



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	19T1.20
True Name	Porcine Reproductive & Respiratory Syndrome Vaccine, Reproductive & Respiratory Forms, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Fostera PRRS - No distributor specified Fostera PRRS - Zoetis (Thailand) Limited Fostera PRRS - Zoetis Japan Inc. Fostera PRRS - Zoetis Korea Fostera PRRS - Zoetis Mexico
Date of Compilation Summary	January 15, 2022

**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.**

<b>Study Type</b>	Efficacy																		
<b>Pertaining to</b>	Porcine Reproductive and Respiratory Syndrome Virus																		
<b>Study Purpose</b>	Demonstrate effectiveness against respiratory disease caused by Porcine Reproductive and Respiratory Syndrome Virus at 26 weeks post-vaccination																		
<b>Product Administration</b>	One dose administered intramuscularly																		
<b>Study Animals</b>	24 vaccinated and 24 control piglets, one day of age																		
<b>Challenge Description</b>	Porcine Reproductive and Respiratory Syndrome Virus administered 26 weeks post-vaccination																		
<b>Interval Observed After Challenge</b>	Animals were observed for 10 days after challenge. Lung tissue evaluated at 10 days after challenge.																		
<b>Results</b>	<p>Lung lesions (percent) was the efficacy variable.</p> <p>Summary of percent lung lesions pooling together all litters</p> <table border="1"> <thead> <tr> <th></th> <th>Minimum</th> <th>25<sup>th</sup> Percentile</th> <th>Median</th> <th>75<sup>th</sup> Percentile</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td>Control</td> <td>5</td> <td>10</td> <td>19</td> <td>23</td> <td>46</td> </tr> <tr> <td>Vaccinate</td> <td>0</td> <td>&lt;1</td> <td>1</td> <td>3</td> <td>10</td> </tr> </tbody> </table> <p>See individual data attached.</p>		Minimum	25 <sup>th</sup> Percentile	Median	75 <sup>th</sup> Percentile	Maximum	Control	5	10	19	23	46	Vaccinate	0	<1	1	3	10
	Minimum	25 <sup>th</sup> Percentile	Median	75 <sup>th</sup> Percentile	Maximum														
Control	5	10	19	23	46														
Vaccinate	0	<1	1	3	10														
<b>USDA Approval Date</b>	October 24, 2012																		

**Lung Lesions (Percent) by Treatment, Pen, and Animal**

**Controls**

Animal	Pen	Lung Lesions (%)	Affected
267	1	18.75	Yes
268		21.25	
142	3	7.75	Yes
143		5	
133	5	17.5	Yes
138		16.25	
108	8	8.75	Yes
109		4.5	
225	9	28.75	Yes
228		16.95	
134	12	25.5	Yes
136		27.75	
242	14	13.5	Yes
243		6.5	
251	15	9.55	Yes
252		35.5	
155	18	41	Yes
158		51	
130	19	18.75	Yes
244		5.25	
120	21	27.5	Yes
131		34.25	
104	23	7.75	Yes
111		11.7	

**Vaccinates**

Animal	Pen	Lung Lesions (%)	Affected
285	2	0.1	No
292		0	
286	4	2.7	Yes
290		1.65	
185	6	5.75	Yes
193		0.2	
190	7	0.5	No
192		0.2	
218	10	0.1	No
220		0.55	
278	11	11	Yes
281		0.7	
205	13	0.3	Yes
207		20	
297	16	0.3	Yes
298		2.5	
177	17	0	No
181		0	
196	20	0.45	No
204		0.9	
165	22	0.4	No
166		0.95	
197	24	5.75	Yes
199		0.1	

