



Summary of Studies Supporting USDA Product Licensure

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|---|---|
| Establishment Name | Elanco US Inc. |
| USDA Vet Biologics Establishment Number | 196 |
| Product Code | 46J9.29 |
| True Name | Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Duramune Max 5-CvK/4L - Elanco US Inc. Duramune Max 5-CvK/4L The Puppyshot Booster - Elanco US Inc. |
| Date of Compilation Summary | December 20, 2019 |

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 | Infectious Canine Hepatitis Virus | | | | | | | | | |
| Study Purpose | To demonstrate effectiveness against Infectious Canine Hepatitis (ICH) | | | | | | | | | |
| Product Administration | Two doses were administered subcutaneously (SC) 21 days apart | | | | | | | | | |
| Study Animals | Seventeen (17) 6-week-old puppies, seronegative for ICH, were randomly sorted into one group of 11 SC vaccinates and one group of 6 controls. | | | | | | | | | |
| Challenge Description | 21 days after second vaccination all dogs were challenged with Infectious Canine Hepatitis Virus. | | | | | | | | | |
| Interval observed after challenge | Puppies were observed for 21 days after challenge for clinical signs. | | | | | | | | | |
| Results | <p>The study was satisfactory per the criteria in 9 CFR 113.305 (1)(ii) (A)(B)</p> <table border="1" data-bbox="582 920 1227 1115"> <thead> <tr> <th></th> <th>Mortality</th> <th>Clinical Signs of CDV Infection</th> </tr> </thead> <tbody> <tr> <td>SC Vaccinates</td> <td>0/11 (0%)</td> <td>0/11 (0%)</td> </tr> <tr> <td>Controls</td> <td>6/6 (100%)</td> <td>6/6 (100%)</td> </tr> </tbody> </table> | | Mortality | Clinical Signs of CDV Infection | SC Vaccinates | 0/11 (0%) | 0/11 (0%) | Controls | 6/6 (100%) | 6/6 (100%) |
| | Mortality | Clinical Signs of CDV Infection | | | | | | | | |
| SC Vaccinates | 0/11 (0%) | 0/11 (0%) | | | | | | | | |
| Controls | 6/6 (100%) | 6/6 (100%) | | | | | | | | |
| USDA Approval Date | March 31, 1998 | | | | | | | | | |

| | |
|--|---|
| Study Type | Efficacy |
| Pertaining to | Canine Adenovirus Type II |
| Study Purpose | To demonstrate effectiveness against Canine Adenovirus Type II (CAV2) |
| Product Administration | Two doses were administered subcutaneously 21 days apart |
| Study Animals | Twenty-two (22) 6 week old puppies seronegative for CAV2 were randomly sorted into one group of 11 SC vaccinates and one group of 11 controls. |
| Challenge Description | 21 days after second vaccination all dogs were challenged with CAV2 |
| Interval observed after challenge | Puppies were observed for 21 days after challenge for clinical signs. |
| Results | <p>The study was considered satisfactory by the reduction in clinical signs and virus shedding in the vaccinates when compared to the control animals.</p> <p>Raw Data: Data tables are appended to the end of this summary</p> |
| USDA Approval Date | April 3, 1998 |

CAV2 Clinical Signs Observed Post Challenge

| Dog | Group | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC | 15DPC | 16DPC | 17DPC | 18DPC | 19DPC | 20DPC | 21DPC |
|-----|---------|----------------------|------|--------------|------|-------------------------|------|------------------------------------|-----------|------|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 1 | Control | | | | | | 1 | 1,2 | | | 2 | 2 | | | | | | | | | | | |
| 2 | Control | | | | | | 1 | 1,2 | 1,2 | 1,2 | 2 | 2 | | | | | | | | | | | |
| 3 | Control | | | | | | 1 | 1,2 | 1 | 1 | 1 | 1 | | | | | | | | | | | |
| 4 | Control | | | | | | 1,2 | 1,2 | 1,2,4 | 1,2, | 2 | 2 | | | | | | | | | | | |
| 5 | Control | | | | | | 1 | 1 | 1,4 | 1 | 1 | 1 | | | | | | | | | | | |
| 6 | Control | | | | | 2 | | 4 | | | 1 | 1 | | | | | | | | 1 | 1 | | |
| 7 | Control | | | | | | 1 | 1,2,4 | 1,2,4,5,6 | 1 | 1 | 2,4 | 1 | 1,2 | 1 | 1,2 | 1 | 1,2 | | | | | |
| 8 | Control | 1 | 1,2 | 1,2 | 1 | 1,2 | 1,2 | 1,6 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | | | |
| 9 | Control | | | | | | 1 | 1 | 1 | 4 | 4 | 4 | | | | | | | | | | | |
| 10 | Control | | | | | 1 | 1 | 1 | 1 | 1 | 1,2 | | | 1 | | | | | | | | | |
| 11 | Control | | | | | 2 | | 1,2 | 1,2 | 1 | 1 | 1 | | | | | | | | | | | |
| 23 | SC | | | | | | | | | | | | | | | | | | | | | | |
| 24 | SC | | | | | | | | | | | | | | | | | | | | | | |
| 25 | SC | | | | | | 1 | | | 1 | | | | | | | | | | | | | |
| 26 | SC | | | | | | | | | | | | | | | | | | | | | | |
| 27 | SC | | | | | | | | | | | | | | | | | | | | | | |
| 28 | SC | | | | | | | 1 | | | | | | | | | | | | | | | |
| 29 | SC | | | | | | | 1 | 1 | | | | | | | | | | | | | | |
| 30 | SC | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 31 | SC | | | | | | 1 | 1 | 1 | 1 | 1,2 | | | | | | | | | | | | |
| 32 | SC | | | | | | | | | | | | | | | | | | | | | | |
| 33 | SC | | | | | | | | | | | | | | | | | | | | | | |
| | | 1 - Ocular Discharge | | 3 - Sneezing | | 5 - Retching | | 7 - Inappetence | | | | | | | | | | | | | | | |
| | | 2 - Nasal Discharge | | 4 - Coughing | | 6 - depression/lethargy | | Blank - No Clinical signs observed | | | | | | | | | | | | | | | |

CAV2 Isolation from Nasal Swab Samples (TCID₅₀/100ul)

| Dog | Group | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC | 15DPC | 16DPC | 17DPC | 18DPC | 19DPC | 20DPC | 21DPC | |
|--------------------------------|---------|------|------|------|-------|-------|-------|------|-------|------|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 1 | Control | | | | 2 | 2.5 | 3.63 | 3.5 | ≤1.83 | | | | | | | | | | | | | | | |
| 2 | Control | | | | 2 | 2.83 | 3.5 | 3.83 | 2.17 | | | | | | | | ≤1.83 | | | | | | | |
| 3 | Control | | | | ≤1.63 | 3.5 | 4.17 | 3.38 | | | | | | | | 2.17 | | | | | | | | |
| 4 | Control | | | | | 2.63 | 3.38 | 4.31 | 2.35 | | | | ≤1.63 | | | | | | | | | | | ≤1.63 |
| 5 | Control | | | | 2.38 | 2.6 | 4.38 | 3.6 | ≤2.63 | | | | | | | | | | | | | | | |
| 6 | Control | | | | ≤1.83 | ≤1.83 | 4.5 | 3.63 | 3.63 | | | | | | | | | | | | | | | |
| 7 | Control | | | | ≤1.63 | 2.75 | 4.5 | 4.5 | ≤1.83 | | | | | | | | | | | | | | | |
| 8 | Control | | | | 2.38 | 2.83 | 3.63 | 3.17 | | | | | | | | | | | | | | | | |
| 9 | Control | | | | ≤1.63 | 2.83 | 2.83 | 4.38 | | | | | | | | | | | | | | | | |
| 10 | Control | | | | ≤1.63 | 2.17 | 3.63 | 3.5 | | | | | ≤1.63 | 2.38 | 2.5 | ≤1.83 | | | | | | | | |
| 11 | Control | | | | ≤1.83 | 2.5 | 4.5 | 4.38 | | | | | | ≤1.63 | ≤1.83 | ≤1.63 | ≤1.63 | | | ≤1.63 | | | | |
| 23 | SC | | | | | | | | | | | | | | | | | | | | | | | |
| 24 | SC | | ≤1.6 | | | | 2.38 | | | | | | | | | | | | | | | | | |
| 25 | SC | | | | | ≤1.63 | | | | | | | | | | | | | | | | | | |
| 26 | SC | | | | | | | | 2.63 | | | | | | | | | | | | | | | ≤1.63 |
| 27 | SC | | | | | | | | | | | | | | | | | | | | | | | |
| 28 | SC | | | | | | | | | | | ≤1.63 | | | | | | | | | | | | |
| 29 | SC | | | | | 2 | ≤1.83 | | | | | | | | | | | | | | | | | |
| 30 | SC | | | | | | | | | | | | | | | | | | | | | | | |
| 31 | SC | | | | | | | | | | | | | | | | | | | | | | | |
| 32 | SC | | | | | | ≤1.83 | 2.63 | 2.5 | | | | | | | | | | | | | | | |
| 33 | SC | | | | | | | | | | | | | | | | | | | | | | | |
| Blank - No CAV2 titer detected | | | | | | | | | | | | | | | | | | | | | | | | |
| DPC - Days Post Challenge | | | | | | | | | | | | | | | | | | | | | | | | |

| | |
|--|---|
| Study Type | Efficacy |
| Pertaining to | Canine coronavirus |
| Study Purpose | To demonstrate effectiveness against intestinal disease due to canine coronavirus |
| 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 | December 3, 1984 |

| | |
|--|---|
| Study Type | Efficacy |
| Pertaining to | <i>Leptospira canicola</i> |
| Study Purpose | To demonstrate effectiveness against <i>Leptospira canicola</i> in 6 week old dogs. |
| Product Administration | Two doses were administered subcutaneously (SC) 3 weeks apart. |
| Study Animals | Twenty-three (23) 6 week old puppies serologically negative for <i>Leptospira</i> were randomized into one group of 11 SC vaccinates and one group of 12 controls. |
| Challenge Description | Twenty-one (21) days after second vaccination all animals were challenged with <i>Leptospira canicola</i> organisms. |
| Interval observed after challenge | Dogs were observed daily for 21 days after challenge for clinical signs associated with <i>L. canicola</i> . Blood samples were collected through 14 days after challenge. |
| Results | <p>Efficacy was determined by comparing vaccinates versus controls in clinical signs, thrombocytopenia, and leukopenia.</p> <p>A dog was considered to have thrombocytopenia if the platelet count dropped below 200 k/μL and the count was less than 50% of the baseline value.</p> <p>A dog was considered to have leukopenia if the platelet count dropped below 6 k/μL and the count was less than 50% of the baseline value.</p> <p>Data tables are appended to the end of this summary.</p> |
| USDA Approval Date | April 3, 1998 |

