



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	16D7.20
True Name	Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live & Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Ultra Hybrid FVRCP - Elanco US Inc.
Date of Compilation Summary	November 27, 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>	Feline Calicivirus (FCV)
<b>Study Purpose</b>	To demonstrate effectiveness against respiratory disease due to Feline Calicivirus
<b>Product Administration</b>	Two doses administered subcutaneously three weeks apart.
<b>Study Animals</b>	Forty-four (44) cats, eight weeks of age, randomized into 22 vaccinates and 22 placebo controls.
<b>Challenge Description</b>	FCV was administered 28 days after second vaccination.
<b>Interval observed after challenge</b>	Cats were observed daily for clinical signs for 14 days post challenge.
<b>Results</b>	<p>The primary outcome was the presence or absence of clinical signs. An animal was considered affected if FCV-specific clinical signs (ulcers, nasal discharge, ocular discharge, or sneezing) were observed for 2 or more days.</p> <p>Positive for clinical FCV:  Vaccinates: 2/22 (9%) positive  Placebo controls: 20/22 (91%) positive</p> <p>Raw Data:  Data Table is appended to the end of the summary.</p>
<b>USDA Approval Date</b>	March 14, 2014

### FCV Post Challenge Daily Clinical Signs

Vaccinates															
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1															
2															
3															
4															
5								1	1	1	1	1	1	1	1
6															
7															
8															
9															
10															
11															
12															
13															
14															
15										7					
16															
17															
18															
19															
20							1	1	1	1	1,7				
21										6					
22															

1- One oral ulcer <4mm

2- One oral ulcer ≥4mm

3- Serous discharge from one or both nostrils

4- Muroid discharge from one or both nostrils

5- Mucopurulent discharge from one or both nostrils

Blank=no signs observed

6- Serous discharge from one or both eyes

7- non-productive sneeze

8- Violent, productive sneezing bursts

9 - lethargic

10-salivating

11 - dehydration

12 - bleeding lip

13 - bleeding gums

14 - scab on nose

15 - limp

### FCV Post Challenge Daily Clinical Signs

Placebo Controls															
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1				1	2	2,7	2,5,9	2,3,7	2,3,8,15	2,7	2,3,8	2	2,3	2	2
2				2,9,10	2,9,10	2,3,9,10	2,9,10	2,3,9,10,11	2,11	2	2,3	2	2	2	2
3									1	1	1				1
4							2,3,13	2,5	2	2	1	2	2	2	2
5				2	2	2,3,9	2	2	2	2	2,7	2	2	2	1
6							12	1	2	1	1	1	1	1	1
7	7							14	14	14	14	14	14		
8				1,9	2,3	1	2,3,9	2	2,3	2,3	2	2	2	2	2,3
9					9	2	2,3	2,3,8	2,11	2,3	2,3	2	2,3	2	2,3
10						9	1	2	2	2	2	2	2	2	2
11				2	2	2	2,3	2,3,8	2,3	2	2,3	2	2	2	2
12							1	1	1	1	1	1			
13				1	2	9	2	2	2	2	2	2	2	1	1
14				9	9	1,9	1,9	1,9	2	1	1	1	1	1	1
15						1	2	2	2	2,7	2	2	2	1	1
16				9	9,13	1	9,13	2,9	2	2	2	2	2	2	2
17					2	2	2	2	2	2	2	2,3	2	2	2
18					9	9				1	1	1	1	1	1
19					1,9	2	2	2,3	2	2	2	2	2	1	1
20							2,12	2	2	2	2	2	2	2	2
21				1		1	1	2	2	2	1	1	1	1	1
22					9,15	3,9	9,13	13	11						

