.0</td> <td>1.5</td> <td>4.0</td> <td>9.5</td> <td>20.0</td> </tr> </tbody> </table> <p>If coughing was observed at either of the two daily observation periods on a day, that day was positive for coughing.</p> <p>The raw data is shown on the attached page</p>	Treatment	Number of Days Animal Coughed					Min	Q1	Median	Q3	Max	Control	4.0	10.0	18.0	25.5	28.0	Vaccine	0.0	1.5	4.0	9.5	20.0
Treatment	Number of Days Animal Coughed																							
	Min	Q1	Median	Q3	Max																			
Control	4.0	10.0	18.0	25.5	28.0																			
Vaccine	0.0	1.5	4.0	9.5	20.0																			
<b>USDA Approval Date</b>	June 20, 2014																							

Table 3: Individual Animal Data for Coughing Post-challenge

Animal	Trt	Pre-challenge		Post-challenge		Day 370	Day 371	Day 372	Day 373	Day 374	Day 375	Day 376	Day 377	Day 378	Day 379	Day 380	Day 381	Day 382	Day 383	Day 384	Day 385	Day 386	Day 387	Day 388	Day 389	Day 390	Day 391	Day 392	Day 393	Day 394	Day 395	Day 396	Day 397	Day 398											
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM												
LGA-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0												
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0												
LHA-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0												
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0											
LBA-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0											
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0										
LCA-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0										
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0									
LDA-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0									
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0								
LVA-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0								
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0							
LWA-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0							
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0						
LVA-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0						
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
OVA-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
PBA-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
QBA-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
QVA-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
QBA-2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Key  
 Trt = treatment      1 = mild cough  
 2 = moderate cough    3 = severe cough

<b>Study Type</b>	Efficacy																																		
<b>Pertaining to</b>	Bordetella bronchiseptica ( <i>B. bronchiseptica</i> )																																		
<b>Study Purpose</b>	To demonstrate efficacy against <i>B. bronchiseptica</i> infection																																		
<b>Product Administration</b>	One dose, administered intranasally																																		
<b>Study Animals</b>	Study involved 16 vaccinated and 16 control puppies, 8 weeks of age																																		
<b>Challenge Description</b>	Challenged with <i>B. bronchiseptica</i> , 42 days after vaccination																																		
<b>Interval observed after challenge</b>	After challenge, dogs were observed daily for coughing for 28 days																																		
<b>Results</b>	<p>A dog was considered affected if coughing was observed at least once on 2 or more consecutive days.</p> <p><u>Table 1: Clinical Respiratory Sign (Coughing)</u></p> <table border="1"> <thead> <tr> <th rowspan="2">Treatment</th> <th rowspan="2">Total</th> <th colspan="2">At least 1 day</th> <th colspan="2">At least one occurrence of 2 consecutive days</th> <th colspan="3">Duration</th> </tr> <tr> <th>Positive</th> <th>Negative</th> <th>Positive</th> <th>Negative</th> <th>Q1</th> <th>Median</th> <th>Q3</th> </tr> </thead> <tbody> <tr> <td>Control</td> <td>16</td> <td>16/16 (100%)</td> <td>0/16 (0%)</td> <td>15/16 (94%)</td> <td>1/16 (6%)</td> <td>18.5</td> <td>22.0</td> <td>23.5</td> </tr> <tr> <td>Vaccinated</td> <td>16</td> <td>7/16 (44%)</td> <td>9/16 (56%)</td> <td>0/16 (0%)</td> <td>16/16 (100%)</td> <td>0</td> <td>0</td> <td>9.5</td> </tr> </tbody> </table> <p>Please see attached page for individual raw data.</p>	Treatment	Total	At least 1 day		At least one occurrence of 2 consecutive days		Duration			Positive	Negative	Positive	Negative	Q1	Median	Q3	Control	16	16/16 (100%)	0/16 (0%)	15/16 (94%)	1/16 (6%)	18.5	22.0	23.5	Vaccinated	16	7/16 (44%)	9/16 (56%)	0/16 (0%)	16/16 (100%)	0	0	9.5
Treatment	Total			At least 1 day		At least one occurrence of 2 consecutive days		Duration																											
		Positive	Negative	Positive	Negative	Q1	Median	Q3																											
Control	16	16/16 (100%)	0/16 (0%)	15/16 (94%)	1/16 (6%)	18.5	22.0	23.5																											
Vaccinated	16	7/16 (44%)	9/16 (56%)	0/16 (0%)	16/16 (100%)	0	0	9.5																											
<b>USDA Approval Date</b>	April 18, 2013																																		



