

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	19K5.R9
True Name	Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Ingelvac CircoFLEX AD - No distributor specified
Date of Compilation Summary	March 21, 2025

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.

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Study Type	Efficacy						
Pertaining to	Porcine Circovirus Ty	ype 2a (PCV2a)					
Study Purpose		-week onset of immunity ag	gainst PCV2a				
Product	Single intramuscular	administration of vaccine.					
Administration							
Study Animals	Cesarean-derived, col	lostrum deprived pigs vacci	inated at 22 days old and				
	randomly divided into	o 3 groups:					
	Group 1 Control vacc	* *					
	Group 2 Test vaccine	. ,					
	Group 3 Non-treated,	non-challenged controls (1	NTX) (n=4)				
Challenge	Porcine Circovirus, T	Type 2a challenge virus adm	ninistered 2 weeks				
Description	following vaccination						
Interval observed			udy Day 16-36 or Day 1-21				
after challenge	Post-Challenge). Lym	nphoid tissues were taken 2	1 days after challenge				
	(Study Day 36) and e						
Results			letion if the histopathology				
		· -	hoid tissue samples (tonsil,				
	tracheobronchial lym	ph node, mesenteric lymph	node, or iliac lymph node).				
	A:		:41:4: :6 .41				
			noid colonization if the more of the four lymphoid				
	tissue samples (tonsil, tracheobronchial lymph node, mesenteric lymph node,						
I	or iliac lymph node)	,	ode, mesenteric lymph node,				
	or iliac lymph node).	, 1240-12-15-15-15-15-15-15-15-15-15-15-15-15-15-	ode, mesenteric lymph node,				
		id Tissue Efficacy Results	ode, mesenteric lymph node,				
	Summary of Lympho	id Tissue Efficacy Results	Lymphoid				
	Summary of Lympho Group	id Tissue Efficacy Results Lymphoid Depletion*	Lymphoid Colonization (IHC)*				
	Summary of Lympho Group Control Vaccine	id Tissue Efficacy Results	Lymphoid				
	Summary of Lympho Group Control Vaccine Test Vaccine	Lymphoid Depletion* 25/25 (100%) 10/26 (38%)	Lymphoid Colonization (IHC)* 25/25 (100%) 10/26 (38%)				
	Summary of Lympho Group Control Vaccine Test Vaccine *All non-vaccinated, non-challe	id Tissue Efficacy Results Lymphoid Depletion* 25/25 (100%)	Lymphoid Colonization (IHC)* 25/25 (100%) 10/26 (38%)				
	Summary of Lympho Group Control Vaccine Test Vaccine	Lymphoid Depletion* 25/25 (100%) 10/26 (38%)	Lymphoid Colonization (IHC)* 25/25 (100%) 10/26 (38%)				
	Summary of Lympho Group Control Vaccine Test Vaccine *All non-vaccinated, non-challe colonization on Study Day 14	Lymphoid Depletion* 25/25 (100%) 10/26 (38%) nged control (NTX) pigs were negative for the second	Lymphoid Colonization (IHC)* 25/25 (100%) 10/26 (38%)				
	Summary of Lympho Group Control Vaccine Test Vaccine *All non-vaccinated, non-challe	Lymphoid Depletion* 25/25 (100%) 10/26 (38%) nged control (NTX) pigs were negative for the second	Lymphoid Colonization (IHC)* 25/25 (100%) 10/26 (38%)				
USDA Approval	Summary of Lympho Group Control Vaccine Test Vaccine *All non-vaccinated, non-challe colonization on Study Day 14 Raw data on attached	Lymphoid Depletion* 25/25 (100%) 10/26 (38%) nged control (NTX) pigs were negative for the second	Lymphoid Colonization (IHC)* 25/25 (100%) 10/26 (38%)				
USDA Approval Date	Summary of Lympho Group Control Vaccine Test Vaccine *All non-vaccinated, non-challe colonization on Study Day 14	Lymphoid Depletion* 25/25 (100%) 10/26 (38%) nged control (NTX) pigs were negative for the second	Lymphoid Colonization (IHC)* 25/25 (100%) 10/26 (38%)				