1- One oral ulcer <4mm

2- One oral ulcer ≥4mm

3- Serous discharge from one or both nostrils

4- Mucoïd discharge from one or both nostrils

5- Mucopurulent discharge from one or both nostrils

Blank=no signs observed

6- Serous discharge from one or both eyes

7- non-productive sneeze

8- Violent, productive sneezing bursts

9 - lethargic

10-salivating

11 - dehydration

12 - bleeding lip

13 - bleeding gums

14 - scab on nose

15 - limp

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Feline Calicivirus (FCV)
<b>Study Purpose</b>	To demonstrate effectiveness against hemorrhagic form of Feline Calicivirus.
<b>Product Administration</b>	Two doses administered subcutaneously three weeks apart.
<b>Study Animals</b>	42 cats, 8 weeks old, randomly assigned into 22 Vaccinates and 20 Placebo controls.
<b>Challenge Description</b>	FCV was administered 28 days after second vaccination
<b>Interval observed after challenge</b>	Cats were observed for clinical signs for 14 days post challenge
<b>Results</b>	<p>Clinical disease was defined as mortality or as edema, pyoderma or alopecia, or oral ulcers for 2 or more days.</p> <p>Positive for clinical FCV:  Vaccinates: (0/22) (0%) positive  Controls: 17/20 (85%) positive</p> <p>Raw Data:  Data table is appended to the end of the summary.</p>
<b>USDA Approval Date</b>	March 18, 2014

**Mortality due to FCV Challenge in Placebo Controls**

Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8PC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1	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
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	1	Na	Na	Na	Na	Na	Na	Na
5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	1	Na	Na	Na	Na	Na	Na
8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	1	Na	Na	Na	Na	Na	Na	Na	Na
19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

0 = no

1 = yes (death or euthanasia)

NA = Not Applicable

There was no mortality observed in the vaccinated treatment group

### Clinical Observations after FCV Challenge

Placebo Controls															
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8PC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1															
2									1,5	5	6	6	5		
3											5	5			
4							3	3	Na	Na	Na	Na	Na	Na	Na
5								2	2	1	1				
6								1	5	1	6	6	6	6	5
7							3	3	3,4	Na	Na	Na	Na	Na	Na
8								3	3	3	3	3,5	5	1,5	1,5
9															
10								1	2	2	2				
11							3	3	3	3	3		1	4	
12							1	1	3,5	3,5	5	5	5		
13							2	3	3	3			5		
14									5	1,5	1,5	5			
15								3,5	2,5	1,5	3,5	5	1,5		
16							5		1,5		5				
17									2	3	1				
18						3	3	Na	Na	Na	Na	Na	Na	Na	Na
19							3	3	3	3	1	1	1	1	
20									1						

Blank - No clinical signs observed  
 1 - Mild Edema  
 2 - Moderate Edema

3 - Marked Edema  
 4 - Mild Pyoderma or alopecia  
 5 - One or more oral Ulcers (<4mm)

6 - One or more oral Ulcers (≥4mm)

No clinical signs were observed in any cat in the vaccinated treatment group at any post-challenge time point.

<b>Study Type</b>	Serology										
<b>Pertaining to</b>	Feline calicivirus (FCV)										
<b>Study Purpose</b>	Cross neutralizing antibody response against multiple field FCV isolates to support a dual strain FCV product										
<b>Product Administration</b>	Two doses administered subcutaneously 21 days apart										
<b>Study Animals</b>	44 cats vaccinated with product and 44 cats vaccinated with a matched-placebo product. Blood was collected from cats at 7 and 14 days following the second dose. Blood was pooled and the serum neutralizing antibody titer was measured.										
<b>Challenge Description</b>	NA										
<b>Interval observed after challenge</b>	NA										
<b>Results</b>	<p>In compliance with the CVB Notice 12-11, which requires serological neutralization data for heterologous FCV strains, serum pools were tested for serum neutralizing antibody titer against a panel of 33 FCV field isolates.</p> <p>The Primary Outcome was the number of known or suspect virulent FCV strains the dual strain FCV post-vaccination serum had the ability to neutralize. A titer <math>\geq 2</math> was considered positive.</p> <p>Summary of Results</p> <table border="1"> <thead> <tr> <th>FCV Strains neutralized</th> <th>Vaccinate 7DPV2</th> <th>Vaccinate 14DPV2</th> <th>Placebo 7DPV2</th> <th>Placebo 14DPV2</th> </tr> </thead> <tbody> <tr> <td>Field strains</td> <td>24/33</td> <td>20/33</td> <td>0/33</td> <td>0/33</td> </tr> </tbody> </table> <p>Raw Data is shown below:</p>	FCV Strains neutralized	Vaccinate 7DPV2	Vaccinate 14DPV2	Placebo 7DPV2	Placebo 14DPV2	Field strains	24/33	20/33	0/33	0/33
FCV Strains neutralized	Vaccinate 7DPV2	Vaccinate 14DPV2	Placebo 7DPV2	Placebo 14DPV2							
Field strains	24/33	20/33	0/33	0/33							