<b>Study Type</b>	Efficacy																		
<b>Pertaining to</b>	Porcine Reproductive and Respiratory Syndrome Virus																		
<b>Study Purpose</b>	Demonstrate effectiveness against respiratory disease caused by Porcine Reproductive and Respiratory Syndrome Virus																		
<b>Product Administration</b>	One dose administered intramuscularly																		
<b>Study Animals</b>	24 vaccinated and 24 control piglets, one day of age																		
<b>Challenge Description</b>	Porcine Reproductive and Respiratory Syndrome Virus administered 7 weeks post-vaccination																		
<b>Interval Observed After Challenge</b>	Animals were observed for 10 days after challenge																		
<b>Results</b>	<p>Lung lesions (percent) was the efficacy variable.</p> <p>Summary of percent lung lesions pooling together all litters</p> <table border="1"> <thead> <tr> <th><b>Group</b></th> <th><b>Min</b></th> <th><b>1<sup>st</sup> quartile</b></th> <th><b>Median</b></th> <th><b>3<sup>rd</sup> quartile</b></th> <th><b>Max</b></th> </tr> </thead> <tbody> <tr> <td>Control</td> <td>30</td> <td>37</td> <td>44</td> <td>51</td> <td>62</td> </tr> <tr> <td>Vaccinate</td> <td>&lt;1</td> <td>&lt;1</td> <td>&lt;1</td> <td>1</td> <td>5</td> </tr> </tbody> </table> <p>See individual data attached.</p>	<b>Group</b>	<b>Min</b>	<b>1<sup>st</sup> quartile</b>	<b>Median</b>	<b>3<sup>rd</sup> quartile</b>	<b>Max</b>	Control	30	37	44	51	62	Vaccinate	<1	<1	<1	1	5
<b>Group</b>	<b>Min</b>	<b>1<sup>st</sup> quartile</b>	<b>Median</b>	<b>3<sup>rd</sup> quartile</b>	<b>Max</b>														
Control	30	37	44	51	62														
Vaccinate	<1	<1	<1	1	5														
<b>USDA Approval Date</b>	October 24, 2012																		

**Lung Lesions (Percent) by Treatment, Pen, and Animal**

**Controls**

Animal	Pen	Lung Lesions (%)	Affected
145	1	50	Yes
146		26	
148	5	37.5	Yes
150		21.5	
102	8	42.5	Yes
107		22.5	
122	9	20.5	Yes
125		48	
235	12	40	Yes
241		48	
258	14	68.5	Yes
260		56	
265	15	39.5	Yes
269		61.5	
152	18	68.5	Yes
156		36	
121	19	61	Yes
123		40.5	
129	21	41.75	Yes
140		68	
253	23	60.5	Yes
257		18.5	

**Vaccinates**

Animal	Pen	Lung Lesions (%)	Affected
186	2	0.4	No
188		0.55	
162	6	1.35	No
163		0	
277	7	0.1	No
279		0	
221	10	0.2	No
223		0.7	
200	11	0	No
201		0.2	
210	13	0.2	No
213		1	
299	16	8.25	Yes
302		1.55	
273	17	0.1	No
275		0.1	
175	20	2.25	Yes
176		1.95	
291	22	5.7	Yes
294		0.1	
216	24	0.2	No
217		0.8	

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Porcine Reproductive and Respiratory Syndrome Virus
<b>Study Purpose</b>	Demonstrate effectiveness against reproductive disease caused by Porcine Reproductive and Respiratory Syndrome Virus
<b>Product Administration</b>	One dose administered intramuscularly 6-7 weeks prior to breeding
<b>Study Animals</b>	20 vaccinated and 19 control gilts
<b>Challenge Description</b>	Porcine Reproductive and Respiratory Syndrome Virus administered on the 82–86 day of gestation
<b>Interval Observed After Challenge</b>	Animals were observed until day 110 of gestation
<b>Results</b>	<p>Affected piglets per sow was the efficacy variable. Affected piglets (mummified, stillborn or low viability piglets) vs healthy (live) piglets were aggregated for each sow.</p> <p>Affected piglets:  Controls: 240/244 (98.4%)  Vaccinates: 117/251 (46.6%)</p> <p>See individual data attached.</p>
<b>USDA Approval Date</b>	February 13, 2014