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Сионъ	Die ID		Colonizat	ion (IHC)			Depletion	(Histology)	
Group	Pig ID	Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
NTX	10	0	0	0	0	0	0	0	0
NTX	27	0	0	0	0	0	0	0	0
NTX	35	0	0	0	0	0	0	0	0
NTX	50	0	0	0	0	0	0	0	0
Control	3	1	2	2	3	1	2	0	2
Control	4	3	3	3	3	1	3	2	3
Control	5	3	3	3	3	0	2	1	2
Control	8	1	2	2	2	2	3	2	3
Control	9	2	2	2	3	1	2	0	2
Control	13	1	2	1	2	0	1	0	1
Control	14	2	2	2	2	0	1	0	1
Control	16	3	2	2	2	1	2	2	1
Control	17	3	3	3	3	1	2	2	2
Control	19	3	3	3	3	0	1	2	2
Control	20	1	2	2	2	1	2	2	2
Control	23	3	3	3	3	1	2	1	2
Control	28	3	2	2	2	0	2	1	2
Control	30	3	3	3	3	0	0	0	2
Control	33*	0	0	0	0	0	0	0	0
Control	34	3	3	3	3	2	2	2	2
Control	36	3	3	3	3	1	0	0	2
Control	38	3	3	3	3	1	2	1	2
Control	39	1	2	0	2	0	2	1	2
Control	40	2	1	2	1	1	2	1	2
Control	41	3	2	3	2	1	2	1	2
Control	47	3	3	3	3	2	1	1	2
Control	49	3	3	3	3	1	2	2	3
Control	52	2	2	3	1	1	0	0	1
Control	53	2	3	3	3	2	0	0	1
Control	55	2	3	1	3	0	2	1	2
Test	1	0	0	0	0	0	0	0	0
Test	2	0	0	0	1	0	0	0	1
Test	6	0	0	0	0	0	0	0	0
Test	7	0	0	0	0	0	0	0	1
Test	11	0	0	0	1	0	0	0	1
Test	12	0	0	0	0	0	0	0	0
Test	15	0	0	0	0	0	0	0	0
Test	18	0	0	0	0	0	0	0	0
Test	21	0	0	0	0	0	0	0	0
Test	22	0	0	0	0	0	0	0	0
Test	24	0	1	0	1	0	1	0	1
Test	25	0	0	0	1	0	0	0	0
Test	26	0	0	0	1	0	0	0	0
Test	29	0	1	0	0	0	0	0	0
Test	31	0	0	0	0	0	0	0	1
Test	32	1	0	0	0	0	1	0	0
Test	37	0	0	0	0	0	0	0	0
Test	42	0	0	0	0	0	1	0	0
Test	43	0	0	0	1	0	0	0	0
Test	44	0	0	0	0	0	1	0	0
Test	45	0	0	0	0	0	0	0	0
Test	46	1	0	0	0	0	0	1	0
Test	48	0	0	0	0	0	0	0	0
Test	51	0	0	0	0	0	0	0	0
Test	54	0	0	0	0	0	0	0	0
Test	56	0	0	1	0	0	0	1	0

NTX=non-treated, non-challenged control; MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry; N.A.=tissue was not available to be scored

Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)

Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

*Pig 33 died prior to challenge and was not included in statistical analysis; the pig was negative for both PCV2 and PCV3 by molecular diagnostics and there was no obvious evidence of infection on necropsy or histopathology

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Study Type	Efficacy					
Pertaining to	Porcine Circovirus Ty	pe 2d (PCV2d)				
Study Purpose	Demonstration of a 2-week onset of immunity against PCV2d					
Product		administration of vaccine.				
Administration						
Study Animals	Cesarean-derived, colo	ostrum deprived pigs vaccir	nated at 22 days old and			
	randomly divided into	3 groups:				
	Group 1 Control vacci					
	Group 2 Test vaccine					
	Group 3 Non-treated, 1	non-challenged controls (N	TX) (n=6)			
Challenge	Porcine Circovirus, Ty	ype 2d challenge virus admi	nistered 2 weeks			
Description	following vaccination					
Interval observed	_	days for clinical signs (Stud	• •			
after challenge		phoid tissues were taken 21	days after challenge			
	(Study Day 36) and ex					
Results		positive for lymphoid deple				
		or more of the four lymph				
	tracheobronchial lymp	oh node, mesenteric lymph i	node, or iliac lymph node).			
		1 '4' C 1 1	:1 1 : 4: :6 41			
		red positive for lympho				
		y score is > 0 for one or r tracheobronchial lymph no				
	or iliac lymph node).	tracheodionemai rympii noo	de, mesenterie rymph node,			
	of mac tymph hode).					
	Summary of Lymphoi	d Tissue Efficacy Results				
	Group	Lymphoid Depletion*	Lymphoid			
	_	ŭ 1 1	Colonization (IHC)*			
	Control Vaccine	25/25 (100%)	25/25 (100%)			
	Test Vaccine	11/25 (44%)	8/25 (32%)			
	*All non-vaccinated, non-challen colonization on Study Day 14	ged control (NTX) pigs were negative fo	r lymphoid depletion and lymphoid			
	Raw data on attached	page				
USDA Approval	August 30, 2023					
Date	1105000 50, 2025					
	•					

