



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1555.R1
True Name	Feline Leukemia Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Fel-O-Vax Lv-K - Elanco US Inc.
Date of Compilation Summary	October 12, 2017

**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 Leukemia Virus (FeLV)
<b>Study Purpose</b>	To demonstrate effectiveness against FeLV
<b>Product Administration</b>	Two doses administered 21 days apart subcutaneously (SC) or Intramuscular (IM).
<b>Study Animals</b>	Forty (40) cats 16 to 20 weeks of age. Cats were allocated into one vaccinated group of 20 cats, 10 SC and 10 IM, and one group of 20 non-vaccinated controls.
<b>Challenge Description</b>	14 days post second vaccination all cats were challenged with virulent FeLV.
<b>Interval observed after challenge</b>	All cats were bled once a week for 10 weeks post challenge.
<b>Results</b>	<p>Serum each week was tested for the presence of FeLV (viremia). Animals were considered affected by the challenge if they established a persistent viremia (i.e., tested positive and remained positive).</p> <p>Raw Data: Data tables are appended to the end of the summary.</p>
<b>USDA Approval Date</b>	April 13, 1990

### Development of FeLV Viremia in Cats

#### FeLV Vaccinates

Cat ID	Vaccination Route	ODP C	7DP C	14DP C	21DP C	28DP C	35DPC	45DP C	50DPC	56DPC	63DP C	70DP C
1	IM	-	-	-	-	-	-	-	-	-	-	-
2	IM	-	-	+	+	+	+	+	+	+	+	+
3	IM	-	-	+	-	-	-	-	-	-	-	-
4	IM	-	-	-	-	NA*	NA	NA	NA	NA	NA	NA
5	IM	-	-	+	+	+	+	+	+	+	+	+
6	IM	-	-	-	-	-	-	-	-	-	-	-
7	IM	-	-	-	+	+	+	+	-	-	-	-
8	IM	-	-	+	+	+	+	+	+	+	+	+
9	IM	-	-	-	-	-	-	-	-	-	-	-
10	IM	-	-	+	+	+	-	-	-	-	-	-
11	SC	-	-	-	-	-	-	-	-	-	-	-
12	SC	-	-	+	+	+	+	+	+	+	+	+
13	SC	-	-	-	-	-	-	-	-	-	-	-
14	SC	-	-	-	-	-	-	-	-	-	-	-
15	SC	-	-	+	+	+	+	+	+	+	+	+
16	SC	-	-	-	-	-	-	-	-	-	-	-
17	SC	-	-	-	-	-	-	-	-	-	-	-
18	SC	-	-	-	-	-	-	-	-	-	-	-
19	SC	-	-	-	-	-	-	-	-	-	-	-
20	SC	-	-	-	+	+	+	+	+	+	+	+

#### Non-Vaccinated Controls

Cat ID	Vaccination Route	ODP C	7DP C	14DP C	21DP C	28DP C	35DPC	45DP C	50DPC	56DPC	63DP C	70DP C
21	NA	-	-	-	+	+	+	+	+	+	+	+
22	NA	-	-	+	+	+	+	+	+	+	+	+
23	NA	-	-	-	+	+	+	+	+	+	+	+
24	NA	-	-	+	+	+	+	+	+	+	+	+
25	NA	-	-	+	+	+	+	+	+	+	+	+
26	NA	-	-	+	+	+	+	+	+	+	+	+
27	NA	-	-	-	-	+	+	-	-	-	-	-
28	NA	-	-	-	+	+	+	+	+	+	+	+
29	NA	-	-	+	+	+	+	+	+	+	+	+
30	NA	-	-	+	+	+	+	+	+	+	+	+
31	NA	-	-	+	+	+	+	+	+	+	+	+
32	NA	-	-	-	-	-	-	-	-	-	-	-
33	NA	-	-	-	-	-	-	-	-	-	-	-
34	NA	-	-	-	+	+	-	-	-	-	-	-
35	NA	-	-	+	+	+	+	+	+	+	+	+
36	NA	-	-	-	+	+	+	+	+	+	+	+
37	NA	-	-	-	+	+	+	+	+	+	+	+
38	NA	-	-	-	+	+	+	+	+	+	+	+
39	NA	-	-	+	+	+	+	+	+	+	+	+
40	NA	-	-	-	+	+	+	+	+	+	+	+

