



Summary of Studies Supporting USDA Product Licensure

| | |
|---|---|
| Establishment Name | Ceva Animal Health, LLC |
| USDA Vet Biologics Establishment Number | 368 |
| Product Code | 17H1.R1 |
| True Name | Marek's Disease-Newcastle Disease Vaccine, Serotypes 2 & 3, Live Virus, Live Marek's Disease Vector |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Vectormune HVT NDV & SB1 - No distributor specified |
| Date of Compilation Summary | October 08, 2021 |

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 | Marek's Disease Virus (MDV) |
| Study Purpose | Efficacy against disease caused by the very virulent RB1B strain of Marek's Disease Virus (MDV) |
| Product Administration | <i>In ovo</i> |
| Study Animals | Chickens |
| Challenge Description | |
| Interval observed after challenge | |
| Results | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| USDA Approval Date | May 20, 2003 |

| | |
|--|---|
| Study Type | Efficacy |
| Pertaining to | Marek's Disease Virus (MDV) |
| Study Purpose | Efficacy against disease caused by the very virulent RB1B strain of Marek's Disease Virus (MDV) |
| Product Administration | Subcutaneous |
| Study Animals | Chickens |
| Challenge Description | |
| Interval observed after challenge | |
| Results | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| USDA Approval Date | May 20, 2003 |

| Study Type | Efficacy | | | | | | | | | | | | | | | |
|--|--|--------------------------------|----------------------------|--------------------------------|---------------|-------|-----|---------------------------|-------|-----|--|------|----|-------------------|-------|------|
| Pertaining to | Very virulent Marek's disease, RB1/B strain | | | | | | | | | | | | | | | |
| Study Purpose | To demonstrate effectiveness against very virulent Marek's disease | | | | | | | | | | | | | | | |
| Product Administration | One dose administered via the subcutaneous route | | | | | | | | | | | | | | | |
| Study Animals | 45 SPF day-of-age chicks served as vaccinates. 45 SPF day-of-age chicks served as vaccinates which received a commercial HVT vaccine. 45 SPF day-of-age chicks were placebo-vaccinates and served as challenged positive controls. 44 SPF day-of-age chicks were non-vaccinated and non-challenged to serve as negative controls. | | | | | | | | | | | | | | | |
| Challenge Description | Very virulent Marek's disease, RB1/B strain at 5 days of age | | | | | | | | | | | | | | | |
| Interval observed after challenge | Daily observation for 44 days post challenge | | | | | | | | | | | | | | | |
| Results | <p>A chicken was considered affected by the challenge (positive) if clinical signs of Marek's disease were present. The clinical signs included:</p> <ol style="list-style-type: none"> 1. Enlargement of sciatic nerves 2. Tumors in the kidneys, spleen, liver, heart, gonad, skin, or eyes 3. Mortality <table border="1" data-bbox="587 1216 1433 1554"> <thead> <tr> <th>Treatment Group</th> <th>Number Not Affected</th> <th>Percentage Not Affected</th> </tr> </thead> <tbody> <tr> <td>SQ vaccinates</td> <td>39/45</td> <td>87%</td> </tr> <tr> <td>Commercial HVT vaccinates</td> <td>30/45</td> <td>67%</td> </tr> <tr> <td>Placebo-vaccinates/challenged, positive controls</td> <td>2/45</td> <td>4%</td> </tr> <tr> <td>Negative controls</td> <td>44/44</td> <td>100%</td> </tr> </tbody> </table> <p>The study fulfilled 9CFR 113.330.</p> <p>Raw data are shown on the attached page.</p> | Treatment Group | Number Not Affected | Percentage Not Affected | SQ vaccinates | 39/45 | 87% | Commercial HVT vaccinates | 30/45 | 67% | Placebo-vaccinates/challenged, positive controls | 2/45 | 4% | Negative controls | 44/44 | 100% |
| Treatment Group | Number Not Affected | Percentage Not Affected | | | | | | | | | | | | | | |
| SQ vaccinates | 39/45 | 87% | | | | | | | | | | | | | | |
| Commercial HVT vaccinates | 30/45 | 67% | | | | | | | | | | | | | | |
| Placebo-vaccinates/challenged, positive controls | 2/45 | 4% | | | | | | | | | | | | | | |
| Negative controls | 44/44 | 100% | | | | | | | | | | | | | | |
| USDA Approval Date | June 17, 2014 | | | | | | | | | | | | | | | |