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Group	Pig ID			(Histology)		Colonization (IHC)			
Group	I Ig ID	Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
NTX	60	0	0	0	0	0	0	0	0
NTX	69	0	0	0	0	0	0	0	0
NTX	71	0	0	0	0	0	0	0	0
NTX	84	0	0	0	0	0	0	0	0
NTX	85	0	0	0	0	0	0	0	0
NTX	103	0	0	0	0	0	0	0	0
Control	57	2	2	3	3	3	2	2	2
Control	59*	2	3	3	2	3	3	3	3
Control	62	3	3	3	3	3	3	3	3
Control	64	1	0	0	1	3	0	1	2
Control	66	3	3	3	3	3	2	3	3
Control	67	1	1	1	2	2	2	2	1
Control	72	3	3	3	3	3	3	3	3
Control	74	3	2	3	3	3	3	3	2
Control	75	3	3	3	3	3	2	3	3
Control	78	1	1	1	1	3	3	2	3
Control	79	3	3	3	3	3	3	3	3
Control	81	3	3	3	3	3	3	3	3
Control	87	1	0	1	2	2	2	2	2
Control	88	1	1	0	0	2	1	1	2
Control	89	3	2	2	2	3	1	2	2
Control	92	2	1	1	2	3	1	1	2
Control	94	1	1	1	1	3	2	2	3
Control	95	3	3	3	3	3	2	2	3
Control	99	3	3	2	3	3	3	2	3
Control	102	0	0	1	1	1	2	1	0
Control	104	1	1	1	1	3	0	1	2
Control	105	3	3	3	3	3	3	3	3
Control	106	3	3	2	3	3	3	3	3
Control	110*	3	3	3	3	3	3	3	3
Control	111	0	1	0	2	3	1	2	1
Test	58	0	0	0	0	0	0	0	0
Test	61	0	0	0	1	0	0	0	1
Test	63	0	0	0	0	0	0	0	0
Test	65	0	0	0	0	0	0	0	0
Test	68	0	0	0	1	0	1	0	1
Test	70	0	0	0	0	1	0	0	0
Test	73	0	0	0	0	0	1	0	0
Test	76	0	1	0	0	1	0	0	2
Test	77	0	0	0	0	0	0	0	0
Test	80	0	0	0	0	0	0	0	0
Test	82	0	0	0	0	0	0	0	0
Test	83	0	0	0	0	0	0	0	0
Test	86	0	1	0	0	0	0	0	0
Test	90	0	1	0	0	0	0	0	0
Test	91	0	0	0	1	0	0	0	0
Test	93	0	0	0	1	0	1	0	0
Test	96	0	0	0	0	0	0	0	0
Test	97	0	0	0	0	0	0	0	0
Test	98	1	0	0	0	0	0	0	0
Test	100	0	1	0	0	0	0	0	0
Test	101	0	0	0	0	0	0	0	0
Test	107	0	0	0	0	0	0	0	0
Test	108	0	1	0	0	0	0	0	0
Test	109	0	0	1	0	0	1	0	1
Test	112	0	0	0	0	1	0	0	0

NTX=non-treated, non-challenged control; MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry; N.A.=tissue was not available to be scored

Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)

Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)
*Died prior to scheduled necropsy; lymphoid depletion and PCV2 colonization were observed in each animal. This met the study criteria for

inclusion for analysis and association with PCV2 disease.

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Study Type	Efficacy					
Pertaining to	Porcine Circoviru	us Type 2a (PCV2a)				
Study Purpose	Demonstration of	f a 6-month duration o	of immunity agai	nst PCV2a		
Product		ular administration of				
Administration						
Study Animals	Cesarean-derived, colostrum deprived pigs vaccinated at 22 days old and randomly divided into 3 groups: Group 1 Control vaccine (n=31) Group 2 Test vaccine (n=30) Group 3 Non-treated, non-challenged controls (NTX) (n=7)					
Challenge		Porcine Circovirus, T		virus 6 months		
Description Interval observed		ation (Study Day 183)		1		
after challenge	twice weekly in t	or 21 days for clinical the post-challenge per nge and examined.	_	-		
Results	score is > 0 for or tracheobronchial A pig is consider immunohistocher tissue samples (to node, or iliac lym A pig was consider qPCR in the serue	lered positive for viren m during any of the sa	ric lymphoid tissue ric lymph node, oid colonization one or more of the lymph node, manual if PCV2 DN ampling points poin	is samples (tonsil, or iliac lymph node). if the che four lymphoid esenteric lymph A was detected by ost-challenge.		
	Group	nphoid Tissue and Vir Lymphoid Depletion*	Lymphoid Colonization (IHC)*	Viremia**		
	Control Vaccine	27/31 (87%)	31/31 (100%)	31/31 (100%)		
	Test Vaccine	4/30 (13%)	4/30 (13%)	3/30 (10%)		
		tive for lymphoid colonization a gative for viremia.		, ,		
USDA Approval Date	October 17, 2024	ļ				

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C	D' - ID	C	olonizatio	n (IHC)		De	epletion (H	(listology	
Group	Pig ID	Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
Control	1	1	0	2	0	0	0	1	0
Control	4	3	2	3	2	0	1	1	0
Control	6	2	0	1	0	1	0	0	0
Control	7	0	0	0	1	0	0	0	0
Control	9	1	1	1	0	0	0	0	0
Control	12	3	2	2	2	1	2	1	1
Control	18	2	2	2	2	0	1	1	1
Control	23	2	2	2	0	1	0	1	0
Control	24	3	0	1	0	0	0	0	0
Control	25	2	0	1	1	0	1	0	1
Control	26	2	0	1	2	0	1	1	0
Control	27	3	2	3	3	1	2	2	1
Control	32	3	1	3	2	0	1	1	1
Control	33	2	2	2	2	1	2	1	1
Control	34	1	0	2	3	0	1	0	0
Control	39	3	2	3	3	1	0	0	1
Control	40	1	0	1	0	0	1	0	0
Control	41	3	2	3	1	0	1	0	1
Control	42	3	2	3	2	0	1	2	1
Control	50	0	0	2	1	0	0	0	0
Control	51	3	2	3	2	0	1	0	1
Control	52	3	1	1	1	0	1	1	1
Control	53	3	3	3	3	1	1	1	1
Control	54	0	1	2	1	0	1	0	1
Control	56	3	3	1	3	0	0	0	1
Control	57	0	0	1	0	0	1	0	0
Control	61	0	2	2	1	0	1	1	0
Control	63	3	3	3	3	1	0	2	0
Control	65	3	2	3	2	0	1	1	0
Control	67	3	2	3	2	0	1	1	0
Control MLN=mesenteric lymph	70	3	3	3	3	1	1	2	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry. Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)

Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

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Lymphoid Colonization and Depletion Scores (Continued)

Cusum	Pig		Colonizat	ion (IHC)		Γ	epletion (Histology	·)
Group	ID	Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
Vaccine	2	0	0	0	0	0	0	0	0
Vaccine	3	0	0	0	0	0	0	0	0
Vaccine	5	0	0	0	0	0	0	0	0
Vaccine	8	0	0	0	0	0	0	0	0
Vaccine	10	0	0	0	0	0	0	0	0
Vaccine	11	0	0	0	0	0	0	0	0
Vaccine	14	0	0	0	0	0	0	0	0
Vaccine	15	0	0	1	0	0	0	0	0
Vaccine	16	0	0	0	0	0	0	0	0
Vaccine	17	0	0	0	0	0	0	0	0
Vaccine	19	0	0	1	0	0	0	0	0
Vaccine	21	0	0	0	0	0	0	0	0
Vaccine	28	0	0	0	0	0	0	1	0
Vaccine	29	0	0	0	0	0	0	0	0
Vaccine	30	0	0	0	0	0	0	0	0
Vaccine	35	0	0	0	0	0	0	0	0
Vaccine	36	0	0	0	0	0	0	0	0
Vaccine	37	0	0	1	0	0	0	0	0
Vaccine	38	0	0	0	0	0	0	0	0
Vaccine	43	0	0	0	0	0	0	0	0
Vaccine	45	0	0	1	0	0	0	0	0
Vaccine	46	0	0	0	0	0	1	0	0
Vaccine	49	0	0	0	0	0	0	0	0
Vaccine	55	0	0	0	0	0	1	0	0
Vaccine	59	0	0	0	0	0	0	0	0
Vaccine	60	0	0	0	0	0	1	0	0
Vaccine	62	0	0	0	0	0	0	0	0
Vaccine	66	0	0	0	0	0	0	0	0
Vaccine	68	0	0	0	0	0	0	0	0
Vaccine MIN-masontoria lymph	69	0	0	0	0	0	0	0	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry. Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)

Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

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Lymphoid Colonization and Depletion Scores of NTX pigs

Croun	Dia ID	I	Depletion (Histology)	Colonization (IHC)			
Group	Pig ID	Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
NTX	13	0	0	0	0	0	0	0	0
NTX	22	0	0	0	0	0	0	0	0
NTX	31	0	0	0	0	0	0	0	0
NTX	44	0	0	0	0	0	0	0	0
NTX	47	0	0	0	0	0	0	0	0
NTX	58	0	0	0	0	0	0	0	0
NTX	64	0	0	0	0	0	0	0	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry. Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)

Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

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Viremia (Serum qPCR results, genomic equivalent/mL)

Group	Pig	Day	Day	Day				Day 204
_	ID	182	187	190	Day 194	Day 197	Day 201	•
Control	1	•	•	16,860	37,257	32,301	8,486	4,486
Control	4		•	54,496	1,148,451	1,244,955	620,528	1,005,584
Control	6		•	•	138,184	41,489	124,453	63,055
Control	7	•	•	2,341	52,866	11,075	8,577	3,168
Control	9	•	٠	839	285,414	185,769	142,134	74,440
Control	12			11,037	629,912	734,863	127,889	328,944
Control	18			9,123	722,687	1,171,136	430,541	164,079
Control	23		3,325	408,604	338,738	147,284	148,287	202,820,320
Control	24		•	6,247	1,067,517	228,588	119,670	189,502
Control	25		•	3,361	561,454	49,037	34,100	30,491
Control	26	•		6,112	342,905	180,557	47,519	47,516
Control	27				355,521	756,692	519,658	297,325
Control	32				235,666	170,475	89,806	121,348
Control	33			97,564	1,947,082	853,233	221,151	119,573
Control	34			1,025	23,223	25,604	34,830	7,668
Control	39		•	263,863	4,652,635	1,681,979	1,495,014	1,350,485
Control	40			1,640	40,655	24,505	11,890	10,008
Control	41		•	1,141	108,329	220,431	164,179	705,567
Control	42		•	4,936	4,578,966	2,664,020	6,622,901	6,068,579
Control	50				30,584	25,429	21,619	14,243
Control	51			4,090	70,705	72,028	34,512	312,120
Control	52			6,669	1,026,841	815,278	445,715	93,104
Control	53			16,058	599,321	355,980	326,651	5,584,876
Control	54		•	•	8,479	5,632	6,713	20,817
Control	56		•	•	103,693	239,620	211,500	90,732
Control	57		•	•	54,167	2,561	4,035	4,516
Control	61		•	37,237	168,666	86,068	19,026	8,679
Control	63	•	•	•	510,077	390,666	579,980	255,764
Control	65			2,482	750,652	142,899	417,269	602,177
Control	67			5,201	989,662	957,984	325,278	190,509
Control	70			2,550	833,870	862,087	421,571	494,926

^{. =}result was negative; NA=no sample collected

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Viremia (Serum qPCR results, genomic equivalent/mL) Continued