<b>Geometric Mean Titer from Feline Pooled Sera by Feline Calicivirus Strain</b>				
<b>FCV Strain</b>	<b>Vaccinate 7DPV2</b>	<b>Vaccinate 14DPV2</b>	<b>Placebo 7DPV2</b>	<b>Placebo 14DPV2</b>
1	6	4	<2	<2
2	10	5	<2	<2
3	2	<2	<2	<2
4	18	10	<2	<2
5	<2	<2	<2	<2
6	23	10	<2	<2
7	6	4	<2	<2
8	<2	<2	<2	<2
9	11	6	<2	<2
10	45	23	<2	<2
11	6	3	<2	<2
12	3	<2	<2	<2
13	<2	<2	<2	<2
14	4	3	<2	<2
15	<2	<2	<2	<2
16	<2	<2	<2	<2
17	2	<2	<2	<2
18	7	7	<2	<2
19	2	<2	<2	<2
20	4	3	<2	<2
21	23	23	<2	<2
22	<2	<2	<2	<2
23	<2	<2	<2	<2
24	11	12	<2	<2
25	3	2	<2	<2
26	14	10	<2	<2
27	3	2	<2	<2
28	3	3	<2	<2
29	<2	<2	<2	<2
30	<2	<2	<2	<2
31	12	7	<2	<2
32	18	11	<2	<2
33	90	72	<2	<2
Vaccine strain 1	45	72	<2	<2
Vaccine strain 2	36	41	<2	<2
<b>USDA Approval Date</b>	<b>May 15, 2015</b>			

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Feline Viral Rhinotracheitis (FVR)
<b>Study Purpose</b>	To demonstrate effectiveness against FVR
<b>Product Administration</b>	Two doses administered 21 days apart subcutaneously (SC)
<b>Study Animals</b>	Forty-two (42) cats, 8 weeks of age. Cats were randomized into two vaccinated groups of 22 and 10 cats, respectively, and one group of 10 non-vaccinated controls.
<b>Challenge Description</b>	21 days post second vaccination all cats were challenged with FVR virus.
<b>Interval observed after challenge</b>	Rectal temperatures and clinical signs were observed daily for 14 days post challenge.
<b>Results</b>	<p>Vaccinates and controls were evaluated per the criteria in 9 CFR 113.315(c)(3).</p> <p>A significant difference in clinical signs was observed between vaccinates and controls using a scoring system approved by APHIS.</p> <p>Requirements of 113.315.(3) were met.</p> <p>Raw Data: Data tables are appended to the end of the summary.</p>
<b>USDA Approval Date</b>	July 1, 1999

FVR Post challenge Daily Clinical Signs

Vaccinates - Group 1															
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1				SN	D,DH,DY	DH,NSM,AN	SN,DH,AN	SN,NSM,AN	SN,AN	NSM,AN	SN,OSM,NSM,AN	OSM,NSM,AN	NSM,AN	SN	AN
2	D	D	D	D	OSM,NSM	D,DH,NSM	SN,DH,AN	OSM,NSM,AN	OMM,NMM,AN	OSM,NMM,AN	NSM,AN	NSM,AN		NSM	NMM
3						OSM		OSM,NSM	OSM,NSM	NSM	NSM				NSM
4							SN	SN,NSM	NSM	SN,NSM	NSM	SN,NSM	SN,NSM	SN,NSM	NSM
5							OSM		OSM			OSM,NSM	OSM,NSM	SN,NSM	
6					SN	DH		NSM		SN				NSM	
7			SN			SN,OSM			NSM		SN	NSM	SN,NSM	SN	
8					SN,DY		SN,DY	SN	AN	SN,NSM	NSM	NSM	NSM		NSM
9							SN	SN,OSM,NSM	AN	NSM,AN		NSM	NSM	NSM	NSM
10							OSM	OSM	OSM,NSM	SN,OSM	OSM,NMM	NSM			
11					OSM	OSM,NSM	DY	SN	NSM	NSM	NSM	NSM	NSM	SN,NSM	NMM
12				SN		OSM	OSM	SN,OSM	NSM	NSM	NSM	NSM	OSM		
13								NSM							
14								SN							
15							OSM	OSM	NSM	SN	NSM	NSM		SN	
16			SN		SN	SN,OSM	SN,DY	SN,NSM		SN,NSM	SN,NSM	NSM	SN,OMM,NSM	SN	
17					SN	AN	AN	SN,NSM,AN	AN						
18								NSM	SN,NSM	NSM	SN	NSM	NSM		NSM
19							SN			NSM	NSM			SN	
20						AN	AN	SN,OSM,NSM,AN	AN	NSM,AN	NSM,AN	NSM	NSM	SN	NSM
21					SN,AN	SN,DH,AN	SN,OSM,AN	OSM,NSM,AN	OSM,NMM,AN	SN,DH,OSM,NSM,AN	SN,OSD,NSD,AN	SN,OMM,NMM,AN	SN,OMM,NMM,AN	SN,NSM,AN	NSM,AN
22								SN,NSM,AN	NSM,AN	AN	NSM,AN	NSM			