**Summary of Piglets by Treatment and Sow**

**Controls**

Animal	Outcome	Number of Piglets	
		Healthy	Affected
621	Farrowed	0	12
625	Farrowed	0	16
626	Aborted	0	16
639	Farrowed	0	7
648	Farrowed	0	11
653	Aborted	0	14
656	Farrowed	0	13
664	Farrowed	0	11
666	Farrowed	0	11
673	Aborted	0	14
691	Farrowed	0	13
933	Pregnant	0	12
938	Pregnant	0	10
942	Farrowed	0	13
951	Aborted	0	9
953	Aborted	0	16
958	Farrowed	0	14
959	Farrowed	4	13
960	Farrowed	0	15

**Vaccinates**

Animal	Outcome	Number of Piglets	
		Healthy	Affected
608	Farrowed	7	5
619	Farrowed	4	2
620	Farrowed	10	0
630	Farrowed	3	5
649	Farrowed	7	6
672	Farrowed	11	2
679	Farrowed	7	3
680	Aborted	0	12
681	Aborted	0	11
683	Aborted	0	9
901	Farrowed	12	7
930	Farrowed	7	6
934	Farrowed	3	9
941	Farrowed	1	13
943	Farrowed	4	8
944	Farrowed	5	9
945	Farrowed	13	5
950	Farrowed	14	2
952	Farrowed	13	0
961	Farrowed	13	3

## Piglets by Treatment and Sow

### Controls

Animal	Farrowed	Piglets				Total
		Healthy (Live)	Stillborn	Mummies	Low Viability	
621	Yes	0	0	12	0	12
625	Yes	0	0	15	1	16
626	No	0	16	0	0	16
639	Yes	0	0	7	0	7
648	Yes	0	1	8	2	11
653	No	0	7	7	0	14
656	Yes	0	0	13	0	13
664	Yes	0	0	11	0	11
666	Yes	0	0	10	1	11
673	No	0	2	12	0	14
691	Yes	0	0	13	0	13
933	No	0	12	0	0	12
938	No	0	10	0	0	10
942	Yes	0	0	13	0	13
951	No	0	9	0	0	9
953	No	0	13	3	0	16
958	Yes	0	5	8	1	14
959	Yes	4	3	10	0	17
960	Yes	0	2	13	0	15

### Vaccinates

Animal	Farrowed	Piglets				Total
		Healthy (Live)	Stillborn	Mummies	Low Viability	
608	Yes	7	0	0	5	12
619	Yes	4	2	0	0	6
620	Yes	10	0	0	0	10
630	Yes	3	1	0	4	8
649	Yes	7	1	5	0	13
672	Yes	11	2	0	0	13
679	Yes	7	0	3	0	10
680	No	0	12	0	0	12
681	No	0	10	1	0	11
683	No	0	9	0	0	9
901	Yes	12	3	0	4	19
930	Yes	7	3	3	0	13
934	Yes	3	2	7	0	12
941	Yes	1	8	5	0	14
943	Yes	4	1	7	0	12
944	Yes	5	2	4	3	14
945	Yes	13	2	0	3	18
950	Yes	14	1	1	0	16
952	Yes	13	0	0	0	13
961	Yes	13	1	0	2	16

<b>Study Type</b>	Safety																																					
<b>Pertaining to</b>	ALL																																					
<b>Study Purpose</b>	Demonstrate safety under field conditions																																					
<b>Product Administration</b>	One dose administered intramuscularly																																					
<b>Study Animals</b>	884 vaccinated and 400 control piglets, 14 to 25 days of age, enrolled at four locations																																					
<b>Challenge Description</b>	Not applicable																																					
<b>Interval Observed After Challenge</b>	Animals were observed within two hours of vaccination and at least daily for 21 days after vaccination.																																					
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	*Reactions were 1-5 cm in diameter and resolved within 7-14 days.																																					
<b>USDA Approval Date</b>	January 09, 2012																																					