Leptospira canicola White Blood Cell Count Post Challenge

| Dog | Baseline (Avg -2DPC, -1DPC, 0DPC) | SC Vaccinates | | | | | | | | | | | | | |
|-----|--|---------------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|
| | | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 12 | 22.1 | 25.8 | 15.1 | 17 | 20.3 | 19.3 | 20 | 20.7 | 16.5 | 19.4 | 19.3 | 10.7 | 17.2 | 19.6 | 16.6 |
| 13 | 12.3 | 12.4 | 9.3 | 9.6 | 10.5 | 9 | 8 | 12.5 | 11.8 | 10.4 | 8.8 | 12.7 | 10.2 | 9.7 | 9.1 |
| 14 | 21.7 | 19.8 | 12.3 | 12.9 | 14 | 15.5 | 13.6 | 17.4 | 19.2 | 19.3 | 16.9 | 15.3 | 14 | 23.2 | 15.7 |
| 15 | 13.3 | 8.8 | 9.6 | 12.7 | 8.2 | 11.5 | 12.2 | 13.1 | 11.8 | 8.5 | 8.5 | 13.1 | 9.2 | 10.2 | 9.4 |
| 16 | 14 | 13.2 | 9.5 | 7.6 | 8.4 | 10.1 | 10.2 | 9.4 | 11.4 | 9.7 | 11.3 | 9.3 | 10.1 | 10.8 | 10.5 |
| 17 | 14.3 | 16.1 | 12.8 | 11.8 | 12.2 | 10.7 | 13.2 | 12.5 | 9.8 | 7.3 | 8.8 | 9.5 | 10.3 | 9.9 | 12.3 |
| 18 | 11 | 11.4 | 10.6 | 10.1 | 10.2 | 9.4 | 11.7 | 9.7 | 9.3 | 9.3 | 9.1 | 11.6 | 11.7 | 17.2 | 17.6 |
| 19 | 8.9 | 8.4 | 8 | 9.1 | 8.4 | 6.6 | 7.2 | 7.5 | 6.4 | 8.2 | 7 | 8.8 | 7.3 | 12.3 | 13.4 |
| 20 | 11.2 | 15.8 | 10.7 | 9.1 | 7.6 | 8 | 9 | 9.2 | 10.5 | 11.4 | 7 | 13 | 9.3 | 7.6 | 12.7 |
| 21 | 11 | 10.5 | 9.5 | 15.1 | 14.6 | 14.1 | 13.9 | 13.4 | 20.7 | 14.9 | 11.7 | 16.5 | 13.2 | 14.7 | 21.7 |
| 22 | 10.2 | 15.6 | 9.4 | 12.1 | 9.5 | 12.7 | 11 | 7.3 | 8.3 | 11.7 | 7.7 | 10.2 | 9.2 | 11 | 11.5 |

DPC = Day post-challenge. Values reported as k/ μ L.

Leptospira canicola White Blood Cell Count Post Challenge

| Dog | Baseline (Avg -2DPC, -1DPC, 0DPC) | Controls | | | | | | | | | | | | | | | | |
|-----|--|----------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|---|---|---|
| | | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC | | | |
| 23 | 18.3 | 21.7 | 14.2 | 7.4 | 21.7 | . | . | . | . | . | . | . | . | . | . | . | . | . |
| 24 | 16.1 | 20 | 16.7 | 6.1 | 11.5 | 14.6 | 20.5 | | | | | | | | | | | |
| 25 | 17.1 | 11.3 | 13 | 8.3 | 10 | 13.6 | 17 | 26 | 28.1 | 36.6 | 36.7 | 26.2 | 29.4 | 21.9 | | | | |
| 26 | 9 | 7.9 | 9.6 | 5.6 | 5.7 | 6.7 | 8 | 11.7 | 13.8 | 16.6 | 9.6 | 11.5 | 12.7 | 13.9 | | | | |
| 27 | 10.4 | 8.9 | 5.5 | 4.1 | 5.2 | 8.6 | 19.4 | 21 | 16.2 | 11.3 | 13.9 | 15 | 11.5 | 13.3 | | | | |
| 28 | 9.6 | 18.4 | 6.4 | 3.9 | 7 | 19.4 | 13.2 | | | | | | | | | | | |
| 29 | 12.2 | 19.4 | 7.8 | 4.2 | 5 | 5.3 | 17.5 | | | | | | | | | | | |
| 30 | 9.5 | 11.9 | 9.5 | 3.2 | 6.1 | 7.9 | 10.6 | 11.1 | 10.4 | 11.4 | 9.2 | 12.69 | 16.7 | 12.2 | | | | |
| 31 | 8.9 | 10.6 | 6.4 | 4 | 6 | 10.3 | | | | | | | | | | | | |
| 32 | 11.9 | 12.2 | 11.5 | 5.3 | 6 | 6.6 | 15.8 | | | | | | | | | | | |
| 33 | 11.8 | 17.5 | 6.1 | 2.6 | 5.3 | 4.4 | 8.7 | 13 | 22.8 | 20.5 | 31.5 | 26.3 | 17.4 | 16.9 | | | | |
| 34 | 7 | 9.6 | 10.1 | 3.4 | 5.6 | 3.8 | 6 | 12 | 12.6 | 15.3 | 10.9 | 15.7 | 15.9 | 20.2 | | | | |

DPC = Day post-challenge. Values reported as k/ μ L.

Leptospira canicola Platelet Counts Post Challenge

SC Vaccinates

| Dog | Baseline (Avg -2DPC, -1DPC, 0DPC) | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
|-----|--|------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|
| 12 | 444.3 | 538 | 480 | 452 | 473 | 512 | 531 | 582 | 478 | 631 | 512 | 381 | 483 | 511 | 470 |
| 13 | 551.3 | 679 | 559 | 573 | 576 | 539 | 467 | 636 | 565 | 470 | 501 | 616 | 550 | 510 | 467 |
| 14 | 473.3 | 571 | 452 | 505 | 444 | 536 | 497 | 604 | 693 | 695 | 567 | 568 | 508 | 802 | 640 |
| 15 | 459.7 | 407 | 381 | 543 | 421 | 503 | 612 | 633 | 576 | 497 | 482 | 560 | 438 | 463 | 461 |
| 16 | 477.3 | 377 | 409 | 452 | 456 | 492 | 555 | 558 | 655 | 512 | 519 | 302 | 428 | 399 | 390 |
| 17 | 318 | 243 | 247 | 311 | 324 | 329 | 389 | 351 | 314 | 288 | 270 | 261 | 232 | 257 | 278 |
| 18 | 425.7 | 331 | 356 | 381 | 398 | 453 | 542 | 247 | 463 | 483 | 405 | 480 | 406 | 554 | 572 |
| 19 | 348.7 | 330 | 353 | 324 | 403 | 375 | 376 | 375 | 379 | 476 | 381 | 414 | 418 | 516 | 524 |
| 20 | 555.3 | 494 | 497 | 530 | 483 | 523 | 538 | 706 | 704 | 662 | 493 | 601 | 462 | 464 | 469 |
| 21 | 378.3 | 332 | 354 | 476 | 447 | 469 | 441 | 514 | 650 | 581 | 501 | 521 | 429 | 474 | 583 |
| 22 | 469.3 | 413 | 455 | 581 | 478 | 576 | 517 | 469 | 473 | 597 | 492 | 500 | 497 | 495 | 593 |

DPC = Day post-challenge. Values reported as k/ μ L.

Leptospira canicola Platelet Counts Post Challenge

| Dog | Baseline (Avg -2DPC, -1DPC, 0DPC) | Controls | | | | | | | | | | | | | | | |
|-------------|--|----------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|---|---|
| | | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC | | |
| 23 | 300 | 238 | 148 | 11 | 7.7 | D | D | D | D | D | D | D | D | D | D | D | D |
| 24 | 342 | 204 | 161 | 64.1 | 40.5 | 123 | 207 | D | D | D | D | D | D | D | D | D | D |
| 25 | 519.7 | 267 | 213 | 187 | 134 | 117 | 285 | 160 | 285 | 710 | 714 | 823 | 738 | 810 | 717 | | |
| 26 | 404.7 | 278 | 279 | 196 | 150 | 172 | ND | 194 | ND | 441 | 721 | 648 | 599 | 590 | 588 | | |
| 27 | 482.7 | 281 | 225 | 119 | 55 | 49.9 | 157 | 100 | 157 | 455 | 492 | 552 | 528 | 428 | 435 | | |
| 28 | 242.3 | 209 | 60.4 | 45.9 | 3.9 | 11.1 | D | 11.3 | D | D | D | D | D | D | D | D | D |
| 29 | 529.7 | 521 | 305 | 195 | 37.6 | 15.8 | 42.2 | 42.2 | D | D | D | D | D | D | D | D | D |
| 30 | 329.3 | 292 | 167 | 107 | 61.7 | 81.6 | 242 | 122 | 242 | 412 | 697 | 504 | 632 | 596 | 551 | | |
| 31 | 432.7 | 327 | 150 | 80.2 | 38 | 14 | D | D | D | D | D | D | D | D | D | D | D |
| 32 | 395.7 | 329 | 195 | 103 | 33.3 | 14.2 | D | 44.1 | D | D | D | D | D | D | D | D | D |
| 33 | 563.7 | 409 | 182 | 115 | 67.1 | 8.5 | 11.4 | 2.4 | 11.4 | 87.1 | 417 | 744 | 701 | 726 | 714 | | |
| 34 | 232.7 | 174 | 150 | 64.5 | 41.6 | 8.3 | 82.8 | 6.8 | 82.8 | 142 | 310 | 383 | 479 | 475 | 564 | | |
| ND= No Data | | | | | | | | | | | | | | | | | |
| D = dead | | | | | | | | | | | | | | | | | |

DPC = Day post-challenge. Values reported as k/ μ L.