Empty = no signs observed

Ocular Discharge	Nasal Discharge	SN-Sneezing	CO-Coughing
OSM-Mild serous	NSM - Mild Serous	AN-Anorexia	BR-Open Mouth Breathing
OSD-Moderate serous	NSD-Moderate Serous	DH-Dehydration	D-Depression
OMM-Mild Mucoid	NMM-Mild Mucoid	DY-Snuffing	
OMD-Moderate Mucoid	NMD-Moderate Mucoid		

FVR Post challenge Daily Clinical Signs

Vaccinates - Group 2															
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1					SN			NSM	SN, NSM	NMM	AN	NSM	SN, NSM	SN, NSM	
2			SN	SN, CO, OSM	SN, OSM, BR	SN, OSM	SN, OSM, NSM	SN, OSM, NSM	SN, OSM, NSM	SN, OSM, NSM	SN, OSM	OSM	SN, OSM		
3				OSM	OSM	OSM	OSM	OSM	SN, NSM	SN, OSM, NSM	NSM	OSM, NSM		NSM	
4				OSM	OSM	OSM	SN, NSM	SN, NSM	SN, NSM	SN, NSM	NSM			SN	NMM
5				OSM	OSM	OSM	NSM	SN	SN, NSM	NSM, AN	SN, OSM	OSM	SN, OSM	SN	
6				SN, OSM	SN, OSM	SN, OSM	SN, NSM	SN, NSM	NSM	NSM	SN, OSM	SN	NSM	SN	
7				D											
8			SN	SN, OSM	AN	SN	NSM, AN	NSM, AN	OSM, NSM, AN	NMM, AN	NMM, AN	NMM, AN		SN	AN
9			SN	SN, OSM	SN, OSM	SN	SN, OSM, NSM	SN, OSM, NSM	NSM	SN	SN, OSM	SN	SN, NSM	SN	
10				DY, OSM			SN, OSM, NSM, AN	SN, OSM, NSM, AN	OSM, NMM, AN	SN, NMM	OSM, NSM	NSM	NSM	SN, NSM	NSM

  

Non-Vaccinated Controls															
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1						SN, D, OSM	SN	SN, OSM, NSM	NSM	SN, NSM		SN, NSM	NSM		
2					OSM	OSM	SN, AN	SN, NSM, AN	OSM, AN	DH, OMM, NMM, AN	SN, OMM, NMM, AN	OMM, NMM, AN	OMM, NMM, AN	SN, OMM, NMM, AN	NSM, AN
3				SN	SN	DH, OSM	SN	NSM, AN	SN, D, DY, OSM, AN	SN, OSM, NSM, AN	OMM, AN	OMM, AN	OSM, AN	SN	AN
4				OSM	OSM	OSM	OSM	OSM	OSM, NSM, AN	SN, OSM, AN	OSM	OSM	NSM		
5		AN			SN, CO	SN, OSM, AN	OSM	SN, OSM, NSM	NSM, AN	NSM, AN	SN, AN	NSM, AN	NSM, AN	SN, NSM, AN	NSM, AN
6					SN, CO	SN, OSM	SN	SN	SN, NSM	NSM	SN, NSM		SN, NSM	SN, NSM	
7					SN	DY	SN	SN, AN	SN, OSM, AN	SN, NSM, AN	SN, AN	SN	SN		
8					SN	SN, NSM	SN	SN	DY, NSM	SN, OSM	SN	SN	SN	NSM	
9							SN, OSM	SN, OSM	NSM	OSM	SN, NSM	NSM	NSM	SN, NSM	
10					SN, DY	SN, OSM, BR, AN	SN, OSM, AN	SN, OSM, NSM, AN	DY, OSM, NSM, AN	SN, OSM, NSM, AN	OSM, NSM, AN	OSM, NSM, AN	SN	SN	AN

