### Summary of Studies Supporting USDA Product Licensure

<table>
<thead>
<tr>
<th>Establishment Name</th>
<th>Elanco US Inc.</th>
</tr>
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<tbody>
<tr>
<td>USDA Vet Biologics</td>
<td></td>
</tr>
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<tr>
<td>Product Code</td>
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<tr>
<td>True Name</td>
<td>Canine Distemper-Adenovirus Type 2-Coronavirus-Parvovirus Vaccine, Modified Live &amp; Killed Virus</td>
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<tr>
<td>Tradename(s) / Distributor or Subsidiary (if different from manufacturer)</td>
<td>ULTRA Duramune DAP + C - Elanco US Inc.</td>
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<td>Date of Compilation Summary</td>
<td>December 19, 2019</td>
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**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.
<table>
<thead>
<tr>
<th><strong>Study Type</strong></th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pertaining to</strong></td>
<td>Infectious Canine Hepatitis Virus</td>
</tr>
<tr>
<td><strong>Study Purpose</strong></td>
<td>To demonstrate effectiveness against Infectious Canine Hepatitis (ICH)</td>
</tr>
<tr>
<td><strong>Product Administration</strong></td>
<td>Two doses were administered subcutaneously (SC) 21 days apart</td>
</tr>
<tr>
<td><strong>Study Animals</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Challenge Description</strong></td>
<td>21 days after second vaccination all dogs were challenged with Infectious Canine Hepatitis Virus.</td>
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<tr>
<td><strong>Interval observed after challenge</strong></td>
<td>Puppies were observed for 21 days after challenge for clinical signs.</td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td>The study was satisfactory per the criteria in 9 CFR 113.305 (1)(ii) (A)(B)</td>
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<table>
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<tr>
<th></th>
<th>Mortality</th>
<th>Clinical Signs of CDV Infection</th>
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<td>Controls</td>
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| **USDA Approval Date** | March 31, 1998 |
## Canine Infectious Hepatitis Clinical Signs Observed Post Challenge

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### Clinical Signs

- Depression/Lethargy
- Serous ocular discharge
- Excessive Salivation
- Other
- Dehydration
- Mild/Moderate mucopurulent ocular discharge
- Icteric Gums
- Petechial Pain / Ecchymotic
- Severe Conjunctivitis
- Vomiting
- Icteric lumbar and ears
- Moribund and euthanization

**NO Clinical signs observed in any group after 16DPC**
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<th><strong>Study Type</strong></th>
<th>Efficacy</th>
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<td><strong>Pertaining to</strong></td>
<td>Canine Adenovirus Type II</td>
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<td><strong>Study Purpose</strong></td>
<td>To demonstrate effectiveness against Canine Adenovirus Type II (CAV2)</td>
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<td><strong>Product Administration</strong></td>
<td>Two doses were administered subcutaneously 21 days apart</td>
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<td><strong>Study Animals</strong></td>
<td>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.</td>
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<td><strong>Challenge Description</strong></td>
<td>21 days after second vaccination all dogs were challenged with CAV2</td>
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<td><strong>Interval observed after challenge</strong></td>
<td>Puppies were observed for 21 days after challenge for clinical signs.</td>
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<td><strong>Results</strong></td>
<td>The study was considered satisfactory by the reduction in clinical signs and virus shedding in the vaccinates when compared to the control animals.</td>
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<tr>
<td><strong>USDA Approval Date</strong></td>
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Raw Data:
Data tables are appended to the end of this summary
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| 27  | SC     |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |
| 28  | SC     |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |
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| 30  | SC     | 1    |      |      |      | 1    |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |
| 31  | SC     |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |
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| 33  | SC     |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |

1. Ocular Discharge  
2. Nasal Discharge  
3. Sneezing  
4. Coughing  
5. Retching  
6. Depression/Lethargy  
7. Inappetence  
Blank - No Clinical signs observed
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Blank - No CAV2 titer detected
DPC - Days Post Challenge
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<td>Product Administration</td>
<td>Two doses were administered subcutaneously 21 days apart</td>
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<td>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.</td>
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<td>Challenge Description</td>
<td>21 days after second vaccination all dogs were challenged with CDV.</td>
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<td>Results</td>
<td>The study was satisfactory per the criteria in 9 CFR 113.306 (b)(3) (i-ii)</td>
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<th></th>
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<td>0/11 (0%)</td>
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Raw Data: Data tables are appended to the end of this summary

<p>| USDA Approval Date | April 6, 1998 |</p>
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**CDV Clinical Signs Observed Post Challenge - Control Dogs**

1. Depression/Lethargy
2. Mild/Mod. Ocular Discharge Mucoid
3. Dehydration
4. Mucuous Stool
5. Watery Stool
6. Bloody Stool
7. Blank - No Clinical signs observed