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|--|--|
| Study Type | Efficacy |
| Pertaining to | <i>Leptospira grippotyphosa</i> |
| Study Purpose | To demonstrate effectiveness against <i>Leptospira grippotyphosa</i> in 6-week-old dogs. |
| Product Administration | Two doses were administered subcutaneously (SC) 3 weeks apart. |
| Study Animals | Twenty (20) 6-week-old puppies were randomized into one group of 10 SC vaccinates and one group of 10 controls. |
| Challenge Description | Fifteen (15) days after second vaccination all animals were challenged with <i>Leptospira grippotyphosa</i> organisms. |
| Interval observed after challenge | Dogs were observed daily for 21 days after challenge |
| Results | <p>Efficacy was based on the reduction in spirochetemia in vaccinates when compared to controls.</p> <p>A data table is appended to the end of this summary.</p> |
| USDA Approval Date | January 12, 1999 |

Isolation of Leptospira from Blood Collected from Dogs Post Challenge

| Control Animals | | | | | | | | | | | | | |
|-----------------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|
| Dog | 0DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 1 | | | | | | + | | | | | | | |
| 2 | | | | | + | | + | + | | | | | |
| 3 | | | | + | + | | | | | | | | |
| 4 | | | | | + | + | | | | | | | |
| 5 | | | | + | + | + | | | | | | | |
| 6 | | | | | | + | + | + | + | + | NA | NA | NA |
| 7 | | | | + | + | + | + | + | + | NA | NA | NA | NA |
| 8 | | | | | + | + | + | + | + | + | NA | NA | NA |
| 9 | | | | + | + | + | + | + | + | + | NA | NA | NA |
| 10 | | | | | + | + | + | + | + | + | NA | NA | NA |

NA - Animal Dead or euthanized / no sample taken

+ - Positive for Leptospira

*Leptospira was not isolated in any of the SC vaccinates

| | |
|--|---|
| Study Type | Efficacy |
| Pertaining to | <i>Leptospira icterohaemorrhagiae</i> |
| Study Purpose | To demonstrate effectiveness against <i>Leptospira icterohaemorrhagiae</i> in 6 week old dogs. |
| Product Administration | Two doses were administered subcutaneously (SC) 3 weeks apart. |
| Study Animals | Twenty-two (22) 6 week old puppies serologically negative for <i>Leptospira icterohaemorrhagiae</i> were randomized into one group of 10 SC vaccinates and one group of 12 controls. |
| Challenge Description | Twenty-one (21) days after second vaccination all animals were challenged with <i>Leptospira icterohaemorrhagiae</i> organisms. |
| Interval observed after challenge | Dogs were observed daily for 21 days after challenge for clinical signs associated with <i>L. icterohaemorrhagiae</i> . Blood samples were collected through 14 days after challenge. |
| Results | <p>Efficacy was determined by comparing vaccinates versus controls in clinical signs, thrombocytopenia, and leukopenia.</p> <p>A dog was considered to have thrombocytopenia if the platelet count dropped below 200 k/μL and the count was less than 50% of the baseline value.</p> <p>A dog was considered to have leukopenia if the platelet count dropped below 6 k/μL and the count was less than 50% of the baseline value.</p> <p>Data tables are appended to the end of this summary.</p> |
| USDA Approval Date | March 31, 1998 |

Leptospira Ictero Clinical Signs Observed Post Challenge

| Dog | SC Vaccinates | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------------|---------------|------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|---|--|
| | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC | 15DPC | 16DPC | 17DPC | 18DPC | 19DPC | 20DPC | 21DPC | | |
| 11 | | | | | | | A | | | | | | | | | | | | | | | | | |
| 12 | | | | | | | | | | | | | | | | | | | | | | | | |
| 13 | | | | E | | D | | | | | | | | E | | | | E | | D | | | E | |
| 14 | | | | E | | | E | | F | | | | | | | | | | | D | | E | E | |
| 15 | | A,E | | | | | | | E | | | | | | | | | | | | | | | |
| 16 | | | | | | | | | | | | | | | | | | | | | | | A | |
| 17 | | | | | | | | | | | | | | | | | | | | | | | | |
| 18 | | | | | | | | | | | | | | | | | | | | | | D | | |
| 19 | | | | | | | | | | | | | | | | | | | | | | | | |
| 20 | | | D | D | | D | D | | | | | | | E | | | | | | D | | E | | |
| A-inappetance | | | | | | | | | | | | | | | | | | | | | | | | |
| B-Vomiting | | | | | | | | | | | | | | | | | | | | | | | | |
| C- Depression/Lethargy | | | | | | | | | | | | | | | | | | | | | | | | |
| D-Ocular Discharge Serous | | | | | | | | | | | | | | | | | | | | | | | | |
| E-Ocular Discharge Mucoïd | | | | | | | | | | | | | | | | | | | | | | | | |
| F- Nasal Discharge Serous | | | | | | | | | | | | | | | | | | | | | | | | |
| G- Nasal Discharge Mucoïd | | | | | | | | | | | | | | | | | | | | | | | | |
| H- Diarrhea Mild (loose stool) | | | | | | | | | | | | | | | | | | | | | | | | |
| I- Diarrhea Moderate (Watery stool) | | | | | | | | | | | | | | | | | | | | | | | | |
| J- Diarrhea Severe (bloody stool) | | | | | | | | | | | | | | | | | | | | | | | | |

DPC = Day post-challenge

Leptospira Ictero Clinical Signs Observed Post Challenge

| | | Controls | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----|-------------------------------------|----------|------|------|---------|------|------|------|------|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|--|--|--|--|--|--|--|--|--|
| Dog | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC | 15DPC | 16DPC | 17DPC | 18DPC | 19DPC | 20DPC | 21DPC | | | | | | | | | |
| 21 | | | | | F | | A | | | | | | | | | | | | | | | | | | | | | | | | |
| 22 | | | | | F | | | | | B | | | | | | | | | | | E | | | | | | | | | | |
| 23 | | | L | L | | | | | | | | E | | | E | E | E | E | | | | | | | | | | | | | |
| 24 | | | L | L | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 25 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 26 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 27 | | | L | D | D | E | | J | A | | | | E | | | D | | | | | | | | | | | | | | | |
| 28 | | | L,E | K | A,C,D,J | | | | | | M | | | | | | | | | | | | | | | | | | | | |
| 29 | | | L | | | D | | | | | | | | | | | | | | | | | | | | | | | | | |
| 30 | | | | L,D | A,E | | | | | | M | | | | | | | | | | | | | | | | | | | | |
| 31 | | | L | E | | | A | | | | | E | | | | | E | | | | | | | | | | | | | | |
| 32 | | | | | | | E | | | | | | | | | | | | | | | | | | | | | | | | |
| | A-inappetance | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | B-Vomiting | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | C-Depression/Lethargy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | D-Ocular Discharge Serous | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | E-Ocular Discharge Mucoid | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | F - Nasal Discharge Serous | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | G - Nasal Discharge Mucoid | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | H- Diarrhea Mild (loose stool) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | I- Diarrhea Moderate (Watery stool) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | J- Diarrhea Severe (bloody stool) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | K - Bloody Urine | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | L - Fever >103.0°F | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | M - Death | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Blank - no clinical sign observed | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

DPC = Day post-challenge

Leptospira ictero White Blood Cell Count Post Challenge

SC Vaccinates

| Dog | Baseline (Avg -2DPC, -1DPC, 0DPC) | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
|-----|--|------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|
| 11 | 7.2 | 7.3 | 12.4 | 7.9 | 6.8 | 10.1 | 6.4 | 6.4 | 6.4 | 8.5 | 8.9 | 9.7 | 9.6 | 7.2 | 6.4 |
| 12 | 10 | 13.9 | 10.4 | 8.9 | 9.1 | 12.4 | 15.2 | 8.2 | 11.1 | 8.6 | 7.7 | 10.2 | 9 | 9.1 | 12.3 |
| 13 | 7.6 | 15.4 | 9.6 | 13.2 | 9.1 | 14.2 | 8.8 | 9.2 | 9.6 | 8.3 | 10.6 | 6.7 | 7.8 | 7.8 | 8.4 |
| 14 | 13.4 | 7.6 | 12.6 | 8.2 | 12.6 | 11.3 | 9.3 | 7.3 | 11.8 | 8 | 13.2 | 9.8 | 10 | 12.8 | 9.1 |
| 15 | 9.8 | 11.4 | 9.8 | 9 | 8 | 8.3 | 11.2 | 10.2 | 8 | 7.5 | 10.4 | 7.7 | 11.1 | 7.5 | 10.9 |
| 16 | 9.1 | 8.8 | 9.5 | 6.8 | 8.1 | 9.1 | 9.4 | 8.4 | 10.1 | 7.7 | 8.7 | 9.5 | 10 | 8.3 | 8.3 |
| 17 | 9.1 | 7.1 | 7.8 | 8.1 | 7.5 | 7.2 | 10.5 | 9.4 | 11.4 | 7.6 | 11.7 | 7.1 | 10.2 | 7.5 | 7.3 |
| 18 | 7.2 | 7.7 | 10.5 | 9.1 | 6.6 | 7.3 | 7.1 | 8.4 | 7.4 | 8 | 9 | 8.1 | 6.5 | 7.8 | 6.4 |
| 19 | 9.5 | 13.8 | 8.4 | 11.7 | 11.7 | 8.7 | 6.7 | 10.5 | 7.5 | 8.2 | 7.7 | 7.8 | 7 | 8.8 | 6.7 |
| 20 | 13.1 | 9.9 | 5.3 | 9.1 | 11.9 | 14.8 | 14.4 | 6.4 | 9.1 | 8.7 | 12.5 | 12.6 | 7.6 | 8.1 | 8.9 |

DPC = Day post-challenge. Values reported as k/ μ L.

Leptospira ictero White Blood Cell Count Post Challenge

| Dog | Baseline (Avg -2DPC, -1DPC, 0DPC) | Controls | | | | | | | | | | | | | |
|----------|--|----------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|
| | | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 21 | 7.4 | 6.6 | 9.6 | 6.7 | 8.2 | 6.2 | 8.6 | 6.7 | 6.5 | 8.1 | 10.4 | 6.4 | 8.5 | 6.5 | 6.2 |
| 22 | 7.4 | 8.5 | 9.3 | 8.2 | 6.5 | 7.3 | 13.4 | 9.4 | 7.2 | 8.2 | 13.4 | 10.1 | 7.7 | 7.6 | 9.4 |
| 23 | 9.3 | 12.2 | 9.4 | 11.6 | 7.1 | 9 | 10 | 7 | 6.5 | 7.1 | 11.9 | 7 | 9.6 | 11 | 11.8 |
| 24 | 13.7 | 19.6 | 10.6 | 7.8 | 11.8 | 15.3 | 16.7 | 19.8 | 16 | 13.7 | 19.2 | 24.9 | 13.3 | 24.4 | 12.3 |
| 25 | 10 | 13.9 | 8.5 | 6.9 | 9.1 | 7 | 10.9 | 12.8 | 9.6 | 10 | 13.9 | 9.4 | 8.3 | 9 | 7.1 |
| 26 | 8.4 | 8.6 | 9 | 3.9 | 11.8 | 12.2 | 15.4 | 11.3 | 11.8 | 9 | 10.2 | 13.3 | 8.6 | 8.9 | 10.5 |
| 27 | 7.8 | 7.5 | 9.4 | 15.8 | 14.6 | 10.7 | 9.8 | 7.5 | 8.6 | 12.1 | 8.6 | 8.3 | 11.4 | 7.4 | 9.5 |
| 28 | 7.8 | 8.8 | 6.7 | 4.5 | 7.3 | 7.3 | 8.8 | 14.7 | 10 | 11.6 | 11.7 | 14 | 8.3 | 7.8 | 7.7 |
| 29 | 7.8 | 6.7 | 5.8 | 4.1 | 26.4 | D | | | | | | | | | |
| 30 | 8.8 | 7.6 | 5 | 7.2 | 7.8 | 7.5 | 7.8 | 6.2 | 9.9 | 8 | 10.3 | 10.1 | 9.9 | 9.4 | 9.6 |
| 31 | 11 | 8.1 | 8.3 | 4.2 | 19 | D | | | | | | | | | |
| 32 | 8.3 | 9.3 | 6.2 | 5 | 10.7 | 12.6 | 10.6 | 13.5 | 14.5 | 9.6 | 14.1 | 9.9 | 10 | 10.1 | 9.3 |
| D = dead | | | | | | | | | | | | | | | |

DPC = Day post-challenge. Values reported as k/ μ L.

