



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	19A5.RC
True Name	Swine Influenza Vaccine, H1, RNA Particle
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Merck Animal Health
Date of Compilation Summary	March 04, 2024

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	Swine Influenza Virus, H1																																				
Study Purpose	To demonstrate efficacy against swine influenza virus, H1N1																																				
Product Administration	Two doses, administered intramuscularly 3 weeks apart																																				
Study Animals	Commercial pigs, 3 weeks of age, 28 vaccinates and 29 controls (placebo vaccinated)																																				
Challenge Description	All pigs were challenged 31 days post second vaccination with swine influenza strain A/swine/Iowa/A01778877/2016 (H1N1).																																				
Interval observed after challenge	Lung lesion scores were assessed 5 days post challenge on a subgroup of 18 vaccinates and 19 controls. Nasal swabs were collected daily 14 days post challenge from 10 vaccinates and 10 controls.																																				
Results	Five number summary for lung lesion scores*: <table><tr><th>Group</th><th>Min</th><th>Q1</th><th>Med</th><th>Q3</th><th>Max</th></tr><tr><td>vaccinates</td><td>0</td><td>0</td><td>0</td><td>0</td><td>3</td></tr><tr><td>positive controls</td><td>3</td><td>10</td><td>11</td><td>20</td><td>24</td></tr></table> *Lesion scores were calculated as the percentage of total lung area Five number summary for duration of nasal shedding (days): <table><tr><th>Group</th><th>Min</th><th>Q1</th><th>Med</th><th>Q3</th><th>Max</th></tr><tr><td>vaccinates</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr><tr><td>positive controls</td><td>2</td><td>3</td><td>3</td><td>3</td><td>4</td></tr></table> Raw data are shown below.	Group	Min	Q1	Med	Q3	Max	vaccinates	0	0	0	0	3	positive controls	3	10	11	20	24	Group	Min	Q1	Med	Q3	Max	vaccinates	0	0	0	0	0	positive controls	2	3	3	3	4
Group	Min	Q1	Med	Q3	Max																																
vaccinates	0	0	0	0	3																																
positive controls	3	10	11	20	24																																
Group	Min	Q1	Med	Q3	Max																																
vaccinates	0	0	0	0	0																																
positive controls	2	3	3	3	4																																
USDA Approval Date	October 5, 2021																																				

