



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	1559.20
True Name	Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci Vaccine, Killed Virus, Killed Chlamydia
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Elanco US Inc. Fel-O-Vax Lv-K IV - Elanco US Inc. Fel-O-Vax Lv-K IV - No distributor specified
Date of Compilation Summary	November 06, 2023

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	Feline Calicivirus
Study Purpose	To demonstrate effectiveness against respiratory disease due to feline calicivirus
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance. Study data, however, are no longer available.
USDA Approval Date	April 13, 1990

Study Type	Efficacy
Pertaining to	Feline Chlamydia Psittaci (FCP)
Study Purpose	To demonstrate effectiveness against FCP
Product Administration	Two doses administered 21 days apart subcutaneously (SC) or Intramuscular (IM).
Study Animals	Thirty (30) 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 10 non-vaccinated controls.
Challenge Description	21 days post second vaccination all cats were challenged with FCP.
Interval observed after challenge	Rectal temperatures and clinical signs were observed daily for 28 days post challenge.
Results	Vaccinates and controls were evaluated per the criteria in 9 CFR 113.71.(3) A significant difference in clinical signs was observed between vaccinates and controls using a scoring sytem approved by APHIS. Requirements of 9 CFR 113.71 (3) were met. Raw Data: Data tables are appended to the end of the summary.
USDA Approval Date	April 13, 1990