Leptospira ictero Platelet Counts Post Challenge

| Dog | Baseline (Avg -2DPC, -1DPC, 0DPC) | SC Vaccinates | | | | | | | | | | | | | |
|-----|--|---------------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|
| | | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 11 | 449.7 | 432 | 619 | 476 | 440 | 667 | 457 | 447 | 488 | 442 | 591 | 586 | 536 | 471 | 359 |
| 12 | 518.3 | 475 | 456 | 447 | 428 | 526 | 645 | 435 | 480 | 505 | 487 | 453 | 473 | 461 | 517 |
| 13 | 489.3 | 595 | 425 | 560 | 424 | 580 | 445 | 517 | 416 | 508 | 522 | 415 | 347 | 337 | 349 |
| 14 | 451.7 | 258 | 413 | 349 | 457 | 374 | 344 | 335 | 376 | 331 | 431 | 330 | 263 | 351 | 281 |
| 15 | 357.7 | 380 | 297 | 286 | 275 | 282 | 435 | 400 | 314 | 285 | 388 | 288 | 401 | 290 | 369 |
| 16 | 369 | 264 | 298 | 217 | 264 | 278 | 308 | 268 | 281 | 253 | 316 | 258 | 286 | 284 | 294 |
| 17 | 473.7 | 407 | 400 | 386 | 332 | 214 | 542 | 457 | 513 | 436 | 529 | 417 | 498 | 373 | 381 |
| 18 | 506 | 482 | 569 | 392 | 397 | 351 | 393 | 419 | 327 | 424 | 406 | 388 | 283 | 391 | 287 |
| 19 | 477 | 467 | 386 | 552 | 529 | 417 | 459 | 500 | 378 | 489 | 356 | 383 | 331 | 406 | 352 |
| 20 | 502.3 | 412 | 506 | 483 | 525 | 515 | 555 | 352 | 392 | 358 | 488 | 501 | 325 | 340 | 378 |

DPC = Day post-challenge. Values reported as k/μL.

Leptospira ictero Platelet Counts Post Challenge

| Controls | | | | | | | | | | | | | | | |
|-----------------|--|------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|
| Dog | Baseline (Avg -2DPC, -1DPC, 0DPC) | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 21 | 534.3 | 291 | 315 | 207 | 301 | 341 | 545 | 506 | 529 | 537 | 575 | 434 | 399 | 414 | 410 |
| 22 | 428.7 | 238 | 250 | 168 | 126 | 184 | 261 | 288 | 340 | 412 | 520 | 421 | 369 | 386 | 367 |
| 23 | 411.3 | 374 | 307 | 265 | 289 | 362 | 393 | 361 | 369 | 447 | 546 | 444 | 422 | 583 | 535 |
| 24 | 344.7 | 251 | 130 | 99.5 | 116 | 189 | 312 | 497 | 440 | 480 | 618 | 635 | 461 | 658 | 451 |
| 25 | 566 | 401 | 220 | 146 | 189 | 288 | 483 | 611 | 458 | 466 | 660 | 519 | 427 | 432 | 409 |
| 26 | 392 | 302 | 213 | 94.9 | 84.5 | 210 | 361 | 381 | 421 | 444 | 467 | 578 | 513 | 452 | 388 |
| 27 | 475.7 | 399 | 423 | 483 | 413 | 335 | 386 | 437 | 465 | 575 | 469 | 461 | 540 | 372 | 474 |
| 28 | 411.7 | 214 | 93.5 | 60.5 | 128 | 213 | 307 | 332 | 467 | 612 | 622 | 618 | 495 | 467 | 383 |
| 29 | 332 | 136 | 101 | 6.7 | 11.2 | | | | | | | | | | |
| 30 | 421.9 | 204 | 80.9 | 53.9 | 119 | 231 | 379 | 512 | 549 | 516 | 642 | 494 | 411 | 421 | 427 |
| 31 | 319.3 | 163 | 94.4 | 36.7 | 11.9 | | | | | | | | | | |
| 32 | 267 | 184 | 55 | 7.7 | 88.8 | 196 | 257 | 347 | 525 | 430 | 529 | 360 | 337 | 287 | 301 |
| D = Dead | | | | | | | | | | | | | | | |

DPC = Day post-challenge. Values reported as k/μL.

| | |
|--|--|
| Study Type | Efficacy |
| Pertaining to | <i>Leptospira pomona</i> |
| Study Purpose | To demonstrate effectiveness against <i>Leptospira pomona</i> in 6 week old dogs. |
| Product Administration | Two doses were administered subcutaneously (SC) 3 weeks apart. |
| Study Animals | Twenty (20) 6 week old puppies serologically negative for <i>Leptospira</i> were randomized into one group of 10 SC vaccinates and one group of 10 controls. |
| Challenge Description | Twenty-five (25) days after second vaccination all animals were challenged with <i>Leptospira pomona</i> organisms. |
| Interval observed after challenge | Dogs were observed daily for 21 days after challenge. Blood samples were collected through 14 days after challenge. |
| Results | <p>Efficacy was based on the reduction in spirochetemia in vaccinates when compared to controls.</p> <p>A Data table is appended to the end of this summary.</p> |
| USDA Approval Date | January 12, 1999 |

Isolation of Leptospira from Blood Collected from Dogs Post Challenge

| Control Animals | | | | | | | | | | | | | | | |
|-----------------|------|------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|
| Dog | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 1 | | | + | + | + | + | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | |
| 3 | | | + | + | + | | | | | | | | | | |
| 4 | | | | + | + | | | | | | | | | | |
| 5 | | | + | + | + | + | | | | | | | | | |
| 6 | | | + | + | | | | | | | | | | | |
| 7 | | + | + | + | | | | | | | | | | | |
| 8 | | | + | + | + | | | | | | | | | | |
| 9 | | + | + | + | + | | | | | | | | | | |
| 10 | | + | | + | + | | | | | | | | | | |

DPC= Day post challenge

*Leptospira was not isolated from blood in any of the SC vaccinates

| | |
|--|---|
| Study Type | Efficacy |
| Pertaining to | Canine Parainfluenza Virus |
| Study Purpose | To demonstrate effectiveness against Canine Parainfluenza Virus (CPI) |
| Product Administration | Two doses were administered by the subcutaneous (SC) route three (3) weeks apart |
| Study Animals | Nineteen (19) 6 week old puppies seronegative for CPI were randomly sorted into one group of 13 SC vaccinates and one group of 6 controls. |
| Challenge Description | 21 days after second vaccination all dogs were challenged with CPI |
| Interval observed after challenge | Puppies were observed for 21 days after challenge for clinical signs. Blood and nasal swabs were collected during this period. |
| Results | <p>The study was considered satisfactory based on the serologic response in vaccinates and the decrease in the number of days of virus shedding in vaccinates when compared to controls.</p> <p>Raw Data: Data tables are appended to the end of this summary</p> |
| USDA Approval Date | March 16, 1998 |

CPI Serum Neutralization Antibody Titers

Control Animals

| Dog | ODPV1 | 14DPV1 | ODPV2 | 7DPV2 | 14DPV2 (w) | 14DPV2 | 21DPV2 | 7DPC | 14DPC | 21DPC |
|-----|-------|--------|-------|-------|------------|--------|--------|------|-------|-------|
| 1 | <2 | <2 | <2 | <2 | <2 | <2 | <2 | 2 | 28 | 65 |
| 2 | <2 | <2 | <2 | <2 | <2 | <2 | <2 | 1 | 99 | 182 |
| 3 | <2 | <2 | <2 | <2 | <2 | <2 | <2 | 1 | 81 | 280 |
| 4 | <2 | <2 | 2 | <2 | <2 | <2 | <2 | 3 | 46 | 221 |
| 5 | <2 | <2 | <2 | <2 | <2 | <2 | <2 | 2 | 71 | 289 |
| 6 | <2 | <2 | <2 | <2 | <2 | <2 | <2 | 4 | 64 | 182 |

SC Vaccinates

| Dog | ODPV1 | 14DPV1 | ODPV2 | 7DPV2 | 14DPV2 (w) | 14DPV2 | 21DPV2 | 7DPC | 14DPC | 21DPC |
|-----|-------|--------|-------|-------|------------|--------|--------|------|-------|-------|
| 20 | <2 | <2 | <2 | <2 | 10 | 36 | 42 | 1248 | 7281 | 6295 |
| 21 | <2 | <2 | <2 | <2 | 3 | 16 | 6 | 2892 | 5880 | 4742 |
| 22 | <2 | <2 | <2 | <2 | <2 | 18 | 6 | 1446 | 7037 | 3622 |
| 23 | <2 | <2 | <2 | <2 | 4 | 46 | 10 | 1152 | 10809 | 4581 |
| 24 | <2 | <2 | <2 | <2 | <2 | 3 | 3 | 1579 | 4562 | 4096 |
| 25 | <2 | <2 | <2 | <2 | <2 | <2 | <2 | 811 | 2884 | 10139 |
| 26 | <2 | <2 | <2 | <2 | <2 | <2 | <2 | 227 | 793 | 661 |
| 27 | <2 | <2 | <2 | <2 | <2 | 27 | 12 | 789 | 7079 | 5754 |
| 28 | <2 | <2 | <2 | <2 | <2 | <2 | 4 | 878 | 2253 | 2655 |
| 29 | <2 | <2 | <2 | <2 | <2 | 16 | 5 | 1330 | 9462 | 7228 |
| 30 | <2 | <2 | <2 | <2 | <2 | 3 | 3 | 373 | 1151 | 724 |
| 31 | <2 | <2 | <2 | <2 | <2 | <2 | <2 | 2048 | 2281 | 2586 |
| 32 | <2 | <2 | <2 | 2.2 | <2 | <2 | 3 | 1833 | 1193 | 880 |

DPV - Days Post Vaccination

DPC - Days Post Challenge

A titer of <2 is considered seronegative

CPI Virus Isolation from Nasal Swabs

| Controls | | | | | | | | | | | | | | | |
|----------------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|
| Do g | 0DP C | 1DP C | 2DP C | 3DP C | 4DP C | 5DP C | 6DP C | 7DP C | 8DP C | 9DP C | 10DP C | 11DP C | 12DP C | 13DP C | 14DP C |
| 1 | - | + | + | + | + | + | + | - | - | - | - | - | - | - | - |
| 2 | - | + | + | + | + | + | + | - | - | - | - | - | - | - | - |
| 3 | - | + | + | + | + | + | + | - | + | - | - | - | - | - | - |
| 4 | - | + | + | + | + | + | + | - | + | - | - | - | - | - | - |
| 5 | - | + | + | + | + | + | + | + | - | - | - | - | - | - | - |
| 6 | - | + | + | + | + | + | + | + | + | - | - | - | - | - | - |
| SC Vaccinates | | | | | | | | | | | | | | | |
| Do g | 0DP C | 1DP C | 2DP C | 3DP C | 4DP C | 5DP C | 6DP C | 7DP C | 8DP C | 9DP C | 10DP C | 11DP C | 12DP C | 13DP C | 14DP C |
| 20 | - | + | + | + | + | + | - | - | - | - | - | - | - | - | - |
| 21 | - | + | + | + | + | + | - | - | - | - | - | - | - | - | - |
| 22 | - | + | + | + | + | + | - | | + | - | - | - | - | - | - |
| 23 | - | + | + | + | + | + | - | - | - | - | - | - | - | - | - |
| 24 | - | + | + | + | + | + | - | - | - | - | - | - | - | - | - |
| 25 | - | + | + | + | + | + | - | - | + | - | - | - | - | - | - |
| 26 | - | + | + | + | + | + | - | - | - | - | - | - | - | - | - |
| 27 | - | + | + | + | + | + | - | - | - | - | - | - | - | - | - |
| 28 | - | + | + | + | + | + | + | - | + | - | - | - | - | - | - |
| 29 | - | + | + | + | + | + | - | - | - | - | - | - | - | - | - |
| 30 | - | + | + | + | + | + | - | - | - | - | - | - | - | - | - |
| 31 | - | + | + | + | + | + | - | - | - | - | - | - | - | - | - |
| 32 | - | + | + | + | + | + | - | - | - | - | - | - | - | - | - |