Group	Pig	Day 182	Day 187	Day 190	Day 194	Day 197	Day 201	Day 204
Vaccine	2							
Vaccine	3							
Vaccine	5							
Vaccine	8							
Vaccine	10							
Vaccine	11				934,655			
Vaccine	14							
Vaccine	15							
Vaccine	16							
Vaccine	17		•					
Vaccine	19						827	
Vaccine	21							
Vaccine	28							
Vaccine	29							
Vaccine	30							218,523
Vaccine	35							
Vaccine	36							
Vaccine	37							•
Vaccine	38							
Vaccine	43							
Vaccine	45							•
Vaccine	46							•
Vaccine	49		•					•
Vaccine	55							•
Vaccine	59	•	•					•
Vaccine	60	•	•					•
Vaccine	62	•					•	•
Vaccine	66	•	•					•
Vaccine	68	•	•					•
Vaccine	69	•	•					•

^{. =}result was negative

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Viremia (Serum qPCR results, genomic equivalent/mL) Continued

Group	Pig ID	Day 182
NTX	13	Negative
NTX	22	Negative
NTX	31	Negative
NTX	44	Negative
NTX	47	Negative
NTX	58	Negative
NTX	64	Negative

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Study Type	Efficacy						
Pertaining to	Porcine Circovirus Type 2a (PCV2a)						
Study Purpose	Demonstration of efficacy against PCV2a						
Product	Single intramuscular administration of vaccine.						
Administration							
Study Animals	Cesarean-derived,	colostrum depriv	ed pigs vaccinated a	at 15 days old and			
	randomly divided i	nto 3 groups:					
	Group 1 Control va	` /					
	Group 2 Test vacci	` /	1 1 (NITX) (0)			
	Group 3 Non-treate	ed, non-challeng	ed controls (NTX) (r	1=8)			
Challenge	Challenged with Po	orcine Circovirus	s, Type 2a challenge	virus 4 weeks			
Description	following vaccinate						
Interval observed	_	•	ical signs. Blood san	-			
after challenge			period. Lymphoid tis	ssues were taken 21			
	days after challeng						
Results	1 0	1	nphoid depletion if the	1 0			
			four lymphoid tissue	* ` '			
	tracheobronchial ly	mpn node, mese	enteric lymph node, o	or iliac lymph node).			
	A min is considered	l magitiva famlym	ambaid aalamizatian i	if the			
			nphoid colonization if for one or more of the				
			chial lymph node, me				
	node, or iliac lymp	•	mai rympii node, me	esemene rympn			
	node, or mae tymp	n nous).					
	Summary of Lymp	hoid Tissue Effi	cacy Results				
	Group	Lymphoid	Lymphoid				
	Control Vaccine	Depletion* 24/28 (86%)	Colonization (IHC)* 24/28 (86%)				
	Test Vaccine	6/28 (21%)	6/28 (21%)				
	*All NTX pigs were negative for lymphoid depletion and colonization in all tissues.						
	Raw data on attached page						
USDA Approval	December 2, 2024						
Date	2, 2024						
	1						

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Cwann	Dia ID	C	olonizatio	on (IHC)		De	epletion (H	listology)	
Group	Pig ID	Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
Control	1	3	2	2	1	1	1	2	1
Control	5	2	0	0	1	1	0	1	1
Control	7	0	0	0	0	0	0	0	0
Control	10	1	0	0	0	1	0	0	0
Control	11	3	3	3	3	2	3	2	3
Control	12	2	1	3	1	1	1	2	0
Control	13	1	0	0	0	1	2	1	1
Control	19	3	2	3	2	2	2	2	2
Control	20	1	2	1	3	1	2	1	2
Control	22	0	0	0	0	0	0	0	0
Control	25	3	3	3	3	3	3	3	3
Control	27	3	3	3	3	2	3	3	3
Control	29	2	2	1	1	1	2	1	1
Control	30		•			•			
Control	31	0	0	0	0	0	0	0	0
Control	35	1	1	1	0	1	0	1	0
Control	36	2	2	3	3	2	2	2	2
Control	40	0	0	0	0	0	0	0	0
Control	41	3	3	3	3	2	3	2	3
Control	44	2	1	2	1	1	1	1	1
Control	46	2	1	1	2	1	1	1	1
Control	54	3	3	3	2	1	2	2	2
Control	55	2	1	1	0	1	2	2	1
Control	56	3	3	3	3	3	3	3	3
Control	57	3	3	3	3	3	3	3	3
Control	58	2	2	3	2	2	3	3	3
Control	62	3	3	3	3	2	3	2	3
Control	64	2	2	1	3	1	2	1	2
Control MI Names enteria lymph	66	1	1	1	2	1	2	1	1

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry. Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)

Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive) . = no sample available (pig removed from study prior to challenge and not included in statistical analysis)

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Lymphoid Colonization and Depletion Scores (Continued)