<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Canine Parainfluenza Virus (CPIV)
<b>Study Purpose</b>	To demonstrate effectiveness against Canine Parainfluenza Virus respiratory disease one year after vaccination.
<b>Product Administration</b>	One dose, administered intranasally.
<b>Study Animals</b>	Study involved 20 vaccinated and 10 control puppies seronegative to CPIV, 7-8 weeks of age.
<b>Challenge Description</b>	Challenged with CPIV strain, one year after vaccination.
<b>Interval observed after challenge</b>	After challenge dogs were observed for 14 days and sampled for nasal secretions to measure challenge virus shedding.

**Results**

An animal was considered affected if the nasal virus isolation titer was  $> 0.5 \log_{10} \text{TCID}_{50}/\text{mL}$  at any point post-challenge.

**Table 1:** Frequency distribution of ever having CPIV detected post-challenge in nasal swabs

	Ever Detected?				Total No. of Animals
	No		Yes		
	No. of Animals	%	No. of Animals	%	
<b>Treatment</b>					
<b>Controls</b>	2	20.00	8	80.00	10
<b>Vaccinates</b>	16	80.00	4	20.00	20

The raw data is shown on the attached page.

**USDA Approval Date**

October 3, 2017



**Table 2:** Individual animal data of ever having CPIV detected post-challenge and duration in days of virus detection.

<b>Treatment Number</b>	<b>Animal</b>	<b>Ever Detected</b>	<b>Duration in Days</b>
Un-vaccinated/ Control Animals	6531989	<b>Yes</b>	<b>4</b>
	6532195	<b>Yes</b>	<b>1</b>
	6531814	No	0
	6532004	<b>Yes</b>	<b>1</b>
	6531849	No	0
	6532420	<b>Yes</b>	<b>4</b>
	6531997	<b>Yes</b>	<b>5</b>
	6531857	<b>Yes</b>	<b>4</b>
	6532128	<b>Yes</b>	<b>6</b>
	6532080	<b>Yes</b>	<b>1</b>
Vaccinated Animals	6531881	No	0
	6531962	No	0
	6532136	No	0
	6532446	<b>Yes</b>	<b>1</b>
	6531792	No	0
	6531890	No	0
	6532047	<b>Yes</b>	<b>1</b>
	6532055	No	0
	6531822	No	0
	6531831	No	0
	6532411	No	0
	6532438	No	0
	6532063	No	0
	6532071	No	0
	6531806	No	0
	6531865	<b>Yes</b>	<b>1</b>
	6532098	No	0
	6532110	No	0
	6532101	No	0
6532144	<b>Yes</b>	<b>3</b>	

**Table 3.** Nasal swab virus isolation titer data post-challenge for each animal by treatment group

Animal	Trt	SD 367	SD 368	SD 369	SD 370	SD 371	SD 372	SD 373	SD 374	SD 375	SD 376	SD 377	SD 378	SD 379	SD 380
6531814	Control Animals	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6531849		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6531857		<= 0.5	<= 0.5	1.8	1.8	<= 0.5	1	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6531989		<= 0.5	1	2	2.3	1.3	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6531997		<= 0.5	1	2	1.5	0.8	0.8	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532004		<= 0.5	<= 0.5	<= 0.5	0.8	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532080		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	1	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532128		<= 0.5	1	1	1.5	1	1.5	0.8	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532195		<= 0.5	1	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532420		<= 0.5	<= 0.5	1.8	2.3	1.8	0.8	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6531792	Vaccinated Animals	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6531806		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6531822		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6531831		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6531865		<= 0.5	<= 0.5	0.8	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6531881		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6531890		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6531962		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532047		<= 0.5	<= 0.5	<= 0.5	1.3	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532055		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532063		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532071		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532098		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532101		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532110		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532136		<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532144		<= 0.5	1.8	1	2.8	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5
6532411	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	
6532438	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	
6532446	<= 0.5	1	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	<= 0.5	