- means CPI virus was not detected

+ means CPI virus was detected

| Study Type | Efficacy | | | | | | | | | |
|--|---|---------------------------------|-----------|---------------------------------|---------------|-----------|-----------|----------|-----------|------------|
| Pertaining to | Cannie Distemper Virus (CDV) | | | | | | | | | |
| Study Purpose | To demonstrate effectiveness against CDV | | | | | | | | | |
| Product Administration | Two doses were administered subcutaneously 21 days apart | | | | | | | | | |
| Study Animals | Seventeen (17) 6 week old puppies seronegative for CDV were randomly sorted into one group of 11 SC vaccinates and one group of 6 controls. | | | | | | | | | |
| Challenge Description | 21 days after second vaccination all dogs were challenged with CDV. | | | | | | | | | |
| Interval observed after challenge | Dogs were observed for 42 days after challenge for clinical signs of CDV. | | | | | | | | | |
| Results | <p>The study was satisfactory per the criteria in 9 CFR 113.306 (b)(3) (i-ii)</p> <table border="1" data-bbox="582 884 1228 1075"> <thead> <tr> <th></th> <th>Mortality</th> <th>Clinical Signs of CDV Infection</th> </tr> </thead> <tbody> <tr> <td>SC Vaccinates</td> <td>0/11 (0%)</td> <td>0/11 (0%)</td> </tr> <tr> <td>Controls</td> <td>5/6 (83%)</td> <td>6/6 (100%)</td> </tr> </tbody> </table> <p>Raw Data: Data tables are appended to the end of this summary</p> | | Mortality | Clinical Signs of CDV Infection | SC Vaccinates | 0/11 (0%) | 0/11 (0%) | Controls | 5/6 (83%) | 6/6 (100%) |
| | Mortality | Clinical Signs of CDV Infection | | | | | | | | |
| SC Vaccinates | 0/11 (0%) | 0/11 (0%) | | | | | | | | |
| Controls | 5/6 (83%) | 6/6 (100%) | | | | | | | | |
| USDA Approval Date | April 6, 1998 | | | | | | | | | |

CDV Clinical Signs Observed Post Challenge - Control Dogs

| Dog | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC |
|--------------------------------------|-------------|----------|----------|-------------|------------------------------------|-------------|-----------|------------------|---------------------------|--|-----------|
| 1 | | | 10,12,18 | 10,12,18 | 10,11,12 | 10 | 2,12 | 10,12,16,17,Euth | 20 | 20 | 20 |
| 2 | | | 2,10,12 | 2,10,12 | 10 | 2,10,12 | 1,2,10,12 | 14 | 8,10,12,14,16,17,18, Euth | 20 | 20 |
| 3 | | | 2,10,12 | 2,10,12 | | 10,12 | 12 | 14 | 8,10,11,14 | 1,8,10,11,12 | 2,8,10,12 |
| 4 | | | 2,10,12 | 2,10,12 | | 2,10,12 | 10 | 10,12 | 1,2,8,10,12 | 2,8,17 | 20 |
| 5 | | | | | | | 10,12 | | 10,11 | 2,10,12 | 10,12 |
| 6 | | | | | 2,12 | 2,10,12 | 2,10,12 | 11,12 | 12,2 | 2,10,12 | 2,8,10,12 |
| Dog | 11DPC | 12DPC | 13DPC | 14DPC | 15DPC | 16DPC-26DPC | 27DPC | 28-29DPC | 30DPC | 31-42DPC | |
| 1 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | |
| 2 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | |
| 3 | 8,10,12 | 1,8,10 | 8,10,11 | 1,8,9,10,12 | 20 | 20 | 20 | 20 | 20 | 20 | |
| 4 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | |
| 5 | 8,10,12,14 | | 2,11 | | 11,12 | | 10,12 | | 10,12 | | |
| 6 | 1,2,8,10,12 | 1,2,8,12 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | |
| 1 - Depression/Lethargy | | | | | 14 - Vomiting | | | | | | |
| 2- Mild/Mod. Ocular Discharge Mucoïd | | | | | 16 - Excessive Salivation | | | | | Intermittent minor stool abnormalities observed were not considered clinical signs of CDV infection. | |
| 8 - Dehydration | | | | | 17 - Chewing gum fits | | | | | | |
| 10-Mucous stool | | | | | 18 - neuromuscular Tics | | | | | | |
| 11-watery Stool | | | | | 20 - death | | | | | | |
| 12-Bloody stool | | | | | Blank - No Clinical signs observed | | | | | | |

DPC – Days post-challenge

CDV Clinical Signs Observed Post Challenge - Vaccinated Dogs

SC Vaccinates

| Dog | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC | 15DPC | 16DPC | 17DPC | 18DPC | 19DPC | 20DPC | 21DPC | | |
|-----|--|------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----|
| 18 | | | | | | | | | | | | | | | | | | | | | | | 10,12 | |
| 19 | | | | | | | | | | | | | | | | | | | 14 | | | | | |
| 20 | | | | | | | | | | | | | | | | | | | | 10 | | | | |
| 21 | | | | | | | | | | | | | | | | | | | | | | | | |
| 22 | | | | | | | | | | | | | | | | | | | | | | | | |
| 23 | | | | | 10 | | | | | | | | | | | | | | | | | | | |
| 24 | | | | | | | | | | | | | | | | | | | | | | | | |
| 25 | | | | | | | | | | | | | | | | | | | | | | | | |
| 26 | | | | | | | | | | | | | | | | | | | | | | | | |
| 27 | | | | | | | | | | | | | | | | | | | 10,12 | 11,12 | 11,12 | 12 | 12 | 12 |
| 28 | | | | | | | | | | | | | | | | | | | 10,12 | 10,12 | | | | |
| | 1 - Depression/Lethargy | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 - Mild/Mod. Ocular Discharge Muroid | | | | | | | | | | | | | | | | | | | | | | | |
| | 8 - Dehydration | | | | | | | | | | | | | | | | | | | | | | | |
| | 10-Mucous stool | | | | | | | | | | | | | | | | | | | | | | | |
| | 11-watery Stool | | | | | | | | | | | | | | | | | | | | | | | |
| | 12-Bloody stool | | | | | | | | | | | | | | | | | | | | | | | |
| | 14 - Vomiting | | | | | | | | | | | | | | | | | | | | | | | |
| | 16 - Excessive Salivation | | | | | | | | | | | | | | | | | | | | | | | |
| | 17 - Chewing gum fits | | | | | | | | | | | | | | | | | | | | | | | |
| | 18 - neuromuscular Tics | | | | | | | | | | | | | | | | | | | | | | | |
| | 20 - death | | | | | | | | | | | | | | | | | | | | | | | |
| | Blank - No Clinical signs observed | | | | | | | | | | | | | | | | | | | | | | | |
| | Intermittent minor stool abnormalities observed were not considered clinical signs of CDV infection. | | | | | | | | | | | | | | | | | | | | | | | |

DPC – Days post-challenge

CDV Clinical Signs Observed Post Challenge - Vaccinated Dogs

| Dog | SC Vaccinates | | | | | | | | | | | | | | | | | | | | | |
|---|---------------|-------|-------|-------|-------|----------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----|
| | 22DPC | 23DPC | 24DPC | 25DPC | 26DPC | 27DPC | 28DPC | 29DPC | 30DPC | 31DPC | 32DPC | 33DPC | 34DPC | 35DPC | 36DPC | 37DPC | 38DPC | 39DPC | 40DPC | 41DPC | 42DPC | |
| 18 | 11 | | | | | | | | | | | | | | | | | | | | | |
| 19 | | | | | | | | | | | | | | | | | | | | | | |
| 20 | | | | | | | | | | | | | | | | | | | | | | |
| 21 | | | | | | | | | | | | | | | | | | | | | | |
| 22 | | | | 10,12 | | | | | | | | | | | | | 14 | | | | | |
| 23 | 10 | | | | 10 | 10 | 10 | | | | 12 | | | | | | | | | | | |
| 24 | | | | | | | | | | | | | | | | | | | | | | |
| 25 | | | | | | | | | | | | | | | | | | | | | | |
| 26 | | | | | | 10 | | | 10 | 10 | | | | | | | | | | | | |
| 27 | 11,12 | | | | 10,12 | 10,11,12 | 12 | | | | | | | | | | | | | | | |
| 28 | 11 | 10,12 | 10,12 | | | | | 10,12 | 10,12 | | | 12 | 12 | 12 | 12 | 12 | | | | | | 12 |
| <p>1 - Depression/Lethargy 2- Mild/Mod. Ocular Discharge Mucoïd 8 - Dehydration 10-Mucous stool 11-watery Stool 12-Bloody stool</p> | | | | | | | | | | | | | | | | | | | | | | |
| <p>14 - Vomiting 16 - Excessive Salivation 17 - Chewing gum fits 18 - neuromuscular Tics 20 - death Blank - No Clinical signs observed</p> | | | | | | | | | | | | | | | | | | | | | | |
| <p>Intermittent minor stool abnormalities observed were not considered clinical signs of CDV infection.</p> | | | | | | | | | | | | | | | | | | | | | | |

DPC – Days post-challenge

| | |
|--|--|
| Study Type | Efficacy |
| Pertaining to | Canine Parvovirus (CPV) |
| Study Purpose | To demonstrate effectiveness against CPV in 6-week-old puppies. |
| Product Administration | Two doses, given at an interval of 21 days, were administered subcutaneously (SC). |
| Study Animals | Study analysis was conducted on twenty-one 6-week-old puppies seronegative for CPV, 17 vaccinates and 4 non-vaccinated controls. |
| Challenge Description | Twenty-one (21) days after second vaccination puppies were challenged with CPV 2b strain. |
| Interval observed after challenge | Puppies were observed daily for 14 days after challenge |
| Results | <p>The data were analyzed according to 9CFR 113.317</p> <p>Number affected by challenge according to 9CFR 113.317: Vaccinates: 0/17 (0%) Controls: 2/4 (50%)</p> <p>Raw data: Data table are appended to the end of this summary.</p> |
| USDA Approval Date | August 31, 2001 |