Intermittent minor stool abnormalities observed were not considered clinical signs of CDV infection.
| Dog | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 |
| 18  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 14 |   |   | 10 |   |
| 19  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 10 |   |   |   |   |
| 20  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 10 |   |   |
| 21  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 22  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 23  |   |   |   |   |   |   |   | 10 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 24  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 25  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 26  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 32 |
| 27  |   |   |   |   |   |   |   |   |   |   | 10 | 12 |   |   |   |   |   |   |   |   |   | 11 | 12 |   |   |   |   |
| 28  |   |   |   |   |   |   |   |   |   |   |   |   | 10 | 12 |   |   |   |   |   |   |   | 10 | 12 |   |   |   |   | 12 |

1 - Depression/Lethargy  14 - Vomiting
2 - Mild/Mod. Ocular Discharge Mucoid  15 - Excessive Salivation
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

Intermittent minor stool abnormalities observed were not considered clinical signs of CDV infection.
## CDV Clinical Signs Observed Post Challenge - Vaccinated Dogs

| Dog | 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  |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
| 23  | 10    |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
| 24  |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
| 25  |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
| 26  |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
| 27  | 11,12 | 30,12 | 10,12 | 10,11,12 | 12   | 10,12 | 12    |       |       |       |       |       |       |       |       |       |       |       |       |       |
| 28  | 11    | 10,12 | 30,12 |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |

**Key**
- 1 - Depression/Lethargy
- 2 - Mild/Mod. Ocular Discharge Mucoid
- 3 - Dehydration
- 4 - Vomiting
- 5 - Excessive Salivation
- 6 - Chewing gum fits
- 7 - Mucous stool
- 8 - watery Stool
- 9 - Bloody stool
- 10 - Neurorheumatic Tics
- 11 - death
- 12 - Blank - No Clinical signs observed

Intermittent minor stool abnormalities observed were not considered clinical signs of CDV infection.
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<th>Study Type</th>
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<td>To demonstrate effectiveness against CPV in 6-week-old puppies.</td>
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<tr>
<td>Product Administration</td>
<td>Two doses, given at an interval of 21 days, were administered subcutaneously (SC).</td>
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<td>Study Animals</td>
<td>Study analysis was conducted on twenty-one 6-week-old puppies seronegative for CPV, 17 vaccinates and 4 non-vaccinated controls.</td>
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<td>Twenty-one (21) days after second vaccination puppies were challenged with CPV 2b strain.</td>
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<td>Puppies were observed daily for 14 days after challenge</td>
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**Non-Vaccinated Controls**

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**Vaccinates**

- 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

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<1.5 is considered negative
NS = No sample
DPC = Days Post Challenge
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<td>Two doses given at an interval of 28 days were administered subcutaneously (SC).</td>
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<td>6-week old puppies seropositive for parvovirus, 20 vaccinates and 5 non-vaccinated controls.</td>
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<td>Fifty-six days (56) after second vaccination puppies were challenged with CPV type 2c strain.</td>
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**Vaccines**

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**CV Post Challenge Clinical Observations**
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**Legend:**
- **0DPC:** Days post challenge
- **1DPC:** Days post first vaccination
- **2DPC:** Days post second vaccination
- **3DPC:** Days post third vaccination
- **4DPC:** Days post fourth vaccination
- **5DPC:** Days post fifth vaccination
- **6DPC:** Days post sixth vaccination
- **7DPC:** Days post seventh vaccination
- **8DPC:** Days post eighth vaccination
- **9DPC:** Days post ninth vaccination
- **10DPC:** Days post tenth vaccination

**Notes:**
- Days post challenge (0DPC) values are consistent across all dogs.
- Days post first vaccination (1DPC) values are consistent across all dogs.
- Days post second vaccination (2DPC) values are consistent across all dogs.
- Days post third vaccination (3DPC) values are consistent across all dogs.
- Days post fourth vaccination (4DPC) values are consistent across all dogs.
- Days post fifth vaccination (5DPC) values are consistent across all dogs.
- Days post sixth vaccination (6DPC) values are consistent across all dogs.
- Days post seventh vaccination (7DPC) values are consistent across all dogs.
- Days post eighth vaccination (8DPC) values are consistent across all dogs.
- Days post ninth vaccination (9DPC) values are consistent across all dogs.
- Days post tenth vaccination (10DPC) values are consistent across all dogs.
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**Lymphocyte Counts Post Challenge (x10^9/l) (jul)***
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**Body Temperature Post Challenge**