TRT – Treatment Group

SD – Study Day

<=0.5 is considered negative

<b>Study Type</b>	Efficacy																		
<b>Pertaining to</b>	Canine Parainfluenza (CPIV)																		
<b>Study Purpose</b>	To demonstrate effectiveness against CPIV infection																		
<b>Product Administration</b>	One dose, administered intranasally																		
<b>Study Animals</b>	Study involved 20 vaccinated and 10 control puppies, 7-9 weeks of age																		
<b>Challenge Description</b>	Challenged with CPIV, 3 weeks after vaccination																		
<b>Interval observed after challenge</b>	After challenge, dogs were observed daily for 2 weeks and nasal swab samples were collected daily for 12 days.																		
<b>Results</b>	<p>CPIV was detected in nasal swabs of 9/10 controls and 6/20 vaccinates during the observation period.</p> <p><u>Number of days of nasal shedding</u> Five-number summary (<i>Q</i>=quartile)</p> <table border="1"> <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><i>Vaccinates</i></td> <td>0</td> <td>0</td> <td>0</td> <td>1</td> <td>5</td> </tr> <tr> <td><i>Controls</i></td> <td>0</td> <td>2</td> <td>3.5</td> <td>6</td> <td>6</td> </tr> </tbody> </table> <p>Please see attached page for individual raw data.</p>	<i>Group</i>	<i>Min</i>	<i>Q1</i>	<i>Median</i>	<i>Q3</i>	<i>Max</i>	<i>Vaccinates</i>	0	0	0	1	5	<i>Controls</i>	0	2	3.5	6	6
<i>Group</i>	<i>Min</i>	<i>Q1</i>	<i>Median</i>	<i>Q3</i>	<i>Max</i>														
<i>Vaccinates</i>	0	0	0	1	5														
<i>Controls</i>	0	2	3.5	6	6														
<b>USDA Approval Date</b>	March 14, 2013																		

**Table 2: Individual animal data for CPIV Quantitative Virus Isolation from Nasal Swabs Post-Challenge**

Animal	Trt	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28	Day 29	Day 30	Day 31	Day 32	Day 33	
1220604	Control	0.5	2.5	2	0.5	0.8	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
1220701		0.5	0.5	0.5	0.5	0.5	0.5	2.3	0.5	0.5	0.5	0.5	0.5	
1220705		0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
1220706		0.5	2.3	2.8	3	2.5	2.5	0.5	0.5	0.5	0.5	0.5	0.5	
1221003		0.5	2.5	0.5	0.5	0.5	0.8	0.5	0.5	0.5	0.5	0.5	0.5	
1221201		0.5	3	2.5	3.5	1.3	1.8	1	0.5	0.5	0.5	0.5	0.5	
1221302		0.5	2.8	3	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
1221401		0.8	3	2.8	1.5	1.8	0.8	0.5	0.5	0.5	0.5	0.5	0.5	
1221404		1.8	1.5	2.3	0.8	0.8	1.5	0.5	0.5	0.5	0.5	0.5	0.5	
1221406		0.5	2.8	3.5	2.8	0.8	1	0.5	0.5	0.5	0.5	0.5	0.5	
1220601		Vaccinated	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
1220602			0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
1220603			0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
1220702			0.5	0.8	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
1220703	0.5		0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
1220704	0.5		0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
1220901	0.5		0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
1220902	0.5		0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
1221001	0.5		0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
1221002	0.5		0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
1221101	0.5		0.5	0.5	0.5	0.8	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
1221102	0.5		1.3	2.8	3	0.8	0.8	1.5	0.5	0.5	0.5	0.5	0.5	
1221202	0.5		0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
1221203	0.5		0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	
1221301	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5		
1221303	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5		
1221402	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5		
1221403	0.5	0.5	0.8	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5		
1221405	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5		
1221407	0.5	0.5	0.5	2.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5		

Trt = treatment  
 Green shading denotes positive virus isolation

<b>Study Type</b>	Safety
<b>Pertaining to</b>	Canine Adenovirus Type 2 (CAV-2)
<b>Study Purpose</b>	Safety Evaluation to demonstrate the development of corneal opacity is not associated with the use of this product.
<b>Product Administration</b>	
<b>Study Animals</b>	Dogs
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	15 August, 1977