	Nasal Discharge	SN-Sneezing	CO-Coughing
Ocular Discharge	NSM - Mild Serous	AN-Anorexia	BR-Open Mouth Breathing
OSM-Mild serous	NSM - Mild Serous	DH-Dehydration	D-Depression
OSD-Moderate serous	NSD-Moderate Serous	DY-Snuffing	
OMM-Mild Mucoid	NMM-Mild Mucoid		
OMD-Moderate Mucoid	NMD-Moderate Mucoid		

Empty = no signs observed

**FVR Post challenge Daily Body Temperature (°F)**

Cat ID	Vaccinates - Group 1																					
	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC							
1	100.4	100.0	101.1	100.0	103.4	101.6	101.2	101.1	100.3	101.4	101.2	101.5	101.5	101.7	100.0							
2	101.6	100.8	100.9	100.9	104.7	101.3	101.3	101.5	101.4	101.1	101.7	101.1	101.7	101.3	101.0							
3	100.8	100.8	100.7	100.3	101.4	103.6	101.2	101.1	100.0	100.5	101.4	101.2	100.6	100.7	101.2							
4	101.3	100.3	101.3	100.6	101.5	101.2	101.3	102.3	102.4	102.3	102.0	101.1	102.1	101.7	101.9							
5	100.2	101.2	100.9	100.8	100.5	102.9	100.8	101.5	102.5	102.4	102.2	102.1	101.2	102.2	101.0							
6	101.4	100.9	101.0	101.0	104.7	101.4	101.1	101.2	100.7	101.5	102.0	101.7	102.3	101.9	101.3							
7	100.6	101.2	100.7	100.4	101.7	102.3	101.6	102.4	101.4	101.4	102.4	100.9	101.9	102.1	100.9							
8	100.9	100.3	100.7	100.8	103.4	100.6	100.2	100.3	100.4	100.0	101.2	101.5	100.8	101.7	102.0							
9	101.4	100.8	100.8	101.3	104.6	101.4	101.2	100.4	100.0	99.9	100.6	100.0	101.2	100.7	100.5							
10	101.2	100.6	101.3	101.1	104.4	101.5	101.8	100.7	101.2	101.5	101.7	101.8	101.2	101.7	100.3							
11	100.9	100.1	101.0	101.3	103.8	101.0	101.3	101.7	100.7	100.6	100.4	101.5	101.3	101.2	100.7							
12	100.9	100.4	101.0	100.0	101.9	101.8	100.6	101.2	101.3	101.4	101.7	101.8	101.8	101.7	101.4							
13	100.6	99.9	100.3	100.1	100.8	100.8	101.3	100.1	101.3	100.7	101.2	101.0	101.0	101.4	101.0							
14	100.0	100.5	100.4	100.2	101.3	102.2	101.8	100.9	100.7	100.8	102.2	100.9	101.8	101.5	101.7							
15	101.5	101.0	101.0	100.9	101.3	102.0	100.8	100.8	100.6	100.1	100.8	101.4	100.9	101.0	100.4							
16	101.2	101.1	101.5	101.1	101.8	102.8	101.2	101.7	101.7	101.3	101.5	102.3	101.7	101.1	101.1							
17	101.2	100.8	100.9	101.5	102.9	101.9	101.2	100.8	101.1	100.9	101.0	100.6	101.4	100.0	100.3							
18	100.8	100.5	101.1	101.3	102.1	100.4	101.1	101.2	101.3	101.3	101.5	101.1	101.4	100.1	100.8							
19	100.8	100.4	100.8	101.1	103.8	103.1	101.5	102.8	102.5	102.6	102.6	101.9	102.1	102.3	101.9							
20	101.2	101.1	101.0	101.5	101.8	102.1	101.7	102.4	102.5	102.4	103.1	102.4	102.2	101.3	101.3							
21	100.3	100.0	100.5	101.7	104.1	101.8	101.9	102.2	102.5	101.7	101.4	100.8	100.7	100.7	99.9							
22	100.6	101.2	101.1	100.7	103.3	101.2	101.0	101.9	101.2	101.2	101.1	100.5	101.3	101.4	100.2							