CPV Post Challenge Daily Observations

| Non-Vaccinated Controls | | | | | | | | | | | | | | | |
|-------------------------|------|------|------|------|------|------|-------------|------|------|------|-------|-------|-------|-------|-------|
| Dog ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 1 | | D | | | | | E,H | | | | | | | | |
| 2 | | | | | | | B,C,H | C | C | | | | | | |
| 3 | | | | | H | D | B,G,H | I | | | | | | | |
| 4 | | | | | | G,H | B,C,D,F,G,H | I | | | | | | | |

| Vaccinates | | | | | | | | | | | | | | | |
|------------|------|------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|
| Dog ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 1 | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | |
| 3 | D | | | | | | H | | | | E | | | | |
| 4 | | | | | | | | | | | | | | | |
| 5 | | | | | | | | | | | D | | | | |
| 6 | | | | | | | | | | | | | | | |
| 7 | | | | | | | | | | | | E | | | |
| 8 | | | | | | | | | | | | | | | |
| 9 | | | | | | | | | | | | | | | |
| 10 | | | | | | | | | | D | | | | | |
| 11 | | D | | | | D | | | | | | | | | |
| 12 | | | | | | | | | | | | | | | |
| 13 | | | D | | | | | | | | | | | | |
| 14 | | | | | | | | | | | | | | | |
| 15 | | | | | | | | | | | | | | | |
| 16 | | | | | | | | | | | | | | | |
| 17 | | | | | | | | | | | | | | | |

B - Lethargy
 C - Dehydration
 D - Mucous Stool
 E - Watery Stool
 F - Bloody Stool
 G - Anorexia
 H - Vomiting
 I - Death
 DPC = Days Post Challenge

Daily Rectal Temperature (°F)

| Non-Vaccinated Controls | | | | | | | | | | | | | | | |
|-------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Cat ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
| 1 | 100.4 | 101.3 | 101.3 | 101.1 | 102.1 | 101.9 | 100.7 | 101.3 | 101.3 | 101.0 | 100.8 | 101.4 | 100.6 | 101.4 | 101.2 |
| 2 | 99.7 | 101.2 | 101.7 | 100.9 | 103.0 | 102.6 | 99.3 | 101.0 | 101.0 | 101.0 | 101.5 | 101.6 | 101.3 | 102.4 | 102.0 |
| 3 | 101.2 | 101.6 | 102.5 | 101.3 | 104.5 | 101.3 | 100.0 | Na | Na | Na | Na | Na | Na | Na | Na |
| 4 | 100.4 | 101.2 | 101.4 | 101.2 | 104.1 | 101.7 | 93.4 | Na | Na | Na | Na | Na | Na | Na | Na |

Vaccinates

| Cat ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
|--------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 5 | 101.1 | 101.9 | 101.2 | 101.3 | 101.7 | 101.5 | 101.0 | 101.0 | 101.5 | 101.7 | 101.1 | 101.8 | 101.7 | 101.3 | 101.8 |
| 6 | 101.1 | 100.5 | 101.5 | 101.3 | 101.1 | 101.5 | 101.5 | 101.3 | 101.7 | 101.6 | 101.4 | 101.7 | 101.7 | 101.3 | 102.1 |
| 7 | 101.0 | 100.5 | 101.0 | 100.8 | 101.3 | 101.1 | 100.6 | 100.5 | 101.4 | 101.2 | 100.9 | 101.0 | 101.3 | 101.4 | 100.8 |
| 8 | 100.7 | 100.9 | 101.4 | 101.7 | 101.4 | 101.1 | 101.3 | 101.3 | 101.7 | 101.4 | 101.3 | 101.4 | 101.2 | 100.9 | 102.3 |
| 9 | 101.0 | 101.0 | 101.4 | 101.5 | 101.2 | 101.0 | 101.3 | 101.1 | 101.3 | 101.5 | 101.6 | 101.7 | 101.5 | 101.3 | 101.8 |
| 10 | 101.3 | 101.9 | 102.1 | 101.5 | 102.0 | 101.6 | 101.1 | 101.4 | 101.5 | 101.8 | 102.3 | 102.4 | 102.5 | 102.7 | 102.0 |
| 11 | 100.5 | 100.8 | 101.0 | 101.2 | 100.9 | 100.8 | 100.8 | 101.2 | 101.3 | 101.0 | 101.2 | 101.0 | 101.3 | 101.1 | 101.6 |
| 12 | 99.7 | 100.7 | 101.5 | 101.1 | 101.1 | 101.3 | 100.9 | 101.0 | 101.1 | 101.1 | 101.1 | 101.3 | 101.0 | 101.3 | 101.2 |
| 13 | 100.5 | 101.6 | 102.1 | 101.0 | 101.2 | 101.0 | 101.1 | 100.9 | 101.5 | 101.3 | 101.7 | 102.3 | 101.4 | 101.8 | 102.1 |
| 14 | 101.3 | 100.8 | 101.6 | 101.4 | 101.2 | 101.2 | 100.6 | 100.9 | 101.1 | 101.1 | 101.1 | 101.2 | 101.1 | 101.0 | 101.6 |
| 15 | 101.3 | 101.5 | 102 | 101.8 | 102.1 | 102.2 | 101.8 | 101.5 | 102.3 | 102.3 | 101.7 | 102.5 | 101.9 | 102.1 | 102.2 |
| 16 | 100.9 | 102.2 | 101.4 | 101.5 | 101.4 | 101.8 | 101.3 | 101.5 | 101.0 | 101.2 | 101.3 | 101.6 | 101.4 | 101.8 | 101.9 |
| 17 | 99.9 | 100.4 | 101.8 | 101.3 | 101.0 | 101.5 | 100.3 | 101.7 | 101.1 | 101.3 | 101.1 | 101.1 | 101.2 | 101.1 | 101.3 |
| 18 | 99.7 | 101.1 | 101.0 | 101.4 | 101.0 | 101.4 | 101.5 | 100.7 | 100.7 | 100.4 | 101.4 | 100.8 | 101.0 | 100.5 | 101.7 |
| 19 | 100.7 | 101.2 | 101.1 | 101.0 | 101.6 | 101.4 | 100.8 | 100.7 | 101.4 | 101.8 | 101.2 | 101.4 | 101.3 | 101.7 | 102.3 |
| 20 | 100.9 | 102.1 | 101.9 | 101.7 | 101.8 | 102.5 | 100.9 | 101.3 | 101.6 | 101.9 | 101.7 | 101.3 | 101.4 | 101.8 | 102.3 |
| 21 | 101.8 | 101.6 | 102.0 | 102.1 | 101.2 | 101.9 | 100.8 | 101.3 | 101.7 | 101.4 | 101.6 | 101.2 | 101.4 | 101.2 | 101.7 |

DPC = Days Post Challenge

Total White Blood Cell Counts (x1000/uL)

| Non-Vaccinated Controls | | | | | | | | | | | |
|-------------------------|------|------|------|------|------|------|------|------|------|------|-------|
| CatID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC |
| 1 | 12.3 | 10.7 | 13.2 | 11.5 | 11.2 | 13.9 | 8.2 | 9.0 | 9.7 | 10.5 | 10.3 |
| 2 | 9.9 | 12.3 | 14.4 | 11.7 | 17.0 | 12.7 | 13.0 | 7.5 | 10.0 | 9.0 | 12.9 |
| 3 | 20.6 | 18.0 | 23.0 | Na | 30.2 | 15.6 | 13.7 | Na | Na | Na | Na |
| 4 | 14.7 | 18.4 | 17.4 | 17.4 | 19.9 | 6.3 | 0.3 | Na | Na | Na | Na |

Vaccinates

| CatID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC |
|-------|------|------|------|------|------|------|-------|------|------|------|-------|
| 5 | 10.2 | 11.8 | 11.8 | 8.4 | 10.3 | 12.7 | 9.18 | 9.1 | 9.8 | 10.3 | 10.7 |
| 6 | 11.0 | 10.2 | 12.7 | 11.0 | 9.3 | 10.1 | 9.61 | 9.8 | 10.3 | 9.3 | 10.0 |
| 7 | 13.5 | 9.0 | 9.3 | 9.1 | 9.4 | 10.2 | 8.73 | 8.9 | 10.9 | 10.0 | 8.4 |
| 8 | 11.9 | 10.4 | 10.2 | 10.0 | 9.0 | 9.3 | 8.40 | 8.6 | 8.2 | 8.4 | 9.7 |
| 9 | 12.5 | 12.8 | 12.8 | 10.3 | 9.7 | 9.3 | 8.17 | 8.1 | 8.2 | 7.3 | 7.3 |
| 10 | 12.7 | 13.7 | 15.1 | 12.3 | 9.9 | 10.0 | 8.00 | 10.2 | 20.3 | 12.0 | 9.9 |
| 11 | 11.3 | 11.7 | 9.8 | Na | 9.4 | 8.8 | 7.71 | 10.7 | 18.9 | 8.8 | 14.9 |
| 12 | 27.2 | 18.5 | 21.8 | 15.3 | 13.9 | 10.4 | 10.70 | 12.1 | 11.2 | 10.8 | 10.1 |
| 13 | 7.8 | 17.6 | 16.1 | 15.1 | 11.0 | 11.2 | 11.80 | 11.5 | 14.1 | 13.9 | 9.5 |
| 14 | 20.4 | 21.6 | 17.6 | Na | 20.4 | 14.0 | 17.10 | 14.1 | 11.4 | 10.0 | 10.3 |
| 15 | 16.7 | 17.6 | 14.5 | 12.6 | 10.6 | 10.9 | 11.0 | 10.4 | 10.3 | 14.2 | 23.2 |
| 16 | 21.6 | 18.5 | 16.0 | 16.0 | 16.0 | 14.7 | 12.6 | 15.4 | 12.0 | 12.8 | 13.1 |
| 17 | 13.6 | 10.8 | 9.1 | Na | 9.3 | 12.7 | 7.8 | 9.9 | 11.0 | 14.4 | 8.5 |
| 18 | 12.4 | 14.8 | 11.0 | 14.6 | 14.7 | 14.9 | 11.8 | 9.4 | 9.4 | 10.0 | 8.8 |
| 19 | 37.0 | 28.2 | 27.7 | 20.0 | 21.9 | 28.6 | 17.2 | 20.3 | 16.3 | 17.7 | 16.2 |
| 20 | 19.0 | 21.3 | 18.7 | 17.4 | 18.9 | 28.2 | 14.1 | 19.6 | 18.3 | 19.6 | 16.2 |
| 21 | 16.7 | 11.6 | 14.3 | 15.9 | 12.8 | 14.4 | 12.9 | 14.5 | 10.1 | 12.1 | 14.3 |

DPC = Days Post Challenge

CPV Titer From Fecal Material (Log FAID₅₀/mg Feces)

| Non-Vaccinated Controls | | | | | | | | | | | |
|-------------------------|------|------|------|------|------|------|------|------|------|------|-------|
| Cat ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC |
| 1 | <1.5 | <1.5 | <1.5 | <1.5 | 2.4 | 4.2 | 5.8 | 5.5 | 5.2 | 2.0 | 1.5 |
| 2 | <1.5 | <1.5 | <1.5 | <1.5 | 1.5 | 3.8 | 5.6 | 5.4 | 4.5 | 3.5 | 3.4 |
| 3 | <1.5 | <1.5 | <1.5 | <1.5 | 3.2 | 5.5 | NS | NS | NS | NS | NS |
| 4 | <1.5 | <1.5 | <1.5 | <1.5 | 3.5 | NS | 6.2 | NS | NS | NS | NS |

| Vaccinates | | | | | | | | | | | |
|------------|------|------|------|------|------|------|------|------|------|------|-------|
| Cat ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC |
| 5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | NS | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 6 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 7 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | NS | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 8 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 9 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 10 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | NS | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 11 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 12 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 13 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 14 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 15 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 16 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 17 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 18 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 19 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 20 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | NS | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |
| 21 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 | <1.5 |