<b>Study Type</b>	Safety																																				
<b>Pertaining to</b>	ALL																																				
<b>Study Purpose</b>	To demonstrate safety under conditions of normal use																																				
<b>Product Administration</b>	One dose, administered intranasally																																				
<b>Study Animals</b>	Study involved 674 dogs total, with 239 dogs approximately 7-9 weeks of age and 435 dogs 10 weeks of age or older. Dogs were assigned to one of two lots of vaccine (T01- 309 animals; T02- 305 animals) or to a non-treated control group (T03- 60 animals).																																				
<b>Challenge Description</b>	N/A																																				
<b>Interval observed after challenge</b>	Immediate abnormal health events were assessed for approximately 10-15 minutes post-vaccination and late abnormal health events were assessed for 14 days post-vaccination.																																				
<b>Results</b>	<p>There were no immediate post-vaccination reactions observed in any of the vaccinated groups (T01, T02). There were no abnormal health events associated with the control group (T03).</p> <p><u>Frequency Distribution of Late Abnormal Health Events with dogs administered the product (T01 and T02)</u></p> <table border="1"> <thead> <tr> <th>Clinical Signs Associated with Abnormal Health Event †</th> <th>Number/Total Number of Animals (%)</th> </tr> </thead> <tbody> <tr> <td>Anorexia</td> <td>3/614 (0.49%)</td> </tr> <tr> <td>Ataxia</td> <td>1/614 (0.16%)</td> </tr> <tr> <td>Cough*</td> <td>7/614 (1.14%)</td> </tr> <tr> <td>Cystitis</td> <td>2/614 (0.33%)</td> </tr> <tr> <td>Dermatitis</td> <td>1/614 (0.16%)</td> </tr> <tr> <td>Diarrhea</td> <td>4/614 (0.65%)</td> </tr> <tr> <td>Emesis*</td> <td>3/614 (0.49%)</td> </tr> <tr> <td>Emesis</td> <td>5/614 (0.80%)</td> </tr> <tr> <td>Internal ear disorder (head tilt)</td> <td>1/614 (0.16%)</td> </tr> <tr> <td>Lethargy</td> <td>5/614 (0.81%)</td> </tr> <tr> <td>Nystagmus</td> <td>1/614 (0.16%)</td> </tr> <tr> <td>Otitis externa</td> <td>2/614 (0.33%)</td> </tr> <tr> <td>Pruritis</td> <td>1/614 (0.16%)</td> </tr> <tr> <td>Pyrexia</td> <td>2/614 (0.33%)</td> </tr> <tr> <td>Rhinitis</td> <td>2/614 (0.33%)</td> </tr> <tr> <td>Sneezing*</td> <td>8/614 (1.30%)</td> </tr> <tr> <td>Urticaria**</td> <td>1/614 (0.16%)</td> </tr> </tbody> </table> <p>†One dog accounted for the abnormal health events of anorexia, ataxia, head tilt, nystagmus, lethargy, and otitis externa which was affirmed by licensee to not be related to vaccination.</p> <p>*Mild, transient, and associated with the normal response to vaccination by licensee.</p>	Clinical Signs Associated with Abnormal Health Event †	Number/Total Number of Animals (%)	Anorexia	3/614 (0.49%)	Ataxia	1/614 (0.16%)	Cough*	7/614 (1.14%)	Cystitis	2/614 (0.33%)	Dermatitis	1/614 (0.16%)	Diarrhea	4/614 (0.65%)	Emesis*	3/614 (0.49%)	Emesis	5/614 (0.80%)	Internal ear disorder (head tilt)	1/614 (0.16%)	Lethargy	5/614 (0.81%)	Nystagmus	1/614 (0.16%)	Otitis externa	2/614 (0.33%)	Pruritis	1/614 (0.16%)	Pyrexia	2/614 (0.33%)	Rhinitis	2/614 (0.33%)	Sneezing*	8/614 (1.30%)	Urticaria**	1/614 (0.16%)
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	**Urticaria occurred six days after administration of the vaccination.
<b>USDA Approval Date</b>	July 09, 2015