Table 1: Lung Lesion Score (LLS) by 1st Scorer

Pig ID	Treatment	DLA	DLC	DLD	DRA	DRC	DRD	VLA	VLC	VLD	VRA	VRC	VRD	INT	Total Lung Score	LLS
763	Vaccinate	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.50	0.04
766	Vaccinate	0.00	0.00	0.00	0.00	1.00	0.00	0.00	1.50	0.00	0.00	0.50	0.00	0.00	3.00	0.25
770	Vaccinate	0.00	0.50	0.00	0.00	1.00	0.00	0.00	0.00	0.50	0.00	1.00	0.50	0.00	3.50	0.30
771	Vaccinate	0.00	0.50	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	0.08
777	Vaccinate	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
782	Vaccinate	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00	1.00	0.08
784	Vaccinate	0.00	6.50	0.00	0.00	1.50	0.00	0.00	6.00	1.00	0.00	1.50	0.00	0.00	16.50	1.40
787	Vaccinate	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	1.00	0.08
796	Vaccinate	0.00	0.00	1.00	0.00	2.50	0.50	0.00	0.00	2.50	0.50	3.00	0.50	0.50	11.00	0.93
797	Vaccinate	0.00	6.00	1.50	9.50	1.50	0.50	0.00	5.50	1.00	7.00	2.00	0.00	0.00	34.50	2.92
802	Vaccinate	0.00	1.50	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.50	0.00	0.00	0.00	2.50	0.21
810	Vaccinate	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.50	0.04
817	Vaccinate	0.00	0.50	0.50	0.00	1.50	0.00	0.00	1.00	0.50	0.00	2.00	0.50	0.00	6.50	0.55
819	Vaccinate	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.50	0.00	0.00	0.50	0.00	0.00	1.50	0.13
821	Vaccinate	0.50	1.00	0.00	0.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00	2.50	0.21
822	Vaccinate	0.00	1.50	0.50	0.00	0.00	0.00	0.00	1.00	0.50	0.00	0.00	0.00	0.00	3.50	0.30
825	Vaccinate	0.00	1.00	0.00	1.00	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	2.50	0.21
826	Vaccinate	0.00	1.00	0.00	0.00	0.00	0.50	0.00	0.50	0.00	0.00	0.00	0.00	0.00	2.00	0.17
760	Placebo	0.50	22.00	10.00	2.50	12.50	10.50	0.00	13.50	8.50	3.50	29.00	7.00	1.00	120.50	10.20
767	Placebo	1.50	8.00	7.00	0.00	11.00	5.00	7.00	8.00	5.50	0.50	16.00	8.50	3.50	81.50	6.90
773	Placebo	1.00	7.00	5.00	1.50	19.00	8.00	4.50	7.00	2.50	1.50	17.00	7.50	2.00	83.50	7.07
780	Placebo	6.00	37.00	21.50	25.50	29.50	7.50	12.00	26.00	14.50	20.00	52.00	11.50	10.50	273.50	23.16
781	Placebo	5.50	16.00	13.00	11.00	27.00	6.50	8.00	15.00	5.50	8.50	21.00	3.50	6.00	146.50	12.40
785	Placebo	1.50	7.50	4.50	1.50	22.50	6.50	2.50	4.00	5.00	1.50	37.50	9.00	3.50	107.00	9.06
791	Placebo	2.00	14.00	7.50	4.00	5.50	4.00	3.00	7.00	5.00	3.00	9.50	3.00	4.00	71.50	6.05
792	Placebo	2.00	12.50	6.50	7.00	18.00	8.00	2.00	15.00	6.50	7.50	22.00	6.50	5.00	118.50	10.03
793	Placebo	1.00	5.00	2.00	2.50	5.00	1.00	1.00	3.50	1.50	1.00	7.00	1.50	2.00	34.00	2.88
800	Placebo	16.50	30.50	27.00	13.00	22.50	10.00	14.00	37.00	36.00	19.50	24.50	21.00	4.00	275.50	23.33
801	Placebo	1.00	39.50	22.00	14.00	15.50	1.50	8.00	33.50	48.00	11.00	17.50	11.50	22.00	245.00	20.75
804	Placebo	5.00	15.50	32.50	12.50	22.50	29.00	7.50	14.00	43.00	11.50	35.50	24.50	6.00	259.00	21.93
807	Placebo	3.50	18.50	10.00	8.00	25.50	6.00	9.50	9.00	12.50	9.50	31.00	10.50	9.00	162.50	13.76
816	Placebo	1.50	26.50	18.00	0.50	29.00	2.00	1.50	13.00	17.00	0.00	25.00	2.50	4.50	141.00	11.94
818	Placebo	4.00	28.00	20.50	13.00	24.50	25.50	13.00	23.00	10.00	23.00	39.00	23.00	6.00	252.50	21.38
820	Placebo	3.50	35.00	16.00	6.50	21.50	6.00	5.00	20.50	7.50	7.50	22.00	5.50	2.00	158.50	13.42
823	Placebo	5.00	18.00	6.50	12.00	19.50	2.50	6.00	11.50	5.50	9.00	18.00	5.00	2.00	120.50	10.20
824	Placebo	5.00	12.00	2.00	6.00	17.50	9.00	9.50	10.00	1.50	6.50	29.50	4.00	2.50	115.00	9.74
827	Placebo	3.00	24.00	24.50	7.00	31.00	3.00	6.00	19.00	17.00	7.50	55.00	5.50	6.00	208.50	17.65

Code

DLA = Dorsal Left Apical Lobe	VLA = Ventral Left Apical Lobe
DLC = Dorsal Left Cardiac Lobe	VLC = Ventral Left Cardiac Lobe
DLD = Dorsal Left Diaphragmatic Lobe	VLD = Ventral Left Diaphragmatic Lobe
DRA = Dorsal Right Apical Lobe	VRA = Ventral Right Apical Lobe
DRC = Dorsal Right Cardiac Lobe	VRC = Ventral Right Cardiac Lobe
DRD = Dorsal Right Diaphragmatic Lobe	VRD = Ventral Right Diaphragmatic Lobe
INT = Intermediate Lobe	