<1.5 is considered negative
 NS = No sample
 DPC = Days Post Challenge

C

| | |
|--|--|
| Study Type | Efficacy |
| Pertaining to | Canine Parvovirus (CPV) |
| Study Purpose | To demonstrate effectiveness against CPV |
| Product Administration | Two doses given at an interval of 28 days were administered subcutaneously (SC). |
| Study Animals | 6-week old puppies seropositive for parvovirus, 20 vaccinates and 5 non-vaccinated controls. |
| Challenge Description | Fifty-six days (56) after second vaccination puppies were challenged with CPV type 2c strain. |
| Interval observed after challenge | Puppies were observed for clinical signs daily for 14 days after challenge |
| Results | <p>Dogs were determined affected by the criteria of 9CFR 113.317(c)(3)(i)</p> <p>Number affected: Vaccinates: 1/20 (5%) Controls: 4/5 (80%)</p> <p>Requirements of 9CFR 113.317 (c)(3)(i) were met.</p> <p>Raw data: Data tables are appended to the end of this summary.</p> |
| USDA Approval Date | January 31, 2012 |

CPV Post challenge Clinical Observations

Non-Vaccinated Controls

| Dog ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
|--------|------|------|------|------|------|-------|-------|-------|-------|------|-------|-------|-------|-------|-------|
| 9 | | | | | | 1,2,3 | 1,2,3 | 1,2,3 | 2,3,4 | Na | Na | Na | Na | Na | Na |
| 11 | | | | | | 1,2,3 | 1,2,3 | 1,2,3 | 2,3 | | | | | | |
| 19 | | | | | | | 1 | 1 | 1 | | | | | | |
| 21 | | | | | | | | 2,3 | 1,3 | | | | | | |
| 27 | | | | | | | | | | | | | | | |

Vaccinates

| Dog ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | 11DPC | 12DPC | 13DPC | 14DPC |
|--------|------|------|------|------|------|------|------|------|------|------|-------|-------|-------|-------|-------|
| 1 | | | | | | | | | | | | | | 1,3 | |
| 2 | | | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | 1 | | | | |
| 4 | | | | | | | | | | | | | | | |
| 5 | | | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | | | |
| 7 | | | | | | | | | | | | | | | |
| 8 | | | | | | | | | | | | | | | |
| 10 | | | | | | | | | | | | | | | |
| 13 | | | | | | | | | | | | | | | |
| 14 | | | | | | | | | | | | | | | |
| 15 | | | | | | | | | | | | | | 1 | |
| 16 | | | | | | | | | | | | | | | 1 |
| 17 | | | | | | | | | 1 | 2 | | | | | |
| 18 | | | | | | | | | | | | | | | |
| 20 | | | | | | | | | | | | | | | |
| 22 | | | | | | | | | | | | | | | |
| 23 | | | | | | | | | | | | | | | |
| 24 | | | | | | | | | | | | | | | |
| 28 | | | | | | | | | | | | | | | |

1 - Mucous Stool
 2-Diarrhea (Watery stool)

3-Bloody Stool
 4-Death

Blank - No clinical signs observed

DPC – Days Post Challenge

| Serum Neutralization Titer | | | | | | | | |
|----------------------------|---------|-------|------|-------------------|--------|--------|--------|------------------|
| Non-Vaccinated Controls | | | | | | | | |
| Dog ID | -24DPV1 | 0DPV1 | 7PV1 | 28DPV1 (0DPV2) | 41DPV1 | 56DPV1 | 70DPV1 | 84DPV1 (ODPC) |
| 9 | 724 | 8 | 4 | <2 | <2 | <2 | <2 | <2 |
| 11 | 91 | 4 | 3 | <2 | <2 | <2 | <2 | <2 |
| 19 | 23 | 64 | 23 | <2 | <2 | <2 | <2 | <2 |
| 21 | <2 | 11 | 10 | <2 | <2 | <2 | <2 | <2 |
| 27 | 10 | 8 | 6 | <2 | <2 | <2 | <2 | <2 |

| Vaccinates | | | | | | | | |
|------------|---------|-------|------|-------------------|--------|---------|--------|------------------|
| Dog ID | -24DPV1 | 0DPV1 | 7PV1 | 28DPV1 (0DPV2) | 41DPV1 | 56DPV1 | 70DPV1 | 84DPV1 (ODPC) |
| 1 | 91 | 32 | 8 | <2 | 1024 | 11585 | 11585 | =>23170 |
| 2 | 64 | 32 | 23 | <2 | 362 | 6871 | 16384 | 16384 |
| 3 | 54 | 45 | 23 | 2 | 1024 | 5793 | 5793 | 6871 |
| 4 | 153 | 64 | 23 | <2 | 724 | 19534 | 23170 | =>46341 |
| 5 | 2048 | 45 | 16 | <2 | 45 | 4096 | 8192 | 23170 |
| 6 | 1024 | 23 | 23 | <2 | <2 | 512 | 2896 | 9767 |
| 7 | 1448 | 6 | 4 | <2 | 1024 | 8192 | 8192 | =>23170 |
| 8 | 512 | 32 | 8 | <2 | <2 | 2896 | 11585 | =>46341 |
| 10 | 128 | 45 | 64 | 2 | <2 | 11585 | 11585 | 11585 |
| 13 | 181 | 6 | 6 | <2 | 45 | 2048 | 5793 | 8192 |
| 14 | 32 | 8 | 16 | 2 | <2 | 2896 | 4884 | 11585 |
| 15 | 23 | 6 | 2 | <2 | 512 | 11585 | 11585 | 16384 |
| 16 | 8 | 11 | 11 | 2 | <2 | 9767 | 11585 | 23170 |
| 17 | 32 | 32 | 23 | 5 | <2 | 11585 | 8192 | 16384 |
| 18 | 16 | 23 | 19 | <2 | 512 | 23170 | 11585 | 11585 |
| 20 | 45 | 11 | 4 | <2 | 724 | 8192 | 16384 | 11585 |
| 22 | <2 | 11 | 8 | <2 | 4 | 8192 | 11585 | 8192 |
| 23 | 2 | 8 | 11 | <2 | 1448 | NO TEST | 16384 | 11585 |
| 24 | 4 | 11 | 4 | <2 | 1024 | 16384 | 23170 | 16384 |
| 28 | 128 | 32 | 16 | <2 | 1448 | 4096 | 11585 | 9767 |

DPV1 - Days post first Vaccination ODPC - Days post challenge
 DPV2 - Days Post Second Vaccination

Lymphocyte Counts Post Challenge (x10³/µl)

| Controls | | | | | | | | | | | | | | |
|----------|-------|-------|------|---------|------|------|------|------|------|------|------|------|------|-------|
| CatID | -2DPC | -1DPC | 0DPC | Average | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC |
| 9 | 1.24 | 1.20 | 1.38 | 1.27 | 1.71 | 1.45 | 0.80 | 0.30 | 0.28 | 0.74 | 0.27 | Na | Na | Na |
| 11 | 2.24 | 2.59 | 2.07 | 2.30 | 2.28 | 2.36 | 1.82 | 0.29 | 0.58 | 0.69 | 1.04 | 1.17 | 1.27 | 2.13 |
| 19 | 1.57 | 2.14 | 1.87 | 1.86 | 2.32 | 2.26 | 2.42 | 1.42 | 0.70 | 1.59 | 1.66 | 1.52 | 2.11 | 2.70 |
| 21 | 1.67 | 2.19 | 2.52 | 2.13 | 2.68 | 1.92 | 2.31 | 1.17 | 0.67 | 1.75 | 2.03 | 1.52 | 2.09 | 3.35 |
| 27 | 2.68 | 2.26 | 2.30 | 2.41 | 2.29 | 2.37 | 2.25 | 0.92 | 1.00 | 1.09 | 2.04 | 1.74 | 2.08 | 2.60 |

Vaccinates

| CatID | -2DPC | -1DPC | 0DPC | Average | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC |
|-------|-------|-------|------|---------|------|------|------|------|------|------|------|------|------|-------|
| 1 | 3.05 | 3.06 | 2.74 | 2.95 | 2.05 | 2.25 | 2.42 | 2.39 | 2.66 | 3.31 | 2.57 | 3.01 | 2.64 | 3.14 |
| 2 | 2.45 | 2.50 | 2.34 | 2.43 | 3.32 | 3.05 | 3.27 | 3.03 | 2.73 | 3.20 | 3.23 | 2.92 | 3.28 | 1.67 |
| 3 | 2.09 | 2.40 | 2.34 | 2.28 | 2.42 | 2.46 | 2.32 | 1.65 | 1.73 | 2.38 | 2.16 | 2.42 | 2.52 | 2.10 |
| 4 | 1.10 | 1.59 | 2.46 | 1.72 | 3.23 | 2.45 | 2.91 | 2.03 | 2.75 | 2.34 | 2.41 | 2.87 | 2.66 | 3.12 |
| 5 | 0.62 | 0.96 | 1.16 | 0.91 | 1.23 | 1.32 | 1.14 | 1.26 | 1.19 | 1.57 | 1.49 | 1.36 | 1.09 | 1.98 |
| 6 | 1.43 | 1.84 | 1.73 | 1.67 | 1.84 | 1.55 | 1.16 | 1.79 | 1.62 | 2.44 | 1.97 | 2.32 | 2.24 | 2.77 |
| 7 | 1.23 | 1.22 | 1.18 | 1.21 | 1.18 | 1.51 | 1.53 | 1.68 | 1.52 | 1.81 | 0.22 | 1.67 | 1.91 | 2.33 |
| 8 | 2.07 | 1.89 | 2.00 | 1.99 | 1.81 | 1.93 | 1.78 | 1.52 | 1.64 | 2.52 | 2.23 | 2.51 | 2.59 | 2.38 |
| 10 | 2.74 | 2.80 | 3.27 | 2.94 | 1.93 | 2.43 | 2.56 | 3.01 | 2.65 | 2.44 | 2.65 | 2.64 | 2.83 | 2.76 |
| 13 | 1.26 | 2.25 | 2.24 | 1.92 | 2.43 | 1.88 | 2.57 | 2.39 | 2.57 | 3.09 | 3.22 | 3.24 | 3.17 | 2.72 |
| 14 | 2.17 | 2.24 | 3.02 | 2.48 | 3.57 | 3.62 | 3.76 | 3.28 | 3.07 | 3.66 | 4.10 | 4.18 | 4.57 | 4.83 |
| 15 | 2.21 | 2.30 | 2.66 | 2.39 | 3.10 | 2.81 | 3.04 | 2.85 | 2.98 | 3.29 | 2.51 | 0.93 | 2.71 | 2.59 |
| 16 | 1.68 | 2.54 | 2.06 | 2.09 | 2.56 | 2.08 | 3.35 | 2.83 | 2.35 | 3.13 | 2.90 | 2.27 | 3.24 | 3.30 |
| 17 | 2.25 | 2.14 | 2.11 | 2.17 | 2.42 | 2.84 | 2.62 | 2.93 | 2.69 | 3.04 | 2.78 | 1.34 | 2.59 | 3.28 |
| 18 | 2.06 | 2.82 | 2.50 | 2.46 | 2.97 | 2.48 | 2.62 | 3.05 | 3.04 | 3.98 | 3.27 | 2.26 | 3.98 | 4.78 |
| 20 | 1.83 | 2.11 | 2.05 | 2.00 | 2.58 | 2.22 | 2.39 | 2.50 | 1.73 | 1.98 | 2.12 | 2.28 | 2.35 | 3.26 |
| 22 | 3.80 | 3.05 | 3.35 | 3.40 | 3.96 | 3.18 | 3.38 | 3.75 | 2.36 | 2.42 | 3.93 | 3.23 | 3.34 | 4.33 |
| 23 | 0.84 | 1.46 | 1.51 | 1.27 | 1.63 | 1.35 | 1.47 | 1.45 | 1.29 | 1.72 | 1.53 | 1.44 | 1.14 | 1.22 |
| 24 | 0.97 | 2.04 | 2.32 | 1.78 | 2.09 | 2.24 | 2.67 | 2.03 | 2.03 | 2.70 | 2.46 | 2.68 | 2.86 | 3.54 |
| 28 | 2.43 | 2.68 | 2.15 | 2.42 | 2.68 | 2.89 | 3.56 | 3.56 | 2.52 | 2.46 | 3.57 | 3.61 | 3.50 | 0.92 |