C	Pig		Colonizat	ion (IHC)		Γ	epletion ((Histology	·)
Group	ID	Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
Vaccine	3	0	0	0	0	0	0	0	0
Vaccine	4	0	0	0	0	0	0	0	0
Vaccine	6	2	1	1	1	1	1	1	1
Vaccine	8	3	3	3	3	1	2	2	3
Vaccine	9	0	0	0	0	0	0	0	0
Vaccine	14	1	3	1	3	1	2	1	2
Vaccine	15	0	0	0	0	0	0	0	0
Vaccine	16	0	0	0	0	0	0	0	0
Vaccine	18	0	0	0	0	0	0	0	0
Vaccine	23	1	1	1	1	1	0	0	1
Vaccine	24	0	0	0	0	0	0	0	0
Vaccine	26	0	0	0	0	0	0	0	0
Vaccine	28	0	0	0	0	0	0	0	0
Vaccine	33	0	0	0	0	0	0	0	0
Vaccine	34	0	0	0	0	0	0	0	0
Vaccine	37	0	0	0	0	0	0	0	0
Vaccine	38	0	0	0	0	0	0	0	0
Vaccine	39	1	1	1	0	1	1	1	1
Vaccine	43	0	0	0	0	0	0	0	0
Vaccine	45		•	•	•	•	•	•	•
Vaccine	48	0	0	0	0	0	0	0	0
Vaccine	49	0	0	0	0	0	0	0	0
Vaccine	50	0	0	0	0	0	0	0	0
Vaccine	52	0	0	0	0	0	0	0	0
Vaccine	53	1	0	0	0	1	1	1	1
Vaccine	59	0	0	0	0	0	0	0	0
Vaccine	60	0	0	0	0	0	0	0	0
Vaccine	63	0	0	0	0	0	0	0	0
Vaccine	65	0	0	0	0	0	0	0	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry. Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)

Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive) . = no sample available (pig removed from study prior to challenge and not included in statistical analysis)

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Lymphoid Colonization and Depletion Scores of NTX pigs

Cuoun	D:« ID		Colonization (IHC)			Depletion (Histology)			
Group	Pig ID	Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
NTX	2	0	0	0	0	0	0	0	0
NTX	17	0	0	0	0	0	0	0	0
NTX	21	0	0	0	0	0	0	0	0
NTX	32	0	0	0	0	0	0	0	0
NTX	42	0	0	0	0	0	0	0	0
NTX	47	0	0	0	0	0	0	0	0
NTX	51	0	0	0	0	0	0	0	0
NTX	61	0	0	0	0	0	0	0	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry.

Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)

Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

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Study Type	Efficacy						
Pertaining to	Porcine Circovirus Type 2d (PCV2d)						
Study Purpose	Demonstration of efficacy against PCV2d						
Product	Single intramuscular administration of vaccine.						
Administration							
Study Animals	Cesarean-derived, randomly divided in		ed pigs vaccinated at 1:	5 days old and			
	randonny divided i	into 3 groups.					
	Group 1 Control va	accine (n=27)					
	Group 2 Test vacci	` /					
	Group 3 Non-treate	ed, non-challenge	ed controls (NTX) (n=6	5)			
Challenge	_		, Type 2d challenge vir	rus 4 weeks			
Description	following vaccinat						
Interval observed		•	cal signs. Blood sample				
after challenge	days after challeng		period. Lymphoid tissu	es were taken 21			
Results			phoid depletion if the h	histopathology			
Results			our lymphoid tissue sar				
			nteric lymph node, or i	¥ ` .			
		,,		1) 11.p.1 11e 0.e).			
	A pig is considered	d positive for lym	phoid colonization if th	he			
			for one or more of the				
	tissue samples (ton	sil, tracheobronc	hial lymph node, mesei	nteric lymph			
	node, or iliac lymp	oh node).					
	Summary of Lymp						
	Group	Lymphoid Depletion*	Lymphoid Colonization (IHC)*				
	Control Vaccine	26/27 (96%)	27/27 (100%)				
	Test Vaccine	1/27 (4%)	3/27 (11%)				
	* All NTX pigs were negative for lymphoid depletion and colonization in all tissues.						
	Payy data an attached nage						
	Raw data on attached page						
USDA Approval	December 2, 2024						
Date							

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Cwaum	Dia ID	C	olonizatio	n (IHC)		De	pletion (H	(Iistology)
Group	Pig ID	Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
Control	5	3	1	2	2	1	1	2	0
Control	7	2	1	0	0	1	0	1	0
Control	8	1	0	1	0	0	0	0	0
Control	9	3	1	2	1	2	2	2	1
Control	11	2	0	1	0	1	0	0	1
Control	12	3	3	3	2	0	2	2	2
Control	13	3	1	3	1	0	2	2	2
Control	16	1	1	1	1	0	1	1	0
Control	20	2	2	3	2	3	2	3	2
Control	23	3	3	3	3	3	3	3	3
Control	24	3	3	3	3	3	3	3	3
Control	25	3	3	3	2	3	3	3	3
Control	29	3	3	3	3	3	3	3	3
Control	30	3	3	3	3	3	3	3	3
Control	31	1	1	0	0	1	3	1	3
Control	32	1	1	3	0	1	2	2	0
Control	35	3	1	3	0	3	1	3	1
Control	38	3	2	3	2	2	2	3	2
Control	39	3	2	3	3	3	3	3	3
Control	41	3	2	3	1	2	1	1	0
Control	42	3	3	3	3	3	3	3	3
Control	45	2	3	2	0	2	3	3	1
Control	52	2	2	2	2	0	0	1	0
Control	54	3	3	2	2	1	1	2	1
Control	56	3	3	3	0	0	0	1	0
Control	57	1	1	1	0	1	1	0	0
Control MLN=mesenteric lymph	59	3	3	3	3	3	3	3	2