- DPC: Days Post Challenge
- IDPC: Intraday Post Challenge
- GIDPC: Grand Intraday Post Challenge
- 34DPC: Thirty-four Days Post Challenge
- 34IDPC: Thirty-four Intraday Post Challenge
- 34GIDPC: Grand Thirty-four Intraday Post Challenge
- 25DPC: Twenty-five Days Post Challenge
- 25IDPC: Twenty-five Intraday Post Challenge
- 25GIDPC: Grand Twenty-five Intraday Post Challenge
- 20DPC: Twenty Days Post Challenge
- 20IDPC: Twenty Intraday Post Challenge
- 20GIDPC: Grand Twenty Intraday Post Challenge
- 15DPC: Fifteen Days Post Challenge
- 15IDPC: Fifteen Intraday Post Challenge
- 15GIDPC: Grand Fifteen Intraday Post Challenge
- 10DPC: Ten Days Post Challenge
- 10IDPC: Ten Intraday Post Challenge
- 10GIDPC: Grand Ten Intraday Post Challenge
- 5DPC: Five Days Post Challenge
- 5IDPC: Five Intraday Post Challenge
- 5GIDPC: Grand Five Intraday Post Challenge
- 0DPC: Zero Days Post Challenge
- 0IDPC: Zero Intraday Post Challenge
- 0GIDPC: Grand Zero Intraday Post Challenge

Note: The table includes temperature data for different post-challenge days and intraday post-challenge days, categorized under IDPC, DPC, and GIDPC.
<table>
<thead>
<tr>
<th>DPC – Days Post Challenge</th>
<th>196</th>
<th>1599.27</th>
</tr>
</thead>
</table>

| Days | 1  | 2  | 3  | 4  | 5  | 6  | 7  | 8  | 9  | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 |
|------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| DPC  | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 |

**Vacents**

<table>
<thead>
<tr>
<th>DPC</th>
<th>10</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>50</th>
<th>60</th>
<th>70</th>
<th>80</th>
<th>90</th>
<th>100</th>
</tr>
</thead>
</table>

**Contact**

**Real Virus Isolation Titer Post Challenge**
<table>
<thead>
<tr>
<th>Study Type</th>
<th>Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pertaining to</td>
<td>Canine Adenovirus Type 2 (CAV-2)</td>
</tr>
<tr>
<td>Study Purpose</td>
<td>Development of corneal opacity is not associated with the use of this product</td>
</tr>
<tr>
<td>Product Administration</td>
<td></td>
</tr>
<tr>
<td>Study Animals</td>
<td></td>
</tr>
<tr>
<td>Challenge Description</td>
<td></td>
</tr>
<tr>
<td>Interval observed after challenge</td>
<td></td>
</tr>
<tr>
<td>Results</td>
<td>Study data are not available</td>
</tr>
<tr>
<td>Study Type</td>
<td>Safety</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>Pertaining to</td>
<td>ALL</td>
</tr>
<tr>
<td>Study Purpose</td>
<td>Demonstrate safety of product under typical use conditions</td>
</tr>
<tr>
<td>Product Administration</td>
<td>Two doses were administered subcutaneously approximately two weeks apart.</td>
</tr>
<tr>
<td>Study Animals</td>
<td>A total of 675 dogs, privately owned and from commercial kennels were enrolled in the study. From these dogs 234 were 6 weeks of age or younger, at first vaccination. Three geographical sites were represented.</td>
</tr>
<tr>
<td>Challenge Description</td>
<td>NA</td>
</tr>
<tr>
<td>Interval observed after challenge</td>
<td>Animals were observed 30 minutes after each vaccination and daily for two (2) weeks after each vaccination.</td>
</tr>
<tr>
<td>Results</td>
<td>Frequency of adverse events:</td>
</tr>
<tr>
<td></td>
<td>Number of Animals</td>
</tr>
<tr>
<td>No observed adverse events</td>
<td>628</td>
</tr>
<tr>
<td>Injection Site Lesion</td>
<td>1</td>
</tr>
<tr>
<td>Diarrhea-one day of loose stools</td>
<td>23</td>
</tr>
<tr>
<td>Heavy Breathing</td>
<td>1</td>
</tr>
<tr>
<td>Death-Hit by Car *</td>
<td>1</td>
</tr>
<tr>
<td>Death-depression,decreased appetite, weight loss **</td>
<td>1</td>
</tr>
<tr>
<td>Lameness (leg cramp) *</td>
<td>1</td>
</tr>
<tr>
<td>Decreased appetite, weight loss, diarrhea, and dehydration *</td>
<td>4</td>
</tr>
<tr>
<td>Gastroenteritis (vomiting) *</td>
<td>2</td>
</tr>
<tr>
<td>Laceration *</td>
<td>1</td>
</tr>
<tr>
<td>Prolapsed nictitan gland *</td>
<td>7</td>
</tr>
<tr>
<td>Pyoderma *</td>
<td>5</td>
</tr>
</tbody>
</table>

*Affirmed by study investigator to have cause other than vaccination

**Cause of death was not determined by study investigator. Signs appeared 4 days after vaccination and death 8 days later.

The injection site lesion was detected after the second vaccination and resolved within 15 days.

| USDA Approval Date | 13 Jan 2011 |