| Vaccinates | Clinical Signs of Marek's Disease | Positive Controls | Clinical Signs of Marek's Disease | Negative Controls | Clinical Signs of Marek's Disease | Commercial HVT Vaccinates | Clinical Signs of Marek's Disease |
|------------|-----------------------------------|-------------------|-----------------------------------|-------------------|-----------------------------------|---------------------------|-----------------------------------|
| 2 | Neg ¹ | 3 | Pos | 1 | Neg | 17 | Neg |
| 4 | Neg | 6 | Pos | 8 | Neg | 18 | Neg |
| 5 | Neg | 7 | Pos | 9 | Neg | 19 | Neg |
| 13 | Neg | 16 | Pos | 10 | Neg | 25 | Pos |
| 14 | Pos ² | 21 | Pos | 11 | Neg | 26 | Pos |
| 15 | Neg | 23 | Pos | 12 | Neg | 35 | Neg |
| 20 | Neg | 28 | Pos | 22 | Neg | 40 | Neg |
| 24 | Neg | 44 | Pos | 27 | Neg | 43 | Neg |
| 29 | Neg | 47 | Pos | 32 | Neg | 45 | Pos |
| 30 | Pos | 48 | Pos | 36 | Neg | 46 | Neg |
| 31 | Neg | 51 | Pos | 39 | Neg | 49 | Pos |
| 33 | Neg | 54 | Pos | 42 | Neg | 58 | Neg |
| 34 | Neg | 62 | Pos | 50 | Neg | 59 | Pos |
| 37 | Neg | 63 | Pos | 52 | Neg | 71 | Neg |
| 38 | Neg | 65 | Pos | 55 | Neg | 72 | Neg |
| 41 | Neg | 67 | Pos | 56 | Neg | 73 | Neg |
| 53 | Neg | 68 | Neg | 61 | Neg | 75 | Neg |
| 57 | Neg | 85 | Pos | 66 | Neg | 81 | Neg |
| 60 | Neg | 87 | Pos | 69 | Neg | 86 | Neg |
| 64 | Neg | 96 | Pos | 70 | Neg | 89 | Pos |
| 78 | Neg | 101 | Pos | 74 | Neg | 92 | Neg |
| 82 | Neg | 107 | Pos | 76 | Neg | 93 | Pos |
| 83 | Neg | 108 | Pos | 77 | Neg | 94 | Neg |
| 104 | Neg | 109 | Pos | 79 | Neg | 95 | Pos |
| 112 | Neg | 113 | Pos | 80 | Neg | 97 | Pos |
| 122 | Neg | 115 | Pos | 84 | Neg | 99 | Pos |
| 123 | Pos | 116 | Neg | 88 | Neg | 102 | Neg |
| 125 | Neg | 117 | Pos | 90 | Neg | 105 | Pos |
| 126 | Pos | 118 | Pos | 91 | Neg | 106 | Pos |
| 129 | Neg | 120 | Pos | 98 | Neg | 110 | Neg |
| 131 | Neg | 121 | Pos | 100 | Neg | 111 | Neg |
| 135 | Neg | 124 | Pos | 103 | Neg | 127 | Neg |
| 136 | Pos | 132 | Pos | 119 | Neg | 134 | Neg |
| 140 | Neg | 139 | Pos | 128 | Neg | 137 | Neg |
| 142 | Neg | 144 | Pos | 130 | Neg | 145 | Pos |
| 156 | Neg | 147 | Pos | 133 | Neg | 146 | Neg |
| 158 | Neg | 148 | Pos | 138 | Neg | 149 | Neg |
| 164 | Neg | 153 | Pos | 141 | Neg | 150 | Neg |
| 167 | Pos | 154 | Pos | 143 | Neg | 155 | Pos |
| 170 | Neg | 157 | Pos | 151 | Neg | 162 | Neg |
| 172 | Neg | 159 | Pos | 152 | Neg | 163 | Neg |

| | | | | | | | |
|-----|-----|-----|-----|-----|-----|-----|-----|
| 174 | Neg | 168 | Pos | 160 | Neg | 165 | Pos |
| 175 | Neg | 171 | Pos | 161 | Neg | 169 | Neg |
| 176 | Neg | 173 | Pos | 166 | Neg | 178 | Neg |
| 177 | Neg | 180 | Pos | | | 179 | Neg |