Daily Rectal Temperatures Following FCP Challenge

		Vaccinates																												
Cat ID	Route	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC	17DPC	18DPC	19DPC	20DPC	21DPC	22DPC	23DPC	24DPC	25DPC	26DPC	27DPC	28DPC	
1	M	101.8	102.2	102.8	103.8	102.6	102.4	101.6	102.6	102.4	102.8	102.0	102.6	102.0	102.0	102.4	102.8	102.4	101.6	102.6	101.6	102.6	102.0	101.8	101.6	101.4	101.8	103.3	103.2	
2	M	101.9	104.0	101.9	102.6	101.4	102.2	101.6	102.0	101.4	102.2	101.8	101.9	102.6	102.0	102.4	102.4	102.4	102.2	101.6	101.7	101.8	102.2	101.4	101.6	101.7	101.4	101.8	102.0	
3	M	101.4	102.4	102.5	102.6	102.6	102.0	101.8	102.0	102.3	102.4	102.2	102.0	102.4	101.6	102.4	102.6	102.8	102.0	102.0	102.5	102.7	102.6	102.0	102.4	101.8	101.6	102.2	102.4	103.0
4	M	101.4	102.6	103.2	103.4	102.6	102.4	102.2	102.4	102.6	102.6	102.6	103.0	102.2	101.8	102.2	102.4	102.4	102.2	102.4	102.2	102.2	102.0	101.8	102.4	102.0	102.2	102.0	102.6	103.0
5	M	101.4	103.0	102.3	102.0	101.6	102.6	102.0	102.4	102.0	102.8	102.0	102.6	102.0	102.6	102.6	104.0	102.4	102.2	102.4	102.2	102.2	102.0	101.4	102.0	101.8	102.2	102.2	103.0	102.2
6	M	101.8	103.2	102.4	103.6	102.6	102.0	101.6	102.5	102.6	102.4	102.0	103.4	102.2	102.0	101.6	104.0	103.4	101.4	102.2	102.2	102.2	101.6	101.8	102.0	102.4	102.0	102.4	102.0	102.6
7	M	101.8	103.0	103.2	103.6	102.6	102.8	102.4	102.6	101.6	102.4	102.0	102.4	103.0	102.4	102.6	102.6	102.2	101.8	102.2	102.2	102.6	102.6	102.0	102.2	102.2	102.8	102.5	102.6	102.6
8	M	101.4	101.6	103.2	102.6	101.8	101.6	101.6	101.6	101.4	102.0	101.8	102.0	101.6	102.2	101.6	101.6	101.8	101.4	101.7	101.8	101.7	101.8	102.0	102.0	101.2	101.8	101.6	102.4	103.0
9	M	102.0	104.0	103.5	103.6	103.0	102.8	102.6	102.0	102.6	102.8	101.8	102.2	102.2	102.2	102.6	102.6	103.0	101.8	103.2	102.8	102.8	102.4	102.3	102.0	102.8	102.6	103.0	103.2	103.2
10	M	101.8	102.8	102.7	103.8	102.7	102.6	102.2	101.4	102.4	102.6	102.0	103.3	NA	NA	102.8	102.6	102.0	102.0	103.8	102.6	103.0	102.1	102.2	102.0	102.4	102.8	102.7	102.8	102.8
11	SC	101.4	104.0	101.8	103.0	102.2	101.8	101.8	101.6	102.0	102.6	103.0	103.2	103.0	NA	103.2	102.4	102.8	102.0	102.0	103.4	102.2	103.0	102.6	102.2	102.0	103.8	104.2	103.4	103.4
12	SC	102.2	102.8	103.0	103.0	101.4	101.8	102.8	101.6	101.8	102.8	102.4	101.6	101.8	102.2	102.0	104.4	102.2	101.8	102.2	102.6	102.2	101.0	101.8	101.7	102.0	102.2	102.5	103.2	103.2
13	SC	101.8	103.0	103.4	103.6	103.0	102.6	103.2	102.4	102.4	102.6	102.6	102.0	102.4	101.8	102.4	102.8	102.8	102.4	103.2	102.8	102.2	102.4	102.8	102.0	102.0	102.4	102.8	102.4	102.4
14	SC	102.2	102.8	103.0	102.6	101.4	102.4	102.2	101.8	101.6	102.2	101.8	101.7	101.8	101.6	101.6	101.4	102.6	102.2	102.6	102.6	102.5	102.8	103.4	104.0	103.4	102.8	103.6	103.8	103.2
15	SC	102.4	103.2	102.8	102.4	101.4	102.0	101.4	102.2	102.3	103.0	101.8	102.4	104.0	101.6	101.8	102.2	103.0	102.2	102.4	101.4	101.4	102.2	101.6	102.0	101.8	102.2	102.0	101.8	102.2
16	SC	102.2	102.5	102.6	102.6	101.8	102.2	102.0	101.6	102.2	102.4	102.8	102.2	102.0	102.0	102.2	104.2	104.2	102.4	102.2	102.0	102.8	101.4	101.8	102.0	103.4	102.0	102.0	102.6	102.6
17	SC	102.6	102.4	103.1	103.2	102.5	102.4	102.8	102.8	102.1	102.2	102.4	101.6	103.0	102.4	103.4	102.6	102.8	101.4	103.2	103.2	103.2	102.8	101.8	102.4	102.4	103.4	102.8	103.0	103.8
18	SC	101.6	101.6	102.5	103.8	101.8	102.6	102.6	101.4	101.6	102.2	102.0	102.4	101.8	102.2	102.6	103.4	103.2	102.4	102.1	102.0	102.2	101.8	102.0	101.8	102.0	101.6	101.8	102.6	102.6
19	SC	102.6	103.9	103.1	103.0	102.4	102.4	102.6	101.8	102.2	103.0	102.0	101.8	103.2	103.0	102.2	102.6	102.2	101.4	102.4	101.6	102.2	101.6	102.0	101.8	102.6	103.0	102.4	102.2	102.2
20	SC	101.8	102.2	102.2	103.0	101.6	102.0	101.4	101.1	101.6	102.4	102.0	102.3	101.4	102.2	102.0	101.4	101.4	101.8	101.4	102.0	101.6	101.8	102.2	102.2	102.6	102.2	102.0	102.6	102.6