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry. Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)

contain cells with PCV2 antigen staining (Positive)

Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

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Lymphoid Colonization and Depletion Scores (Continued)

Cusum	Pig		Colonizat	ion (IHC)		Γ	Depletion (Histology	·)
Group	ID	Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
Vaccine	1	0	0	0	0	0	0	0	0
Vaccine	2	0	0	0	0	0	0	0	0
Vaccine	3	1	0	0	0	0	0	0	0
Vaccine	6	0	0	0	0	0	0	0	0
Vaccine	10	1	0	0	0	0	0	0	0
Vaccine	15	0	0	0	0	0	0	0	0
Vaccine	17	0	0	0	0	0	0	0	0
Vaccine	18	0	0	0	0	0	0	0	0
Vaccine	19	0	0	0	0	0	0	0	0
Vaccine	21	0	0	0	0	0	1	0	0
Vaccine	22	0	0	0	0	0	0	0	0
Vaccine	26	0	0	0	0	0	0	0	0
Vaccine	27	0	0	0	0	0	0	0	0
Vaccine	33	1	0	0	0	0	0	0	0
Vaccine	34	0	0	0	0	0	0	0	0
Vaccine	36	0	0	0	0	0	0	0	0
Vaccine	37	0	0	0	0	0	0	0	0
Vaccine	40	0	0	0	0	0	0	0	0
Vaccine	43	0	0	0	0	0	0	0	0
Vaccine	44	0	0	0	0	0	0	0	0
Vaccine	47	0	0	0	0	0	0	0	0
Vaccine	48	0	0	0	0	0	0	0	0
Vaccine	50	0	0	0	0	0	0	0	0
Vaccine	51	0	0	0	0	0	0	0	0
Vaccine	53	0	0	0	0	0	0	0	0
Vaccine	58	0	0	0	0	0	0	0	0
Vaccine MLN-mesenteric lymph	60	0	0	0	0	0	0	0	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry.

Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)

contain cells with PCV2 antigen staining (Positive)

Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

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Lymphoid Colonization and Depletion Scores of NTX pigs

Cuoun	Dia ID		Colonization (IHC)				Depletion (Histology)			
Group	Pig ID	Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN	
NTX	4	0	0	0	0	0	0	0	0	
NTX	14	0	0	0	0	0	0	0	0	
NTX	28	0	0	0	0	0	0	0	0	
NTX	46	0	0	0	0	0	0	0	0	
NTX	49	0	0	0	0	0	0	0	0	
NTX	55	0	0	0	0	0	0	0	0	

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry. Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)

Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

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Study Type	Efficacy						
Pertaining to	Porcine Circovirus	Type 2d (PCV2	2d)				
Study Purpose	Demonstration of a 6-month duration of immunity against PCV2d						
Product	Single intramuscular administration of vaccine.						
Administration							
Study Animals	Cesarean-derived, randomly divided	-	ved pigs vaccinated	at 22 days old	and		
	Group 1 Control va Group 2 Test vacca Group 3 Non-treat	ine (n=16)	ged controls (NTX)	(n=4)			
Challenge	Challenged with P	orcine Circoviru	s, Type 2d challeng	ge virus 6 mont	hs		
Description	following vaccinat		, 11	,			
Interval observed			ical signs. Blood sa	imples were co	llected		
after challenge			period. Lymphoid	tissues were tal	ken 21		
Results	days after challeng		nphoid depletion if				
	score is > 0 for one tracheobronchial ly A pig is considered immunohistochem tissue samples (ton node, or iliac lymp A pig was consider qPCR in the serum Summary of Lymp	e or more of the ymph node, mes of positive for lyristry score is > 0 asil, tracheobron of node). The positive for your during any of the phoid Tissue and	four lymphoid tissuenteric lymph node, mphoid colonization of for one or more of chial lymph node, no viremia if PCV2 DN he sampling points provided the sampling points of the samplin	te samples (tons, or iliac lymph n if the The four lymph nesenteric lymph NA was detecte post-challenge.	sil, node).		
	Group	Lymphoid Depletion*	Lymphoid Colonization (IHC)*	Viremia**			
	Control Vaccine	11/19 (58%)	17/19 (90%)	19/19 (100%)	-		
	Test Vaccine 2/16 (13%) 1/16 (6%) 3/16 (19%)						
	*All NTX pigs were all neg ** All NTX pigs were negat Raw data on attach	ative for lymphoid color tive for viremia.	` /				
USDA Approval Date	January 22, 2025						