Table 2: Lung Lesion Score (LLS) by 2nd Scorer

Pig ID	Treatment	DLA	DLC	DLD	DRA	DRC	DRD	VLA	VLC	VLD	VRA	VRC	VRD	INT	Total Lung Score	LLS
763	Vaccinate	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.00	1.00	0.08
766	Vaccinate	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.50	0.04
770	Vaccinate	0.00	1.00	0.00	0.00	1.00	0.00	0.00	0.50	1.50	0.00	1.00	0.50	0.00	5.50	0.47
771	Vaccinate	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
777	Vaccinate	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.50	0.04
782	Vaccinate	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.50	0.04
784	Vaccinate	0.00	4.00	0.00	0.00	1.50	0.00	0.00	4.50	1.00	0.00	1.00	0.00	0.00	12.00	1.02
787	Vaccinate	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	1.00	0.08
796	Vaccinate	0.00	0.00	1.50	0.00	3.00	0.00	0.00	0.00	1.50	0.50	2.50	0.50	0.50	10.00	0.85
797	Vaccinate	0.00	6.00	0.00	8.00	2.00	0.50	1.00	6.50	0.00	4.00	1.50	0.00	0.00	29.50	2.50
802	Vaccinate	0.00	0.50	0.00	1.00	0.00	0.00	0.00	1.00	0.00	1.50	0.00	0.00	0.00	4.00	0.34
810	Vaccinate	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.50	0.04
817	Vaccinate	0.00	1.00	0.50	0.50	1.00	0.00	0.00	1.00	0.00	0.50	2.00	0.00	0.00	6.50	0.55
819	Vaccinate	0.00	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.50	0.00	0.00	1.00	0.08
821	Vaccinate	0.00	0.50	0.00	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	0.08
822	Vaccinate	0.00	2.00	0.50	0.00	0.00	0.00	0.00	1.50	0.50	0.00	0.00	0.00	0.00	4.50	0.38
825	Vaccinate	0.00	0.50	0.00	0.50	0.00	0.00	0.00	0.50	0.00	0.00	0.00	0.50	0.00	2.00	0.17
826	Vaccinate	0.00	1.00	0.00	0.00	0.00	0.00	0.00	1.50	0.00	0.00	0.00	0.00	0.00	2.50	0.21
760	Placebo	0.50	23.50	17.50	1.50	29.00	10.00	0.50	14.00	6.00	3.00	32.50	9.00	1.00	148.00	12.53
767	Placebo	2.50	10.50	8.00	0.00	17.50	5.50	10.00	12.00	3.00	1.50	20.00	8.50	0.50	99.50	8.43
773	Placebo	1.50	11.00	1.50	1.50	17.00	7.00	2.00	7.50	3.00	1.00	29.00	6.00	4.00	92.00	7.79
780	Placebo	7.00	31.00	15.00	20.50	22.50	9.00	9.00	29.00	13.00	19.50	43.50	7.50	10.50	237.00	20.07
781	Placebo	8.50	11.00	7.50	7.00	23.00	4.50	7.00	10.00	2.50	9.00	22.50	5.00	5.50	123.00	10.41
785	Placebo	2.50	6.00	3.50	1.50	19.50	6.00	3.00	6.50	3.50	1.00	46.50	6.00	3.00	108.50	9.19
791	Placebo	2.00	10.00	6.50	4.00	7.00	3.00	1.50	8.50	4.50	2.50	10.00	2.50	1.50	63.50	5.38
792	Placebo	2.00	14.50	6.50	7.50	23.00	6.50	3.00	18.00	6.00	8.00	29.00	5.50	1.50	131.00	11.09
793	Placebo	1.00	4.50	1.50	2.00	4.50	1.00	1.50	3.50	1.50	1.00	9.50	2.50	0.50	34.50	2.92
800	Placebo	18.00	30.00	31.50	23.50	28.00	7.00	22.50	31.50	19.50	18.00	31.50	19.00	3.50	283.50	24.01
801	Placebo	1.50	35.00	20.00	15.00	16.50	1.50	10.00	38.50	52.00	19.50	18.50	8.00	15.00	251.00	21.25
804	Placebo	3.50	24.50	29.50	12.00	26.50	19.50	4.50	20.00	46.00	11.00	38.00	20.50	6.00	261.50	22.14
807	Placebo	4.50	21.00	10.50	7.50	22.00	6.00	5.50	12.50	9.00	7.50	28.50	6.00	5.00	145.50	12.32
816	Placebo	0.50	32.00	13.00	1.00	33.00	0.00	4.50	19.00	8.50	0.00	35.50	4.00	2.50	153.50	13.00
818	Placebo	6.50	26.50	17.00	19.00	28.00	26.00	11.50	21.50	6.00	21.50	36.00	18.00	3.00	240.50	20.36
820	Placebo	5.50	36.00	16.50	7.50	19.50	14.00	7.50	26.00	7.50	8.50	21.50	5.00	0.50	175.50	14.86
823	Placebo	6.50	24.00	3.50	12.00	20.00	3.00	10.50	19.00	4.00	17.00	22.00	5.50	1.00	148.00	12.53
824	Placebo	9.50	12.50	2.00	11.00	33.00	8.00	11.50	11.00	0.00	9.00	25.50	4.50	0.00	137.50	11.64
827	Placebo	6.00	24.50	28.00	5.00	41.00	10.00	5.50	22.50	19.50	15.50	40.50	7.50	5.00	230.50	19.52