**FVR Post challenge Daily Body Temperature (°F)**

Vaccinates <small>Group 2</small>															
Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1	100.0	101.1	100.4	100.7	101.7	101.3	100.2	100.7	101.5	101.6	101.3	101.2	101.4	101.5	100.0
2	100.8	101.0	100.6	100.7	101.7	101.2	101.6	101.2	101.1	101.1	101.3	101.5	101.8	100.7	101.0
3	100.6	101.4	100.8	101.9	101.6	101.8	100.9	102.0	102.4	102.2	102.7	102.5	102.0	102.5	101.1
4	100.9	100.2	100.7	100.4	102.7	101.5	100.2	101.9	101.7	101.9	102.1	101.9	100.0	102.7	101.6
5	100.4	100.1	101.0	100.3	102.0	101.4	101.2	101.7	101.7	101.6	101.5	101.6	101.9	100.8	100.6
6	101.7	100.9	101.5	100.7	104.6	102.7	101.9	102.2	100.6	101.3	102.3	101.1	101.3	100.6	101.5
7	100.7	100.1	101.3	100.7	101.4	102.2	101.0	101.2	100.4	101.0	101.2	100.6	100.6	100.4	100.2
8	100.7	100.6	101.1	101.1	103.1	101.7	102.2	102.5	102.3	101.4	102.3	102.6	101.6	101.8	101.7
9	101.8	101.3	101.6	100.5	102.8	103.2	102.7	102.1	102.5	102.6	102.2	102.6	102.8	101.6	101.8
10	100.6	100.6	100.7	102.5	102.9	101.9	102.0	102.6	102.4	101.3	101.5	101.5	101.9	100.8	100.4

**Non-Vaccinated Controls**

Cat ID	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1	100.7	101.1	101.2	100.4	102.0	105.0	102.0	105.0	101.4	102.2	101.3	101.7	101.8	100.0	100.8
2	101.0	100.3	101.1	100.6	101.4	103.3	101.2	102.3	103.2	101.8	102.5	102.5	101.2	102.2	100.0
3	101.3	101.5	102.0	101.2	101.6	105.3	101.2	101.8	103.5	103.5	101.6	100.5	101.3	101.9	101.7
4	101.5	100.7	101.3	101.2	103.6	101.7	104.0	102.0	102.7	101.1	101.1	101.6	101.4	101.2	101.1
5	102.1	101.4	101.7	101.4	102.1	103.5	101.0	104.7	101.5	102.6	101.4	101.4	102.4	100.8	100.6
6	101.6	101.3	101.3	100.5	103.0	101.8	102.6	103.6	103.4	100.7	101.7	101.0	102.2	100.5	101.0
7	101.3	100.4	101.2	100.9	104.6	101.3	102.8	102.0	103.0	100.5	101.3	101.8	101.7	100.0	100.5
8	101.1	100.3	101.4	100.7	103.7	102.5	103.9	102.4	102.4	101.2	101.4	101.9	101.8	100.6	101.7
9	100.5	100.0	100.9	100.0	102.0	100.9	101.2	105.5	101.8	102.3	102.4	101.5	101.4	101.1	100.0
10	101.5	101.4	101.6	101.1	103.8	102.2	104.3	102.2	102.0	100.6	101.4	100.8	100.7	100.9	100.0