¹Neg= negative for Marek's disease lesions

²Pos= positive for Marek's disease lesions

| Study Type | Efficacy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|--------------|---------------------|-------------------------|--|-----------------|-------------------------------|--------------|---------------------|-------------------------|--------------------------|---------------------------|----|-------|-----|---------------------------|-----------------------------|----|-------|-----|-------------------|-------------|----|------|----|-------------------|---------------|----|-------|------|
| Pertaining to | Very virulent Marek's disease, RB1/B strain | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Purpose | To demonstrate effectiveness against very virulent Marek's disease | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Product Administration | One dose administered via the <i>in ovo</i> route to chicken embryos at 18 days of incubation for the vaccinate and positive control groups. One dose administered via the subcutaneous route to chicks at day of age for the commercial vaccinate and negative control groups. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Animals | 45 SPF chicken embryos at 18 days of incubation served as vaccinates. 45 SPF chicks at day of age served as vaccinates which received a commercial HVT vaccine. 45 SPF chicken embryos at 18 days of incubation were placebo-vaccinates and served as challenged positive controls. 45 SPF chicks at day of age were left non-vaccinated and non-challenged to serve as negative controls. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Challenge Description | Very virulent Marek's disease, RB1/B strain at 5 days of age | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Interval observed after challenge | Daily observation for 44 days post challenge | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Results | <p>A chicken was considered affected by the challenge (positive) if clinical signs of Marek's disease were present. The clinical signs included:</p> <ol style="list-style-type: none"> 1. Enlargement of sciatic nerves 2. Tumors in the kidneys, spleen, liver heart, gonad, skin, or eyes 3. Mortality <table border="1" data-bbox="571 1496 1436 1870"> <thead> <tr> <th>Treatment Group</th> <th>Hatchability (# Hatched/#Set)</th> <th># Challenged</th> <th>Number Not Affected</th> <th>Percentage Not Affected</th> </tr> </thead> <tbody> <tr> <td><i>In ovo</i> vaccinates</td> <td>87% (52/60¹)</td> <td>45</td> <td>40/45</td> <td>89%</td> </tr> <tr> <td>Commercial HVT vaccinates</td> <td>98% (117/120²)</td> <td>45</td> <td>32/45</td> <td>71%</td> </tr> <tr> <td>Positive controls</td> <td>98% (58/60)</td> <td>45</td> <td>2/45</td> <td>4%</td> </tr> <tr> <td>Negative Controls</td> <td>98% (117/120)</td> <td>45</td> <td>45/45</td> <td>100%</td> </tr> </tbody> </table> <p>¹Three birds were weak and excluded. ²117/120= Hatchability data is for all chicks that were vaccinated SQ.</p> <p>The study fulfilled 9CFR 113.330(c). Raw data are shown on the attached page.</p> | | | | | Treatment Group | Hatchability (# Hatched/#Set) | # Challenged | Number Not Affected | Percentage Not Affected | <i>In ovo</i> vaccinates | 87% (52/60 ¹) | 45 | 40/45 | 89% | Commercial HVT vaccinates | 98% (117/120 ²) | 45 | 32/45 | 71% | Positive controls | 98% (58/60) | 45 | 2/45 | 4% | Negative Controls | 98% (117/120) | 45 | 45/45 | 100% |