Code

DLA = Dorsal Left Apical Lobe	VLA = Ventral Left Apical Lobe
DLC = Dorsal Left Cardiac Lobe	VLC = Ventral Left Cardiac Lobe
DLD = Dorsal Left Diaphragmatic Lobe	VLD = Ventral Left Diaphragmatic Lobe
DRA = Dorsal Right Apical Lobe	VRA = Ventral Right Apical Lobe
DRC = Dorsal Right Cardiac Lobe	VRC = Ventral Right Cardiac Lobe
DRD = Dorsal Right Diaphragmatic Lobe	VRD = Ventral Right Diaphragmatic Lobe
INT = Intermediate Lobe	

Table 3: Nasal Shedding Titer ($\log_{10}$ TCID₅₀ per mL)

Pig ID	Treatment	Days Post Challenge							
		-1	1	2	3	4	5	6	7
761	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
764	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
769	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
775	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
776	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
783	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
786	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
789	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
795	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
799	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
762	Placebo	0.5	0.5	0.5	4.5	2.5	1.3	0.5	0.5
765	Placebo	0.5	0.5	0.5	4.0	4.3	0.5	0.5	0.5
772	Placebo	0.5	0.5	0.5	0.8	5.5	4.0	0.5	0.5
774	Placebo	0.5	0.5	0.5	5.3	5.3	0.5	0.5	0.5
778	Placebo	0.5	0.5	0.5	5.0	4.8	3.0	0.5	0.5
779	Placebo	0.5	0.5	3.5	4.8	5.0	1.0	0.5	0.5
788	Placebo	0.5	0.5	0.8	4.5	4.8	3.3	0.5	0.5
790	Placebo	0.5	0.5	2.5	5.3	5.0	4.0	0.5	0.5
794	Placebo	0.5	0.5	0.5	3.8	5.0	2.8	0.5	0.5
798	Placebo	0.5	0.5	0.5	4.8	2.5	2.5	0.5	0.5

Note: Titer of 0.5 $\log_{10}$ TCID₅₀/mL is IAV-S (Swine Influenza A Virus) negative.

Study Type	Safety																																																																				
Pertaining to	All																																																																				
Study Purpose	Demonstrate safety of product under typical use conditions.																																																																				
Product Administration	2 doses administered intramuscularly (IM) 3 weeks apart.																																																																				
Study Animals	733 pigs, 21-24 days of age, distributed among 3 study sites.																																																																				
Challenge Description	Not applicable																																																																				
Interval observed after challenge	Animals were observed for systemic and/or local injection site reactions, and various adverse events (AEs) per VeDDRA guidance for 21 days after each vaccination, or until resolution.																																																																				
Results	<table><tr><th rowspan="2">Site</th><th rowspan="2">Total Number Animals</th><th colspan="3">Max. Size of Injection Site Reaction</th><th rowspan="2">1st or 2nd vaccination</th><th rowspan="2">Injection site reactions not observed</th></tr><tr><th><1.5 cm</th><th>1.5 to 5 cm</th><th><5 to 10 cm</th></tr><tr><td rowspan="2">1</td><td>230</td><td>3</td><td>0</td><td>0</td><td>1</td><td>227</td></tr><tr><td>230</td><td>82</td><td>2</td><td>0</td><td>2</td><td>146</td></tr><tr><td rowspan="2">2</td><td>253</td><td>2</td><td>0</td><td>0</td><td>1</td><td>251</td></tr><tr><td>251</td><td>18</td><td>10</td><td>0</td><td>2</td><td>223</td></tr><tr><td rowspan="2">3</td><td>250</td><td>2</td><td>0</td><td>0</td><td>1</td><td>248</td></tr><tr><td>249</td><td>11</td><td>1</td><td>0</td><td>2</td><td>237</td></tr><tr><td rowspan="2">Total All Sites</td><td>733</td><td>7</td><td>0</td><td>0</td><td>1</td><td>726</td></tr><tr><td>730</td><td>111</td><td>13</td><td>0</td><td>2</td><td>606</td></tr></table> The mean duration of site reactions was 2.4 days after the first vaccination and 2.8 days after the second vaccination.							Site	Total Number Animals	Max. Size of Injection Site Reaction			1st or 2nd vaccination	Injection site reactions not observed	<1.5 cm	1.5 to 5 cm	<5 to 10 cm	1	230	3	0	0	1	227	230	82	2	0	2	146	2	253	2	0	0	1	251	251	18	10	0	2	223	3	250	2	0	0	1	248	249	11	1	0	2	237	Total All Sites	733	7	0	0	1	726	730	111	13	0	2	606
Site	Total Number Animals	Max. Size of Injection Site Reaction			1st or 2nd vaccination	Injection site reactions not observed																																																															
		<1.5 cm	1.5 to 5 cm	<5 to 10 cm																																																																	
1	230	3	0	0	1	227																																																															
	230	82	2	0	2	146																																																															
2	253	2	0	0	1	251																																																															
	251	18	10	0	2	223																																																															
3	250	2	0	0	1	248																																																															
	249	11	1	0	2	237																																																															
Total All Sites	733	7	0	0	1	726																																																															
	730	111	13	0	2	606																																																															