<b>Study Type</b>	Safety																																																
<b>Pertaining to</b>	ALL																																																
<b>Study Purpose</b>	Demonstrate safety under field conditions																																																
<b>Product Administration</b>	One dose administered intramuscularly																																																
<b>Study Animals</b>	200 vaccinated and 100 control piglets, one day of age																																																
<b>Challenge Description</b>	Not applicable																																																
<b>Interval Observed After Challenge</b>	Animals were observed within five hours of vaccination and at least daily for 21 days after vaccination.																																																
<b>Results</b>	<p><u>Clinical Signs*</u></p> <table border="1"> <thead> <tr> <th></th> <th>Controls</th> <th>Vaccinates</th> </tr> </thead> <tbody> <tr> <td>Normal</td> <td>71</td> <td>153</td> </tr> <tr> <td>Anorexia</td> <td>1</td> <td>0</td> </tr> <tr> <td>Body Condition</td> <td>0</td> <td>5</td> </tr> <tr> <td>Cough</td> <td>1</td> <td>0</td> </tr> <tr> <td>Diarrhea</td> <td>0</td> <td>6</td> </tr> <tr> <td>Found Dead</td> <td>1</td> <td>5</td> </tr> <tr> <td>Injection Site Reaction</td> <td>1</td> <td>0</td> </tr> <tr> <td>Scour</td> <td>8</td> <td>14</td> </tr> <tr> <td>Scrotal Disorder</td> <td>5</td> <td>5</td> </tr> <tr> <td>Sore</td> <td>4</td> <td>12</td> </tr> <tr> <td>Unrelated Death</td> <td>3</td> <td>3</td> </tr> <tr> <td>Unthrifty</td> <td>2</td> <td>12</td> </tr> </tbody> </table> <p>*Pigs observed as abnormal may exhibit more than one clinical sign.</p> <p><u>Injection Site Reactions*</u></p> <table border="1"> <thead> <tr> <th></th> <th>Yes</th> <th>No</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>1</td> <td>96</td> </tr> <tr> <td>Vaccinates</td> <td>0</td> <td>198</td> </tr> </tbody> </table> <p>*Injection sites were observed on days 1 and 8 after vaccination; any injection site reaction documented on day 8 was reviewed on day 13 and resolved.</p>		Controls	Vaccinates	Normal	71	153	Anorexia	1	0	Body Condition	0	5	Cough	1	0	Diarrhea	0	6	Found Dead	1	5	Injection Site Reaction	1	0	Scour	8	14	Scrotal Disorder	5	5	Sore	4	12	Unrelated Death	3	3	Unthrifty	2	12		Yes	No	Controls	1	96	Vaccinates	0	198
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<b>USDA Approval Date</b>	November 21, 2013																																																