\* - Cat found dead (causes not due to FeLV) after sampling on 21DPC

DPC = Days post challenge

NA = Not Applicable

<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 416 cats of various ages and breeds were administered 1 dose of vaccine. In addition, 308 of the 416 animals were given a second dose 2- 3 weeks later.																																																												
<b>Study Animals</b>	Client-owned cats presenting to a veterinary clinic.																																																												
<b>Challenge Description</b>	NA																																																												
<b>Interval observed after challenge</b>	Followed for 4-7 days after each vaccination.																																																												
<b>Results</b>	<p>Frequency of Adverse Events:</p> <p style="text-align: center;"><b>Total number of Doses Administered = 724</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">1st Dose</th> <th style="text-align: center;">2nd Dose</th> <th style="text-align: center;">Total</th> <th style="text-align: center;">Percent per # of Doses</th> </tr> </thead> <tbody> <tr> <td>No Adverse Events</td> <td style="text-align: center;">370</td> <td style="text-align: center;">298</td> <td style="text-align: center;">668</td> <td style="text-align: center;">92.27%</td> </tr> <tr> <td>Look at injection site</td> <td style="text-align: center;">4</td> <td style="text-align: center;">1</td> <td style="text-align: center;">5</td> <td style="text-align: center;">0.69%</td> </tr> <tr> <td>Turn in Circles</td> <td style="text-align: center;">1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1</td> <td style="text-align: center;">0.14%</td> </tr> <tr> <td>Scratch at site</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0.28%</td> </tr> <tr> <td>Chew at site</td> <td style="text-align: center;">9</td> <td style="text-align: center;">0</td> <td style="text-align: center;">9</td> <td style="text-align: center;">1.24%</td> </tr> <tr> <td>Vocalize as in pain</td> <td style="text-align: center;">12</td> <td style="text-align: center;">1</td> <td style="text-align: center;">13</td> <td style="text-align: center;">1.80%</td> </tr> <tr> <td>Lethargy</td> <td style="text-align: center;">24*</td> <td style="text-align: center;">9*</td> <td style="text-align: center;">33</td> <td style="text-align: center;">4.56%</td> </tr> <tr> <td>Anorexia</td> <td style="text-align: center;">1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1</td> <td style="text-align: center;">0.14%</td> </tr> <tr> <td>Soreness</td> <td style="text-align: center;">3</td> <td style="text-align: center;">2</td> <td style="text-align: center;">5</td> <td style="text-align: center;">0.69%</td> </tr> <tr> <td>Swelling or Nodule</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0.00%</td> </tr> <tr> <td>Other</td> <td style="text-align: center;">4</td> <td style="text-align: center;">1</td> <td style="text-align: center;">5</td> <td style="text-align: center;">0.69%</td> </tr> </tbody> </table> <p>* It was noted that a large number of test cats were classified to have lethargy. Thirty-one (31) came from the same site location. Upon conversation with the veterinarian, he commented that these cats were observed to be temporarily tired or mellow after vaccination, which were not considered unacceptable or significant reactions by him.</p>		1st Dose	2nd Dose	Total	Percent per # of Doses	No Adverse Events	370	298	668	92.27%	Look at injection site	4	1	5	0.69%	Turn in Circles	1	0	1	0.14%	Scratch at site	2	0	2	0.28%	Chew at site	9	0	9	1.24%	Vocalize as in pain	12	1	13	1.80%	Lethargy	24*	9*	33	4.56%	Anorexia	1	0	1	0.14%	Soreness	3	2	5	0.69%	Swelling or Nodule	0	0	0	0.00%	Other	4	1	5	0.69%
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