	VeDDRA Code	Total Animals	Percent of All Animals
	No adverse events	535	73.0%
	Anorexia	36	4.9%
	Diarrhea	24	3.3%
	Lethargy	10	1.4%
	Lameness	5	0.7%
	Internal ear disorder	4	0.5%
	Cyanosis	2	0.3%
	Dead	2	0.3%
	Dyspnea	2	0.3%
	Rectal prolapse	2	0.3%
	Aural Hematoma	1	0.1%
	Cough	1	0.1%
	Hypothermia	1	0.1%
	Recumbency	1	0.1%
	Seborrhea	1	0.1%
USDA Approval Date	January 4, 2024		

Study Type	Safety																																																										
Pertaining to	All																																																										
Study Purpose	Demonstrate safety of product under typical use conditions.																																																										
Product Administration	2 doses administered intramuscularly (IM) 3 weeks apart.																																																										
Study Animals	776 pregnant sows, between two study sites, separated into three treatment groups. Group 1 and 2 received one of two vaccine serials, Group 3 was non-vaccinated control. Sows were in one of three phases of gestation at the time of the first vaccination; early (30-40 days), mid (50-60 days), and late (70-80 days).																																																										
Challenge Description	Not Applicable																																																										
Interval observed after challenge	Sows were observed daily for general health for 21 days following each vaccination until 7 days post-farrowing, or until resolution of any systemic adverse events. Palpation of injection site areas were performed on Days 3, 4, and 5 following each vaccination.																																																										
Results	Summary of Sow Injection Site Reactions <table><tr><th rowspan="2">Site</th><th rowspan="2">Total Number Animals</th><th colspan="5">Max. Size of Injection Site Reaction</th><th rowspan="2">IVP or Control (C)</th></tr><tr><th>No Swellings</th><th>Draining Abscess</th><th><1.5 cm</th><th>1.5 – 5 cm</th><th>>5 – 10 cm</th></tr><tr><td rowspan="2">1</td><td>283</td><td>282</td><td>0</td><td>1</td><td>0</td><td>0</td><td>IVP</td></tr><tr><td>144</td><td>144</td><td>0</td><td>0</td><td>0</td><td>0</td><td>C</td></tr><tr><td rowspan="2">2</td><td>234</td><td>146</td><td>0</td><td>67</td><td>21</td><td>0</td><td>IVP</td></tr><tr><td>115</td><td>105</td><td>0</td><td>9</td><td>1</td><td>0</td><td>C</td></tr><tr><td rowspan="2">Total All Sites</td><td>517</td><td>428</td><td>0</td><td>68</td><td>21</td><td>0</td><td>IVP</td></tr><tr><td>259</td><td>249</td><td>0</td><td>9</td><td>1</td><td>0</td><td>C</td></tr></table> The mean duration of injection site reactions was 4.2 days after the first vaccination and 1.7 days after the second vaccination.	Site	Total Number Animals	Max. Size of Injection Site Reaction					IVP or Control (C)	No Swellings	Draining Abscess	<1.5 cm	1.5 – 5 cm	>5 – 10 cm	1	283	282	0	1	0	0	IVP	144	144	0	0	0	0	C	2	234	146	0	67	21	0	IVP	115	105	0	9	1	0	C	Total All Sites	517	428	0	68	21	0	IVP	259	249	0	9	1	0	C
Site	Total Number Animals			Max. Size of Injection Site Reaction						IVP or Control (C)																																																	
		No Swellings	Draining Abscess	<1.5 cm	1.5 – 5 cm	>5 – 10 cm																																																					
1	283	282	0	1	0	0	IVP																																																				
	144	144	0	0	0	0	C																																																				
2	234	146	0	67	21	0	IVP																																																				
	115	105	0	9	1	0	C																																																				
Total All Sites	517	428	0	68	21	0	IVP																																																				
	259	249	0	9	1	0	C																																																				