<b>Study Type</b>	Safety																																																																																				
<b>Pertaining to</b>	ALL																																																																																				
<b>Study Purpose</b>	Demonstrate safety under field conditions in pre-breeding and pregnant animals																																																																																				
<b>Product Administration</b>	One dose administered intramuscularly																																																																																				
<b>Study Animals</b>	799 vaccinated and 400 control gilts, pre-breeding and in all stages of gestation, enrolled at two locations																																																																																				
<b>Challenge Description</b>	Not applicable																																																																																				
<b>Interval Observed After Challenge</b>	Animals were observed within six hours of vaccination and at least daily for 21 days after vaccination. Animals were followed through 7 days post-farrowing, and litters observed daily for at least 7 days.																																																																																				
<b>Results</b>	<p><u>Clinical Observations*</u></p> <table border="1"> <thead> <tr> <th></th> <th></th> <th>Normal</th> <th>Abortion</th> <th>Anorexia</th> <th>Death</th> <th>Diarrhea</th> <th>Dyspnea</th> <th>Lameness</th> <th>Stillbirth</th> </tr> </thead> <tbody> <tr> <td rowspan="4">Controls</td> <td>Pre-breeding</td> <td>98</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>1</td> <td>1</td> <td>0</td> </tr> <tr> <td>1-40 days</td> <td>97</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>3</td> <td>0</td> </tr> <tr> <td>41-75 days</td> <td>95</td> <td>1</td> <td>0</td> <td>1</td> <td>0</td> <td>0</td> <td>3</td> <td>0</td> </tr> <tr> <td>76-110 days</td> <td>98</td> <td>1</td> <td>0</td> <td>1</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> </tr> <tr> <td rowspan="4">Vaccinates</td> <td>Pre-breeding</td> <td>192</td> <td>0</td> <td>2</td> <td>1</td> <td>1</td> <td>0</td> <td>6</td> <td>0</td> </tr> <tr> <td>1-40 days</td> <td>193</td> <td>0</td> <td>0</td> <td>2</td> <td>0</td> <td>0</td> <td>6</td> <td>0</td> </tr> <tr> <td>41-75 days</td> <td>195</td> <td>2</td> <td>0</td> <td>2</td> <td>0</td> <td>0</td> <td>1</td> <td>0</td> </tr> <tr> <td>76-110 days</td> <td>198</td> <td>0</td> <td>0</td> <td>1</td> <td>0</td> <td>0</td> <td>0</td> <td>1</td> </tr> </tbody> </table> <p>*Three control and five vaccinate sows were removed from the study due to causes unrelated to vaccination.</p>			Normal	Abortion	Anorexia	Death	Diarrhea	Dyspnea	Lameness	Stillbirth	Controls	Pre-breeding	98	0	0	0	0	1	1	0	1-40 days	97	0	0	0	0	0	3	0	41-75 days	95	1	0	1	0	0	3	0	76-110 days	98	1	0	1	0	0	0	0	Vaccinates	Pre-breeding	192	0	2	1	1	0	6	0	1-40 days	193	0	0	2	0	0	6	0	41-75 days	195	2	0	2	0	0	1	0	76-110 days	198	0	0	1	0	0	0	1
		Normal	Abortion	Anorexia	Death	Diarrhea	Dyspnea	Lameness	Stillbirth																																																																												
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		Day 1	Day 7	Day 14	Day 21
Controls	Pre-breeding	1	1	1	1*
	1-40 days	2	1	1	0
	41-75 days	0	2	0	0
	76-110 days	1	1	1	0
Vaccinates	Pre-breeding	3	1	0	0
	1-40 days	2	0	0	0
	41-75 days	7	5	3	0
	76-110 days	5	3	1	0

Injection Site Reactions

\*Resolved by Day 29

Litter Outcome\*

		Farrowed	Aborted	Not Pregnant	Pregnant Removed	Not Bred	Culled, Died, or Unknown
Controls	Pre-breeding	82	2	6	1	9	0
	1-40 days	99	0	0	0	1	0
	41-75 days	94	1	2	0	0	2
	76-110 days	94	1	2	1	0	0
Vaccinates	Pre-breeding	168	6	9	2	14	1
	1-40 days	192	2	3	1	0	2
	41-75 days	190	3	1	1	0	4
	76-110 days	192	0	3	1	0	0

\*Three control and five vaccinate sows were removed from the study due to causes unrelated to vaccination.

		<u>Litter Details</u>					
		Piglets Born Live*	Normal Piglets	Low Viability Piglets	Piglets Born Dead**	Mummified Piglets	Stillborn Piglets
Controls	Pre-breeding	1073	999	74	95	33	62
	1-40 days	1230	1158	72	100	36	64
	41-75 days	1201	1105	96	65	21	44
	76-110 days	1158	1028	130	84	22	62
Vaccinates	Pre-breeding	2157	2032	134	181	64	117
	1-40 days	2276	2118	158	196	63	133
	41-75 days	2410	2289	132	169	63	106
	76-110 days	2285	2045	240	147	62	85
*Normal and Low Viability Piglets							
**Mummified and Stillborn Piglets							
<b>USDA Approval Date</b>		August 29, 2014					