| Treatment Group | Hatchability (# Hatched/#Set) | # Challenged | Number Not Affected | Percentage Not Affected | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <i>In ovo</i> vaccinates | 87% (52/60 ¹) | 45 | 40/45 | 89% | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Commercial HVT vaccinates | 98% (117/120 ²) | 45 | 32/45 | 71% | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Positive controls | 98% (58/60) | 45 | 2/45 | 4% | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Negative Controls | 98% (117/120) | 45 | 45/45 | 100% | | | | | | | | | | | | | | | | | | | | | | | | | | |
| USDA Approval Date | June 17, 2014 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Vaccinates | Clinical Signs of Marek's Disease | Positive Controls | Clinical Signs of Marek's Disease | Negative Controls | Clinical Signs of Marek's Disease | Commercial HVT Vaccinates | Clinical Signs of Marek's Disease |
|------------|-----------------------------------|-------------------|-----------------------------------|-------------------|-----------------------------------|---------------------------|-----------------------------------|
| 202 | Neg ¹ | 206 | Pos | 205 | Neg | 204 | Neg |
| 217 | Neg | 215 | Pos | 213 | Neg | 208 | Neg |
| 226 | Neg | 218 | Pos | 214 | Neg | 209 | Neg |
| 228 | Neg | 222 | Pos | 216 | Neg | 210 | Neg |
| 231 | Neg | 225 | Pos | 221 | Neg | 212 | Pos |
| 235 | Neg | 230 | Pos | 232 | Neg | 219 | Pos |
| 236 | Neg | 242 | Pos | 237 | Neg | 220 | Neg |
| 244 | Neg | 249 | Pos | 239 | Neg | 223 | Neg |
| 245 | Neg | 250 | Pos | 240 | Neg | 224 | Neg |
| 247 | Neg | 254 | Pos | 251 | Neg | 243 | Pos |
| 265 | Pos ² | 258 | Pos | 256 | Neg | 248 | Neg |
| 273 | Neg | 263 | Pos | 257 | Neg | 253 | Pos |
| 276 | Neg | 264 | Neg | 262 | Neg | 269 | Pos |
| 277 | Neg | 266 | Pos | 271 | Neg | 281 | Neg |
| 279 | Pos | 267 | Pos | 272 | Neg | 288 | Pos |
| 282 | Neg | 283 | Pos | 275 | Neg | 293 | Pos |
| 286 | Neg | 290 | Pos | 280 | Neg | 296 | Pos |
| 287 | Neg | 292 | Pos | 258 | Neg | 302 | Neg |
| 294 | Neg | 295 | Pos | 289 | Neg | 305 | Pos |
| 299 | Neg | 298 | Pos | 291 | Neg | 312 | Neg |
| 300 | Neg | 301 | Pos | 297 | Neg | 315 | Neg |
| 303 | Neg | 304 | Pos | 310 | Neg | 316 | Neg |
| 309 | Neg | 306 | Pos | 311 | Neg | 322 | Pos |
| 313 | Neg | 307 | Pos | 319 | Neg | 325 | Neg |
| 314 | Neg | 326 | Pos | 334 | Neg | 331 | Neg |
| 317 | Neg | 329 | Pos | 341 | Neg | 335 | Neg |
| 321 | Neg | 333 | Pos | 345 | Neg | 338 | Neg |
| 323 | Neg | 344 | Pos | 351 | Neg | 339 | Neg |
| 327 | Pos | 346 | Pos | 352 | Neg | 340 | Neg |
| 332 | Neg | 350 | Pos | 356 | Neg | 353 | Pos |
| 336 | Neg | 354 | Pos | 357 | Neg | 355 | Neg |
| 337 | Neg | 362 | Pos | 372 | Neg | 358 | Neg |
| 342 | Neg | 364 | Pos | 376 | Neg | 360 | Pos |
| 343 | Neg | 365 | Pos | 380 | Neg | 361 | Neg |
| 347 | Neg | 371 | Pos | 389 | Neg | 367 | Neg |
| 349 | Neg | 375 | Pos | 397 | Neg | 373 | Neg |
| 359 | Neg | 377 | Pos | 400 | Neg | 374 | Neg |
| 368 | Pos | 379 | Pos | 402 | Neg | 383 | Pos |
| 381 | Neg | 385 | Pos | 403 | Neg | 408 | Neg |
| 390 | Pos | 387 | Pos | 405 | Neg | 414 | Neg |
| 394 | Neg | 388 | Pos | 406 | Neg | 415 | Neg |
| 396 | Neg | 392 | Neg | 407 | Neg | 417 | Neg |
| 399 | Neg | 393 | Pos | 409 | Neg | 421 | Neg |
| 419 | Neg | 395 | Pos | 410 | Neg | 422 | Neg |
| 423 | Neg | 411 | Pos | 418 | Neg | 424 | Neg |