| Body Temperature Post Challenge °F | | | | | | | | | | | | |
|------------------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|--|
| Non-Vaccinated Controls | | | | | | | | | | | | |
| Dog ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | |
| 9 | 102.0 | 102.0 | 102.6 | 102.9 | 103.2 | 104.6 | 103.2 | 100.9 | Na | Na | Na | |
| 11 | 102.6 | 102.9 | 102.6 | 102.6 | 103.1 | 103.4 | 102.8 | 102.2 | 101.3 | 101.5 | 102.2 | |
| 19 | 102.5 | 102.8 | 102.1 | 102.3 | 101.9 | 103.8 | 102.3 | 102.4 | 101.6 | 102.1 | 101.9 | |
| 21 | 102.2 | 102.3 | 101.3 | 101.4 | 102.0 | 103.4 | 102.0 | 101.8 | 101.5 | 101.5 | 101.4 | |
| 27 | 102.2 | 102.1 | 102.1 | 102.7 | 102.5 | 102.8 | 103.0 | 102.4 | 100.9 | 101.6 | 101.9 | |
| Vaccinates | | | | | | | | | | | | |
| Dog ID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC | |
| 1 | 101.9 | 102.0 | 101.9 | 101.9 | 101.7 | 102.0 | 101.5 | 101.9 | 101.3 | 101.6 | 101.7 | |
| 2 | 102.7 | 103.5 | 103.1 | 103.1 | 103.5 | 102.3 | 103.1 | 102.9 | 102.4 | 102.6 | 102.6 | |
| 3 | 103.0 | 103.0 | 102.5 | 102.2 | 102.7 | 102.7 | 103.1 | 103.0 | 102.1 | 102.5 | 101.9 | |
| 4 | 101.6 | 102.4 | 102.3 | 102.1 | 102.4 | 102.1 | 103.4 | 102.7 | 102.1 | 102.1 | 102.1 | |
| 5 | 103.5 | 103.4 | 103.2 | 103.3 | 103.5 | 102.6 | 102.8 | 103.4 | 102.8 | 103.1 | 102.7 | |
| 6 | 102.7 | 102.6 | 101.7 | 102.8 | 102.4 | 102.4 | 102.8 | 102.7 | 102.2 | 102.4 | 102.1 | |
| 7 | 101.7 | 102.5 | 102.5 | 103.3 | 103.0 | 103.1 | 103.1 | 103.1 | 102.9 | 102.6 | 102.1 | |
| 8 | 102.7 | 102.9 | 102.5 | 102.4 | 102.6 | 102.2 | 102.2 | 102.5 | 101.7 | 101.2 | 102.2 | |
| 10 | 103.1 | 103.3 | 102.3 | 102.8 | 103.0 | 102.5 | 102.2 | 102.7 | 102.8 | 101.9 | 101.9 | |
| 13 | 103.0 | 102.5 | 102.8 | 102.2 | 103.2 | 102.6 | 102.7 | 103.0 | 102.4 | 102.9 | 102.7 | |
| 14 | 102.3 | 102.8 | 102.4 | 102.4 | 102.7 | 102.4 | 102.6 | 102.4 | 102.0 | 101.9 | 102.1 | |
| 15 | 102.5 | 102.7 | 102.3 | 102.0 | 102.8 | 102.2 | 102.4 | 102.4 | 101.9 | 102.2 | 101.7 | |
| 16 | 101.7 | 102.5 | 102.8 | 101.9 | 102.5 | 102.1 | 102.1 | 101.9 | 101.5 | 101.1 | 101.6 | |
| 17 | 101.9 | 102.8 | 102.3 | 102.6 | 102.7 | 102.1 | 102.0 | 101.9 | 102.0 | 101.7 | 102.1 | |
| 18 | 102.2 | 102.5 | 102.1 | 101.5 | 102.3 | 102.6 | 102.0 | 102.0 | 101.9 | 101.8 | 102.0 | |
| 20 | 102.2 | 101.9 | 101.9 | 102.0 | 102.2 | 101.8 | 101.8 | 101.9 | 101.6 | 101.4 | 101.9 | |
| 22 | 102.7 | 102.9 | 102.4 | 101.8 | 102.8 | 102.5 | 102.5 | 102.8 | 102.0 | 102.0 | 101.9 | |
| 23 | 102.5 | 102.8 | 102.7 | 102.7 | 103.2 | 102.4 | 102.7 | 103.1 | 102.1 | 102.4 | 102.2 | |
| 24 | 103.3 | 103.1 | 102.6 | 102.2 | 102.5 | 102.4 | 102.2 | 102.2 | 102.1 | 101.8 | 102.3 | |
| 28 | 102.2 | 102.1 | 102.0 | 102.4 | 102.2 | 102.2 | 102.0 | 102.0 | 101.8 | 101.5 | 101.6 | |

Fecal Virus Isolation Titer Post Challenge

| Controls | | | | | | | | | | | |
|----------|------|------|------|------|------|------|------|------|------|------|-------|
| CatID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC |
| 9 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤2.5 | 6.6 | 7.6 | 5.2 | ≥9.2 | Na | Na |
| 11 | ≤1.5 | ≤1.8 | ≤1.5 | ≤1.5 | 5.5 | 7.2 | 7.5 | ≥8.5 | ≥8.6 | ≥7.6 | 6.6 |
| 19 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | 2.5 | 4.2 | 7.5 | 7.6 | 4.2 | 4 | ≤1.5 |
| 21 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.8 | 4.3 | 4.7 | 6.3 | 6.8 | ≤2.8 | 4.5 | 3.6 |
| 27 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤2.8 | 5.2 | 7.4 | 6.6 | 5.2 | ≤3.0 | ≤1.5 |

| Vaccinates | | | | | | | | | | | |
|------------|------|------|------|------|------|------|------|------|------|------|-------|
| CatID | 0DPC | 1DPC | 2DPC | 3DPC | 4DPC | 5DPC | 6DPC | 7DPC | 8DPC | 9DPC | 10DPC |
| 1 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 2 | ≤1.5 | ≤1.8 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 3 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 4 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 6 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 7 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 8 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 10 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 13 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 14 | ≤1.5 | ≤1.6 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 15 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 16 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 17 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 18 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 20 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 22 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 23 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 24 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 |
| 28 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤1.5 | ≤2.5 | ≤1.5 | ≤2.5 | ≤1.5 | ≤1.5 | ≤1.5 |

Positive For CPV >1.5 log¹⁰ FAID₅₀/mL

DPC – Days Post Challenge

| | |
|--|---|
| Study Type | Safety |
| Pertaining to | Canine Adenovirus Type 2 (CAV-2) |
| Study Purpose | Development of corneal opacity is not associated with the use of this product |
| Product Administration | |
| Study Animals | |
| Challenge Description | |
| Interval observed after challenge | |
| Results | Study data are not available |

| | |
|--|--|
| Study Type | Safety |
| Pertaining to | All |
| Study Purpose | Demonstrate safety of product under typical use conditions |
| Product Administration | Either one or two doses of vaccine 2-4 weeks apart by the subcutaneous route. A total of 1231 doses were administered. |
| Study Animals | A total of 621 dogs, 358 under 6 weeks of age and 263 greater than 6 weeks of age, privately owned and from commercial kennels were enrolled in the study. |
| Challenge Description | NA |
| Interval observed after challenge | No challenge. Observed for 30 minutes after vaccination and then daily for 2 weeks after each vaccination. |
| Results | Frequency of events is appended to the end of this summary. |
| USDA Approval Date | November 15, 2002 |

Summary of Reactions:

| Reaction Type | Puppies up to 6 weeks of age | | | | Dogs > 6 Weeks of Age | | | | Sum of Doses | Reaction Rate |
|-------------------------|------------------------------|--------|-------------------------|--------|-----------------------|--------|-------------------------|--------|--------------|---------------|
| | <24hr | >24hrs | Total Reactions by dose | % | <24hr | >24hrs | Total Reactions by dose | % | | |
| None | NA | NA | 696 | 97.21% | NA | NA | 506 | 98.25% | 1202 | 97.64% |
| Salivation | 0 | 0 | 0 | 0.00% | 1 | 0 | 1 | 0.19% | 1 | 0.08% |
| Lethargy | 3 | 6 | 9 | 1.26% | 0 | 0 | 0 | 0.00% | 9 | 0.73% |
| Anorexia | 3 | 10 | 13 | 1.82% | 0 | 0 | 0 | 0.00% | 13 | 1.06% |
| Injection Site Swelling | 0 | 4 | 4 | 0.56% | 0 | 1 | 1 | 0.19% | 5 | 0.41% |
| Injection Site Pain | 3 | 0 | 3 | 0.42% | 5 | 0 | 5 | 0.97% | 8 | 0.65% |
| Facial Swelling | 0 | 0 | 0 | 0.00% | 1 | 0 | 1 | 0.19% | 1 | 0.08% |
| Vomiting or Diarrhea | 3 | 0 | 3 | 0.42% | 1 | 0 | 1 | 0.19% | 4 | 0.32% |
| Mortality* | 0 | 0 | 0 | 0.00% | 2 | 0 | 2 | 0.39% | 2 | 0.16% |
| Total Doses | 716 | | | | 515 | | | | 1231 | |

*Confirmed by cooperator to be due to causes other than vaccination

Some dogs had more than one adverse event, so total events do not agree with doses administered.