Table 1: Sows Incidence of Occurrence of Adverse Events

VeDDRA Code	Total Vaccinated Animals (N=517)	Total Control Animals (N=259)	Percent of All Animals (N=776)
No Adverse Events	361	187	70.6%
Return to estrus	27	26	6.8%
Bacterial skin infection	23	13	4.6%
Lactation change	16	4	2.6%
Death*	8	3	1.4%
Hyperthermia	4	7	1.4%
Anorexia	4	4	1.0%
Retained placenta	5	3	1.0%
Lameness	2	4	0.8%
Rectal prolapse	2	2	0.5%
Behavioral disorder NOS ^(b)	0	2	0.3%
Cough	2	0	0.3%
Trauma NOS ^(b)	1	1	0.3%
Abortion	0	1	0.1%
Abscess NOS ^(b)	0	1	0.1%
Dermal cyst	1	0	0.1%
Dermal mass	1	0	0.1%
Emesis	1	0	0.1%
Erythema	1	0	0.1%
Loss of condition	0	1	0.1%
Mastitis NOS ^(b)	1	0	0.1%
Paralysis	1	0	0.1%
Recumbency	1	0	0.1%
Salivary gland disorder	0	1	0.1%
Skin disorders NOS ^(b)	1	0	0.1%
Ulceration NOS ^(b)	0	1	0.1%
Uterine prolapse	1	0	0.1%
Vaginal prolapse	1	0	0.1%

*Deaths not attributable to vaccine as affirmed by licensee

(b) NOS = Not otherwise specified

Table 1: Sows Incidence of Occurrence of Adverse Events

VeDDRA Code	Total Vaccinated Animals (N=517)	Total Control Animals (N=259)	Percent of All Animals (N=776)
No Adverse Events	361	187	70.6%
Return to estrus	27	26	6.8%
Bacterial skin infection	23	13	4.6%
Lactation change	16	4	2.6%
Death*	8	3	1.4%
Hyperthermia	4	7	1.4%
Anorexia	4	4	1.0%
Retained placenta	5	3	1.0%
Lameness	2	4	0.8%
Rectal prolapse	2	2	0.5%
Behavioral disorder NOS ^(b)	0	2	0.3%
Cough	2	0	0.3%
Trauma NOS ^(b)	1	1	0.3%
Abortion	0	1	0.1%
Abscess NOS ^(b)	0	1	0.1%
Dermal cyst	1	0	0.1%
Dermal mass	1	0	0.1%
Emesis	1	0	0.1%
Erythema	1	0	0.1%
Loss of condition	0	1	0.1%
Mastitis NOS ^(b)	1	0	0.1%
Paralysis	1	0	0.1%
Recumbency	1	0	0.1%
Salivary gland disorder	0	1	0.1%
Skin disorders NOS ^(b)	1	0	0.1%
Ulceration NOS ^(b)	0	1	0.1%
Uterine prolapse	1	0	0.1%
Vaginal prolapse	1	0	0.1%

*Deaths not attributable to vaccine as affirmed by licensee

(b) NOS = Not otherwise specified

	Birth Events by Gestation							
	Gestation	Serial Group	Born Alive	Dead	Stillborn	Mummified	Weak	Aborted
	Early (30-40 days)	1	1110	35	68	21	16	0
	Early (30-40 days)	2	1160	40	88	28	20	0
	Early (30-40 days)	Control	1082	32	80	24	17	0
	Mid (50-60 days)	1	1124	35	58	13	9	0
	Mid (50-60 days)	2	1072	38	69	19	25	0
	Mid (50-60 days)	Control	1008	36	65	16	18	1
	Late (70-80 days)	1	1132	44	80	15	11	0
	Late (70-80 days)	2	1148	23	80	20	24	0
	Late (70-80 days)	Control	1024	36	74	29	15	0
	One sow aborted 10 piglets.							
USDA Approval Date	February 15, 2024							