No Vaccinated Controls

Cat ID	Route	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC	15DPC	16DPC	17DPC	18DPC	19DPC	20DPC	21DPC	22DPC	23DPC	24DPC	25DPC	26DPC	27DPC	28DPC
1		101.8	102.4	102.5	102.4	102.4	102.6	102.0	102.0	102.6	103.0	102.8	103.6	104.0	103.8	104.2	105.2	104.2	104.8	105.5	104.8	103.8	102.4	103.8	103.6	103.6	102.8	103.2	103.6
2		103.0	102.8	102.7	102.0	101.8	102.4	102.4	102.6	102.3	102.8	102.8	103.3	102.8	102.6	103.2	104.4	102.4	105.2	105.2	105.0	103.8	104.4	104.0	104.1	103.8	103.4	103.3	103.6
3		102.4	103.2	103.5	103.6	103.0	102.2	102.8	102.4	101.7	102.6	102.6	103.4	103.4	102.8	104.4	103.8	104.8	104.8	104.6	103.8	102.6	102.1	103.4	103.0	103.6	103.2	104.0	103.0
4		101.4	102.8	102.8	103.0	101.6	102.2	101.4	101.8	102.2	102.0	102.8	103.6	102.4	101.8	102.2	103.2	103.6	102.6	103.1	103.2	104.0	103.4	103.4	103.8	104.6	103.4	104.3	103.0
5		101.5	102.6	102.1	102.4	102.0	101.6	101.8	101.4	101.4	102.0	102.0	102.5	103.8	105.4	104.2	104.2	103.4	103.6	103.4	103.4	102.2	103.2	103.4	103.1	103.2	103.0	102.6	103.4
6		103.0	102.4	103.5	102.4	102.4	103.0	102.4	101.8	102.4	103.2	101.8	101.7	103.0	102.8	102.6	102.8	102.2	103.0	104.2	103.2	102.6	102.4	102.4	102.8	103.2	103.0	103.3	103.0
7		102.4	102.6	103.1	103.6	103.0	102.2	101.8	102.2	101.6	102.6	102.0	101.8	102.8	102.6	102.6	103.8	103.2	103.8	104.4	104.6	101.4	103.3	102.8	102.8	103.2	102.8	102.5	102.0
8		101.4	103.0	103.0	103.4	103.2	102.0	101.8	102.4	102.2	102.2	102.4	102.8	103.2	101.8	103.8	104.0	104.4	104.6	104.2	104.0	103.8	102.8	103.0	103.6	104.6	103.4	103.3	103.0
9		102.2	103.0	102.1	103.0	103.0	102.2	101.6	102.0	101.6	102.4	102.6	102.4	102.6	102.0	102.2	103.8	103.8	104.6	105.0	103.8	104.0	104.4	104.0	102.6	104.6	103.4	102.3	102.2
10		101.4	104.0	104.2	104.4	103.6	103.8	103.4	101.4	103.8	103.2	102.2	102.4	104.2	103.4	105.0	104.2	102.8	104.4	104.0	104.5	104.8	101.6	104.0	104.0	104.0	103.4	103.8	103.0

Study Type	Efficacy
Pertaining to	Feline Leukemia Virus (FeLV)
Study Purpose	To demonstrate effectiveness against FeLV
Product Administration	Two doses administered 21 days apart subcutaneously (SC) or Intramuscular (IM).
Study Animals	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.
Challenge Description	14 days post second vaccination all cats were challenged with virulent FeLV.
Interval observed after challenge	All cats were bled once a week for 10 weeks post challenge.
Results	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). Raw Data: Data tables are appended to the end of the summary.
USDA Approval Date	April 13, 1990

Development of FeLV Viremia in Cats

FeLV Vaccinates												
Cat ID	Vaccination Route	0DP 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	0DP 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

Study Type	Efficacy
Pertaining to	Feline Rhinotracheitis (FVR)
Study Purpose	To demonstrate effectiveness against FVR
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance. Study data, however, are no longer available.
USDA Approval Date	April 13, 1990

Study Type	Efficacy
Pertaining to	Feline Panleukopenia Virus (FPV)
Study Purpose	To demonstrate effectiveness against FPV
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance. Study data, however, are no longer available.
USDA Approval Date	April 13, 1990

Study Type	Safety				
Pertaining to	All				
Study Purpose	Demostrate safety of product under typical use conditions				
Product Administration	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.				
Study Animals	Client-owned cats presenting to a veterinary clinic.				
Challenge Description	NA				
Interval observed after challenge	Followed for 4-7 days after each vaccination.				
Results	Frequency of Adverse Events:				
	Total number of Doses Administered = 724				
		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%
	* 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.				
USDA Approval Date	September 14, 1990				