¹Neg= Negative for Marek's disease lesions

²Pos= Positive for Marek's disease lesions

| Study Type | Efficacy | | | | | | | | | | | | |
|--|--|---------------------|-----------------|---------------------|---------------|------|----|-----------------------------------|-------|------|-------------------|------|----|
| Pertaining to | Newcastle Disease Virus (NDV) | | | | | | | | | | | | |
| Study Purpose | To demonstrate effectiveness against NDV | | | | | | | | | | | | |
| Product Administration | One dose administered via the subcutaneous route | | | | | | | | | | | | |
| Study Animals | SPF chickens; 29 vaccinates vaccinated at day of age; 31 non-vaccinated, challenged positive controls; 10 non-vaccinated, non-challenged negative controls | | | | | | | | | | | | |
| Challenge Description | NDV Texas GB Standard strain at four weeks of age | | | | | | | | | | | | |
| Interval observed after challenge | Daily observation for 14 days post challenge | | | | | | | | | | | | |
| Results | <p>A chicken was considered affected by the challenge (positive) if clinical signs of Newcastle disease were present. The clinical signs included:</p> <ol style="list-style-type: none"> 1. Respiratory signs: Increased respiration, nasal exudate, and swelling of eyes and head 2. Neurological signs: Tremors, loss of coordination, and paralysis 3. Viscerotropic signs: Listlessness, weakness, diarrhea, and prostration <table border="1" data-bbox="587 1178 1428 1406"> <thead> <tr> <th>Treatment Group</th> <th>Number Affected</th> <th>Percentage Affected</th> </tr> </thead> <tbody> <tr> <td>SQ Vaccinates</td> <td>0/29</td> <td>0%</td> </tr> <tr> <td>NDV challenged, positive controls</td> <td>31/31</td> <td>100%</td> </tr> <tr> <td>Negative Controls</td> <td>0/10</td> <td>0%</td> </tr> </tbody> </table> <p>The study fulfilled 9CFR 113.329(c).</p> <p>Raw data are shown on the attached page.</p> | Treatment Group | Number Affected | Percentage Affected | SQ Vaccinates | 0/29 | 0% | NDV challenged, positive controls | 31/31 | 100% | Negative Controls | 0/10 | 0% |
| Treatment Group | Number Affected | Percentage Affected | | | | | | | | | | | |
| SQ Vaccinates | 0/29 | 0% | | | | | | | | | | | |
| NDV challenged, positive controls | 31/31 | 100% | | | | | | | | | | | |
| Negative Controls | 0/10 | 0% | | | | | | | | | | | |
| USDA Approval Date | May 20, 2003 | | | | | | | | | | | | |

| Vaccinate ID | Clinical Signs of Newcastle Disease | Positive Control ID | Clinical Signs of Newcastle Disease | Negative Control ID | Clinical Signs of Newcastle Disease |
|--------------|-------------------------------------|---------------------|-------------------------------------|---------------------|-------------------------------------|
| 1 | Neg | 1 | Pos | 1 | Neg |
| 2 | Neg | 2 | Pos | 2 | Neg |
| 3 | Neg | 3 | Pos | 3 | Neg |
| 4 | Neg | 4 | Pos | 4 | Neg |
| 5 | Neg | 5 | Pos | 5 | Neg |
| 6 | Neg | 6 | Pos | 6 | Neg |
| 7 | Neg | 7 | Pos | 7 | Neg |
| 8 | Neg | 8 | Pos | 8 | Neg |
| 9 | Neg | 9 | Pos | 9 | Neg |
| 10 | Neg | 10 | Pos | 10 | Neg |
| 11 | Neg | 11 | Pos | | |
| 12 | Neg | 12 | Pos | | |
| 13 | Neg | 13 | Pos | | |
| 14 | Neg | 14 | Pos | | |
| 15 | Neg | 15 | Pos | | |
| 16 | Neg | 16 | Pos | | |
| 17 | Neg | 17 | Pos | | |
| 18 | Neg | 18 | Pos | | |
| 19 | Neg | 19 | Pos | | |
| 20 | Neg | 20 | Pos | | |
| 21 | Neg | 21 | Pos | | |
| 22 | Neg | 22 | Pos | | |
| 23 | Neg | 23 | Pos | | |
| 24 | Neg | 24 | Pos | | |
| 25 | Neg | 25 | Pos | | |
| 26 | Neg | 26 | Pos | | |
| 27 | Neg | 27 | Pos | | |
| 28 | Neg | 28 | Pos | | |
| 29 | Neg | 29 | Pos | | |
| | | 30 | Pos | | |
| | | 31 | Pos | | |

