



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Diamond Animal Health, Inc.
USDA Vet Biologics Establishment Number	213
Product Code	1181.20
True Name	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Diamond Animal Health, Inc. Titanium 5 - Elanco Animal Health - Diamond Animal Health, Inc. Titanium 5 - Elanco Salud Animal, S.A. de C.V. - Diamond Animal Health, Inc. Titanium 5 - Elanco US, Inc. - Diamond Animal Health, Inc. Titanium 5 - Elanco, Division Eli Lilly Canada, Inc. - Diamond Animal Health, Inc. Titanium 5 - Virbac México S.A. de C.V.
Date of Compilation Summary	August 16, 2021

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

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bovine Virus Diarrhea Type 1
<b>Study Purpose</b>	To demonstrate effectiveness against disease caused by bovine virus diarrhea type 1
<b>Product Administration</b>	1 dose to calves 6-8 months of age.
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	BVDV NY-1 Strain non-cytopathic Type 1b
<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>	July 14, 1998

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bovine Virus Diarrhea Virus (BVDV) Type 2
<b>Study Purpose</b>	To demonstrate effectiveness against disease caused by bovine virus diarrhea type 2
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	BVDV Type 2a strain 890
<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>	July 14, 1998

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious Bovine Rhinotracheitis (IBR) Virus
<b>Study Purpose</b>	To demonstrate effectiveness against disease caused by infectious bovine rhinotracheitis virus.
<b>Product Administration</b>	1 dose to calves 6-8 months of age.
<b>Study Animals</b>	Bovine
<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>	July 13, 1998

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious Parainfluenza <sub>3</sub> (PI <sub>3</sub> ) Virus
<b>Study Purpose</b>	To demonstrate effectiveness against disease caused by infectious Parainfluenza <sub>3</sub> Virus
<b>Product Administration</b>	1 dose to calves 6-8 months of age.
<b>Study Animals</b>	Bovine
<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>	May 15, 1998

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bovine Respiratory Syncytial Virus (BRSV)
<b>Study Purpose</b>	To demonstrate effectiveness against disease caused by infectious Bovine Respiratory Syncytial Virus
<b>Product Administration</b>	1 dose to calves 6-8 months of age.
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	BRSV Strain 375
<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>	September 20, 1993

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety of product under typical use conditions
<b>Product Administration</b>	One dose
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	NA
<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>	July 13, 1998

<b>Study Type</b>	Safety																																																									
<b>Pertaining to</b>	ALL																																																									
<b>Study Purpose</b>	To demonstrate safety in pregnant cows and calves nursing pregnant cows																																																									
<b>Product Administration</b>	Two doses administered subcutaneously to heifers and cows, 1 dose prior to breeding and 1 dose during pregnancy at different trimesters. Heifers and cows were confirmed to be pregnant at administration during pregnancy.																																																									
<b>Study Animals</b>	Heifers and cows-separate groups vaccinated during each trimester. Similar sized groups in each trimester were maintained as controls.																																																									
<b>Challenge Description</b>	NA																																																									
<b>Interval observed after challenge</b>	Heifers and cows observed from pre-breeding vaccination through birth of calves. Nursing calves observed through 4 weeks of age.																																																									
<b>Results</b>	<p>Summary of Calving Rates (Normal calves delivered/Total deliveries)</p> <table border="1"> <thead> <tr> <th>Trimester</th> <th>Vaccinates</th> <th>Controls</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>200/208 (96%)</td> <td>205/213 (96%)</td> </tr> <tr> <td>2</td> <td>302/313 (96%)</td> <td>293/308 (95%)</td> </tr> <tr> <td>3</td> <td>193/205 (94%)</td> <td>195/208 (94%)</td> </tr> <tr> <td>Total</td> <td>695/726 (96%)</td> <td>693/729 (95%)</td> </tr> </tbody> </table> <p>First Trimester (<math>\leq 93</math> days of gestation)</p> <table border="1"> <thead> <tr> <th></th> <th>Vaccinate</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>Enrolled</td> <td>209</td> <td>213</td> </tr> <tr> <td>Excluded (not related to vaccination)</td> <td>1</td> <td>0</td> </tr> <tr> <td>Aborted or stillborn</td> <td>6</td> <td>5</td> </tr> <tr> <td>Died at or after birth</td> <td>2</td> <td>3</td> </tr> </tbody> </table> <p>Second Trimester (94-187 days of gestation)</p> <table border="1"> <thead> <tr> <th></th> <th>Vaccinate</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>Enrolled</td> <td>315</td> <td>310</td> </tr> <tr> <td>Excluded (not related to vaccination)</td> <td>2</td> <td>2</td> </tr> <tr> <td>Aborted or stillborn</td> <td>7</td> <td>9</td> </tr> <tr> <td>Died at or after birth</td> <td>4</td> <td>6*</td> </tr> </tbody> </table> <p>*one death was from a set of twins; the other was normal</p> <p>Third Trimester (188-250 days of gestation)</p> <table border="1"> <thead> <tr> <th></th> <th>Vaccinate</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>Enrolled</td> <td>205</td> <td>208</td> </tr> <tr> <td>Aborted or stillborn</td> <td>9</td> <td>9*</td> </tr> <tr> <td>Died at or after birth</td> <td>3</td> <td>4**</td> </tr> </tbody> </table> <p>*one stillborn was from a set of twins; the other was normal **one dead was from a set of twins; the other was normal</p>	Trimester	Vaccinates	Controls	1	200/208 (96%)	205/213 (96%)	2	302/313 (96%)	293/308 (95%)	3	193/205 (94%)	195/208 (94%)	Total	695/726 (96%)	693/729 (95%)		Vaccinate	Control	Enrolled	209	213	Excluded (not related to vaccination)	1	0	Aborted or stillborn	6	5	Died at or after birth	2	3		Vaccinate	Control	Enrolled	315	310	Excluded (not related to vaccination)	2	2	Aborted or stillborn	7	9	Died at or after birth	4	6*		Vaccinate	Control	Enrolled	205	208	Aborted or stillborn	9	9*	Died at or after birth	3	4**
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<b>USDA Approval Date</b>	March 5, 2013