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Cusum	D:~ ID		Colonizat	ion (IHC)			Depletion	(Histology)	
Group	Pig ID	Tonsil	TBLN	MLN	ILN	Tonsil	TBLN	MLN	ILN
	10	0	0	0	0	0	0	0	0
NTX	15	0	0	0	0	0	0	0	0
NIA	26	0	0	0	0	0	0	0	0
	38	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0
	12	0	0	0	0	0	0	0	0
	14	0	0	1	0	0	0	2	0
	16	1	0	0	0	0	0	0	0
	17	1	1	1	0	0	0	0	0
	20	1	0	0	0	0	0	0	0
	21	0	0	1	0	0	0	0	0
	25	1	0	1	0	0	0	0	0
	28	1	0	1	0	1	0	1	0
Control	39	1	1	1	1	1	1	1	0
	41	2	2	1	2	1	1	1	1
	42	1	0	2	1	1	2	1	0
	48	2	0	2	1	1	0	1	1
	49	2	0	1	0	1	0	1	0
	51	0	0	1	0	0	0	1	0
	55	1	0	1	0	1	0	1	0
	60	1	1	1	0	1	0	1	0
	61	3	3	3	3	3	2	3	2
	63	1	0	1	0	1	0	1	0
	2	0	0	0	0	0	0	0	0
	11	0	0	0	0	0	0	0	0
	13	0	0	0	0	0	0	0	0
	18	0	0	1	0	0	0	1	0
	19	0	0	0	0	0	0	0	0
	24	0	0	0	0	0	0	0	0
	27	0	0	0	0	0	0	0	0
Vaccine	30	0	0	0	0	0	0	0	0
v accine	37	0	0	0	0	0	0	0	0
	45	0	0	0	0	0	0	0	0
	46	0	0	0	0	0	0	0	1
	47	0	0	0	0	0	0	0	0
	50	0	0	0	0	0	0	0	0
	52	0	0	0	0	0	0	0	0
	53	0	0	0	0	0	0	0	0
MI Names and	62	0	0	0	0	0	0	0	0

MLN=mesenteric lymph node; ILN=iliac lymph node; TBLN=tracheobronchial lymph node; IHC=immunohistochemistry.

Colonization: 0 = Zero lymphoid cells with PCV2 antigen staining (Negative); 1 = <10% of lymphoid follicles have cells with PCV2 antigen staining (Positive); 2 = 10% to 50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive); 3 = >50% of lymphoid follicles contain cells with PCV2 antigen staining (Positive)

Depletion: 0 = Normal, no lymphoid depletion present (Negative); 1 = Mild lymphoid depletion with loss of overall cellularity (Positive); 2 = Moderate lymphoid depletion (Positive); 3 = Severe lymphoid depletion with loss of lymphoid follicle structure (Positive)

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Viremia (Serum qPCR results, genomic equivalent/mL)

Group	Pig	Day	Day					Day 204
Group	ID	182	187	Day 190	Day 194	Day 196	Day 201	
	10		NA	NA	NA	NA	NA	NA
NTX	15		NA	NA	NA	NA	NA	NA
NIA	26		NA	NA	NA	NA	NA	NA
	38		NA	NA	NA	NA	NA	NA
	5			1,529	95,240	40,344	21,956	34,505
	12		1,307	27,249	232,297	631,454	149,735	156,599
	14			37,333	50,456	146,884	195,755	215,751
	16		1,196	66,229	48,606	103,644	23,864	138,316
	17			170,533	622,385	635,887	195,835	302,725
	20			10,244	3,282	29,807	47,973	134,098
	21			1,241	24,848	69,482	263,111	111,903
	25			5,915	962,615	1,320,554	1,799,449	1,190,948
	28	<u> </u>	1,659	101,429	118,925	1,261,381	833,417	764,336
Control	39			6,605	198,365	628,587	282,118	666,215
	41			65,722	552,301	3,977,072	313,501	309,902
	42			16,143	131,117	685,120	354,364	248,403
	48		1,874	82,368	166,504	2,380,309	198,594	196,875
	49					7,764	214,087	171,345
	51			59,684	37,519	370,207	125,898	204,382
	55			6,256	106,599	1,055,263	753,768	613,905
	60			26,468	47,613	330,085	287,613	351,368
	61		12,289	1,525,269	5,113,265	912,823,866	433,475,224	162,196,100
	63			25,413	60,784	67,130	174,386	284,736
	2							
	11							
	13							
	18							
	19							
	24			1,740		1,088		
	27							
Vaccina	30							•
Vaccine	37							•
	45							
	46						1,704	
	47				•			•
	50							
	52						782	928
	53						•	
	62				•		•	
14		NTA	1 .	11 4 . 1	•	·	·	·

^{. =}result was negative; NA=no sample collected

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Study Type	Safety						
Pertaining to	ALL						
Study Purpose	Demonstrate safety of product under typical use conditions						
Product Administration	Single intramuscular administrat	tion of vaccine					
Study Animals	750 pigs at 7 to 14 days of age						
Challenge Description	Not Applicable						
Interval observed after	Pigs were observed daily for 14	days following vaccination					
challenge							
Results	No injection site reactions were	observed.					
	1	elinical observations occurring at					
	least once during the 14 day stud						
	Clinical Observation	Number in 750 doses					
	Normal* 726						
	Lameness 9						
	Lethargy	5					
	Ataxia	3					
	Anorexia	1					
	Emesis	1					
	Central nervous system	1					
	disorder	1					
	Recumbency	1					
	Death**						
	*For "normal" a pig had to be observed to be without adverse events						
	for the entire observation period of the study.						
	**All deaths were investigated and none of the observed deaths were determined to have been likely due to vaccine administration.						
	determined to have been likely due	to vaccine administration.					
LICDA Ammunual Data	January 22, 2025						
USDA Approval Date	January 22, 2025						

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