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Feline Panleukopenia Virus (FPV)
<b>Study Purpose</b>	To demonstrate effectiveness against FPV
<b>Product Administration</b>	Two doses administered 21 days apart subcutaneously (SC)
<b>Study Animals</b>	Thirty-three (33) cats 8 weeks of age. Cats were randomized into one vaccinated group of 23 cats and one group of 10 non-vaccinated controls.
<b>Challenge Description</b>	85 days post second vaccination all cats were challenged with virulent FPV.
<b>Interval observed after challenge</b>	Rectal temperatures and clinical signs were observed daily for 14 days post challenge.
<b>Results</b>	<p>Vaccinates and controls were evaluated for leukopenia (defined as a <math>\geq 50\%</math> decrease in white blood cells from pre-challenge levels).</p> <p>Positive for Leukopenia:  Vaccinates: 0/0 (0%) positive  Controls: 9/10 (90%) positive</p> <p>Raw Data:  Data tables are appended to the end of the summary.</p>
<b>USDA Approval Date</b>	June 30, 1999

**White Blood Cell Counts (counts/uL blood) Following FPV Challenge**

**Non-Vaccinated Controls**

Cat ID	Baseline Avg.	2DPC	4DPC	6DPC	8DPC	10DPC
1	18938	10890	8800	8360	7425	7810
2	11713	9405	6930	4125	5280	7865
3	12962	9735	4656	5610	3685	6325
4	11110	11000	4290	3630	4840	4510
5	12907	6105	4730	5555	6490	5005
6	15345	11440	3905	5280	9625	7425
7	14630	11550	5170	7095	7535	7920
8	13182	10945	5253	4565	8855	10340
9	12173	9240	7480	7810	8580	10120
10	12760	9405	8250	6050	15510	12045

**Vaccinates**

Cat ID	Baseline Avg.	2DPC	4DPC	6DPC	8DPC	10DPC
11	14777	12155	21725	19305	20845	18040
12	12888	12650	9295	13090	13970	13475
13	11293	9955	11825	14410	12375	10505
14	10102	9955	10945	11275	12980	10725
15	8855	7590	8250	11550	11165	9295
16	13475	11165	11495	10120	10890	13365
17	10560	7755	15180	10450	13090	10505
18	17600	16354	18755	23650	18810	13255
19	16262	13145	14190	15785	16500	15950
20	12797	9625	12375	16280	15345	11825
21	14758	11660	12430	11770	11660	12430
22	14080	10560	10285	13145	17765	20570
23	10908	8690	7370	9900	11935	7810
24	13548	10010	11770	15685	12870	12760
25	13237	10395	11495	13585	18700	10505
26	13640	12320	14080	16225	15840	13860
27	13182	10615	12925	12650	16885	11303
28	10102	8140	8525	9405	12595	11880
29	11807	9570	17160	14350	11770	14465
30	13787	9625	17050	13255	14740	11743
31	13732	12870	17160	15180	15620	10780
32	10835	9515	15840	8305	11220	9900
33	12357	8414	17380	10065	11055	10450

DPC = Days Post Challenge

<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>	A total of 634 cats, 216 eight weeks of age or younger and 418 greater than 8 weeks, were administered two 0.5 mL doses of vaccine 3 weeks apart by the subcutaneous route.
<b>Study Animals</b>	Privately owned felines
<b>Challenge Description</b>	NA
<b>Interval observed after challenge</b>	Observed for 30 minutes after first vaccination and then daily for 3 weeks after first vaccination. Observed for 30 minutes after second vaccination and then daily for 2 weeks after second vaccination
<b>Results</b>	Frequency of events is appended to the end of this summary by Veterinary Dictionary for Drug Related Affairs (VeDDRA) terminology.
<b>USDA Approval Date</b>	January 11, 2016