| Study Type | Efficacy | | | | | | | | | | | | |
|--|---|----------------------------|------------------------|----------------------------|--------------------------|------|----|-----------------------------------|-------|------|-------------------|------|----|
| Pertaining to | Newcastle Disease Virus (NDV) | | | | | | | | | | | | |
| Study Purpose | To demonstrate effectiveness against NDV | | | | | | | | | | | | |
| Product Administration | One dose administered via the <i>in ovo</i> route | | | | | | | | | | | | |
| Study Animals | SPF chickens; 36 vaccinates vaccinated at 18 day embryonation; 31 non-vaccinated, challenged positive controls: 10 non-vaccinated, non-challenged negative controls | | | | | | | | | | | | |
| Challenge Description | NDV Texas GB Standard strain at four weeks of age | | | | | | | | | | | | |
| Interval observed after challenge | Daily observation for 14 days post challenge | | | | | | | | | | | | |
| Results | <p>A chicken was considered affected by the challenge (positive) if clinical signs of Newcastle disease were present. The clinical signs included:</p> <ol style="list-style-type: none"> 1. Respiratory signs: Increased respiration, nasal exudate, and swelling of eyes and head 2. Neurological signs: Tremors, loss of coordination, and paralysis 3. Viscerotropic signs: Listlessness, weakness, diarrhea, and prostration <table border="1" data-bbox="587 1137 1428 1368"> <thead> <tr> <th>Treatment Group</th> <th>Number Affected</th> <th>Percentage Affected</th> </tr> </thead> <tbody> <tr> <td><i>In ovo</i> vaccinates</td> <td>3/36</td> <td>8%</td> </tr> <tr> <td>NDV challenged, positive controls</td> <td>31/31</td> <td>100%</td> </tr> <tr> <td>Negative Controls</td> <td>0/10</td> <td>0%</td> </tr> </tbody> </table> <p>The study fulfilled 9CFR 113.329(c)</p> <p>Raw data are shown on the attached page.</p> | Treatment Group | Number Affected | Percentage Affected | <i>In ovo</i> vaccinates | 3/36 | 8% | NDV challenged, positive controls | 31/31 | 100% | Negative Controls | 0/10 | 0% |
| Treatment Group | Number Affected | Percentage Affected | | | | | | | | | | | |
| <i>In ovo</i> vaccinates | 3/36 | 8% | | | | | | | | | | | |
| NDV challenged, positive controls | 31/31 | 100% | | | | | | | | | | | |
| Negative Controls | 0/10 | 0% | | | | | | | | | | | |
| USDA Approval Date | May 20, 2003 | | | | | | | | | | | | |

| Vaccinate ID | Clinical Signs of Newcastle Disease | Positive Control ID | Clinical Signs of Newcastle Disease | Negative Control ID | Clinical Signs of Newcastle Disease |
|--------------|-------------------------------------|---------------------|-------------------------------------|---------------------|-------------------------------------|
| 1 | Pos | 1 | Pos | 1 | Neg |
| 2 | Pos | 2 | Pos | 2 | Neg |
| 3 | Pos | 3 | Pos | 3 | Neg |
| 4 | Neg | 4 | Pos | 4 | Neg |
| 5 | Neg | 5 | Pos | 5 | Neg |
| 6 | Neg | 6 | Pos | 6 | Neg |
| 7 | Neg | 7 | Pos | 7 | Neg |
| 8 | Neg | 8 | Pos | 8 | Neg |
| 9 | Neg | 9 | Pos | 9 | Neg |
| 10 | Neg | 10 | Pos | 10 | Neg |
| 11 | Neg | 11 | Pos | | |
| 12 | Neg | 12 | Pos | | |
| 13 | Neg | 13 | Pos | | |
| 14 | Neg | 14 | Pos | | |
| 15 | Neg | 15 | Pos | | |
| 16 | Neg | 16 | Pos | | |
| 17 | Neg | 17 | Pos | | |
| 18 | Neg | 18 | Pos | | |
| 19 | Neg | 19 | Pos | | |
| 20 | Neg | 20 | Pos | | |
| 21 | Neg | 21 | Pos | | |
| 22 | Neg | 22 | Pos | | |
| 23 | Neg | 23 | Pos | | |
| 24 | Neg | 24 | Pos | | |
| 25 | Neg | 25 | Pos | | |
| 26 | Neg | 26 | Pos | | |
| 27 | Neg | 27 | Pos | | |
| 28 | Neg | 28 | Pos | | |
| 29 | Neg | 29 | Pos | | |
| 30 | Neg | 30 | Pos | | |
| 31 | Neg | 31 | Pos | | |
| 32 | Neg | | | | |
| 33 | Neg | | | | |
| 34 | Neg | | | | |
| 35 | Neg | | | | |
| 36 | Neg | | | | |

| | |
|--|---|
| Study Type | Safety |
| Pertaining to | ALL |
| Study Purpose | Demonstrate safety under typical use conditions |
| Product Administration | Subcutaneous and <i>in ovo</i> route |
| Study Animals | Chickens at day of age and chicken embryos at 18-19 days of embryonation |
| Challenge Description | |
| Interval observed after challenge | |
| Results | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| USDA Approval Date | February 12, 2007 |