### Summary of Reactions:

VeDDRA Code	number ≤62 Days of age	percent ≤62 Days of age	number >62 Days of age	percent >62 Days of age	Total number of cats	Percent of all cats
Normal	162	75.00%	334	79.90%	496	78.23%
Aggression	2	0.93%	7	1.67%	9	1.42%
Injection site Pyoderma	1	0.46%	0	0.00%	1	0.16%
Hiding	1	0.46%	0	0.00%	1	0.16%
Oral Discomfort	1	0.46%	0	0.00%	1	0.16%
Hyperactivity	1	0.46%	4	0.96%	5	0.79%
Injection site self trauma	1	0.46%	0	0.00%	1	0.16%
Less Social	4	1.85%	0	0.00%	4	0.63%
Mothering Disorder	1	0.46%	0	0.00%	1	0.16%
Vocalization	1	0.46%	5	1.20%	6	0.95%
Estrus	2	0.93%	0	0.00%	2	0.32%
Injection Site Rash	1	0.46%	0	0.00%	1	0.16%
Localized Pain	1	0.46%	0	0.00%	1	0.16%
Skin swelling	1	0.46%	0	0.00%	1	0.16%
Death*	8	3.70%	5	1.20%	13	2.05%
Muscle Pain	2	0.93%	0	0.00%	2	0.32%
Skin warmth	1	0.46%	0	0.00%	1	0.16%
Inappropriate urination	1	0.46%	0	0.00%	1	0.16%
General Pain	1	0.46%	1	0.24%	2	0.32%
Polyuria	2	0.93%	0	0.00%	2	0.32%
Weakness	6	2.78%	2	0.48%	8	1.26%
Polydipsia	2	0.93%	0	0.00%	2	0.32%
Depression	23	10.65%	38	9.09%	61	9.62%
Ataxia	2	0.93%	0	0.00%	2	0.32%
Squinting	1	0.46%	0	0.00%	1	0.16%
Fever	1	0.46%	5	1.20%	6	0.95%
Tremor	1	0.46%	0	0.00%	1	0.16%
Retching	1	0.46%	0	0.00%	1	0.16%
Abnormal Breathing	3	1.39%	0	0.00%	3	0.47%
Increased appetite	4	1.85%	0	0.00%	4	0.63%
Dyspnea	1	0.46%	1	0.24%	2	0.32%
Unthrifty	1	0.46%	0	0.00%	1	0.16%
Angioedema	1	0.46%	0	0.00%	1	0.16%
Otitis externa	1	0.46%	1	0.24%	2	0.32%
Corneal edema	1	0.46%	0	0.00%	1	0.16%
Sneezing	3	1.39%	8	1.91%	11	1.74%
Pinnal irritation	1	0.46%	0	0.00%	1	0.16%
Blepharospasm	2	0.93%	3	0.72%	5	0.79%
Nasal Discharge	2	0.93%	4	0.96%	6	0.95%

\*Investigator attributed to causes other than vaccination

VeDDRA Code	number ≤62 Days of age	percent ≤62 Days of age	number >62 Days of age	percent >62 Days of age	Total number of cats	Percent of all cats
Stressed state	3	1.39%	0	0.00%	3	0.47%
Ocular Discharge	12	5.56%	6	1.44%	18	2.84%
Cough	2	0.93%	0	0.00%	2	0.32%
Unusual Stool Color	1	0.46%	0	0.00%	1	0.16%
Conjunctivitis	4	1.85%	3	0.72%	7	1.10%
Not Drinking	1	0.46%	6	1.44%	7	1.10%
Hypothermia	1	0.46%	0	0.00%	1	0.16%
Anorexia	2	0.93%	10	2.39%	12	1.89%
Closed Eyelid	2	0.93%	0	0.00%	2	0.32%
Decreased appetite	8	3.70%	13	3.11%	21	3.31%
Skin Irritation	1	0.46%	0	0.00%	1	0.16%
Injection Site erythema**	1	0.46%	0	0.00%	1	0.16%
Hypersalivation	1	0.46%	0	0.00%	1	0.16%
Local alopecia	1	0.46%	0	0.00%	1	0.16%
Irritability	2	0.93%	0	0.00%	2	0.32%
Injection Site Bleeding**	1	0.46%	0	0.00%	1	0.16%
Diarrhea	9	4.17%	13	3.11%	22	3.47%
Skin Abscess	1	0.46%	0	0.00%	1	0.16%
Injection site stinging	1	0.46%	0	0.00%	1	0.16%
Gastroenteritis	2	0.93%	25	5.98%	27	4.26%
Folliculitis	1	0.46%	0	0.00%	1	0.16%
Injection site reaction (Swelling <1")**	2	0.93%	0	0.00%	2	0.32%
Loss of condition	12	5.56%	0	0.00%	12	1.89%
Anxious	1	0.46%	0	0.00%	1	0.16%
Hyperesthesia	1	0.46%	0	0.00%	1	0.16%
Injection site Pain**	1	0.46%	1	0.24%	2	0.32%
Head shy	1	0.46%	0	0.00%	1	0.16%

\*\*Injection site reactions were observed for 1 day