



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Epitopix, LLC
USDA Vet Biologics Establishment Number	365
Product Code	2811.00
True Name	Salmonella Newport Bacterial Extract
Tradenname(s) / Distributor or Subsidiary (if different from manufacturer)	SRP Salmonella - No distributor specified SRP Salmonella - Not Listed Salmonella Vetovax SRP - No distributor specified
Date of Compilation Summary	March 12, 2020

**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>	<i>Salmonella enterica</i> Newport																		
<b>Study Purpose</b>	Demonstration of efficacy against <i>Salmonella enterica</i> Newport																		
<b>Product Administration</b>	Two doses administered at 3-week intervals by subcutaneous route.																		
<b>Study Animals</b>	A total of 40 calves between 4 and 5 months of age were randomly assigned to two treatment groups of 20 calves per group designated as Vaccinates and Placebo Controls.																		
<b>Challenge Description</b>	All calves were challenged with <i>Salmonella enterica</i> Newport fourteen days following second vaccination.																		
<b>Interval observed after challenge</b>	Calves were monitored twice daily for clinical signs following challenge. Fecal samples were collected twice a day for fourteen days following challenge.																		
<b>Results</b>	<p>Diarrhea present <math>\geq 1</math> episode and classified as either mild, moderate or severe postchallenge:</p> <ul style="list-style-type: none"> <li>○ Vaccinates: 12/20</li> <li>○ Placebo Controls: 17 /20</li> </ul> <p>Dehydration present <math>\geq 1</math> episode postchallenge:</p> <ul style="list-style-type: none"> <li>○ Vaccinates: 6/20</li> <li>○ Placebo Controls: 18/20</li> </ul> <p>Depression present <math>\geq 1</math> episode and classified as mild or moderate postchallenge:</p> <ul style="list-style-type: none"> <li>○ Vaccinates: 15 /20</li> <li>○ Placebo Controls: 20/20</li> </ul> <p>Fecal Shedding: Summary of maximum quantitative enumeration of the challenge organism (CFU per gram of fecal material):</p> <table border="1"> <thead> <tr> <th></th> <th>Min</th> <th>Q1</th> <th>Med</th> <th>Q3</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>10</td> <td>40</td> <td>250</td> <td>600</td> <td>4,800,000</td> </tr> <tr> <td>Placebo Controls</td> <td>2150</td> <td>108,650</td> <td>10,700,000</td> <td>32,700,000</td> <td>250,000,000</td> </tr> </tbody> </table>		Min	Q1	Med	Q3	Max	Vaccinates	10	40	250	600	4,800,000	Placebo Controls	2150	108,650	10,700,000	32,700,000	250,000,000
	Min	Q1	Med	Q3	Max														
Vaccinates	10	40	250	600	4,800,000														
Placebo Controls	2150	108,650	10,700,000	32,700,000	250,000,000														
<b>USDA Approval Date</b>	10/10/2007																		

## Diarrhea

### Placebo-Treated Calves (Days Post Challenge)

	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	
Animal #:	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9	10	10	11	11	12	12	13	13	14	14	
102	N	N	N	N	N	N	N	N	Md	Md	Md	Md	Md	Mt	Md	N	N	N	N	N	N	N	Md	Md	Md	N	N	N	N
105	N	N	N	N	N	N	N	N	N	N	N	N	N	Mt	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
107	N	N	N	N	N	Md	Mt	Md	S	S	S	Mt	Md	Mt	Md	Md	N	N	N	N	N	N	N	N	N	N	N	N	Md
108	Md	N	N	N	N	Md	Mt	S	S	Mt	S	Mt	Md	Mt	Mt	Mt	N	Md	N	N	N	N	N	N	N	N	N	N	Md
109	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
112	N	N	N	N	N	Mt	Mt	S	N	N	Mt	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
113	Md	N	N	N	Mt	N	Md	Md	N	Md	Md	N	Mt	Mt	Mt	N	Mt	Md	Md	Md	N	N	N	Md	Md	N	N	N	N
117	N	N	N	N	N	N	Mt	Mt	Mt	Mt	Md	N	Mt	Mt	Md	Mt	Mt	Md	Md	N	N	N	Md	N	N	N	N	N	N
118	N	N	N	N	N	N	N	N	N	Md	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Md	N	N
121	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
125	N	N	N	N	N	N	N	N	N	Md	N	N	N	N	N	Md	Md	Mt	N	N	N	Md	N	N	N	N	N	N	Md
133	N	N	N	N	N	N	Mt	Mt	N	N	N	N	N	Md	Md	N	N	N	Md	N	N	N	N	N	N	N	N	N	N
134	Md	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
136	N	N	N	Mt	Mt	Mt	S	S	Mt	S	S	Mt	S	S	N	N	N	N	N	N	N	N	N	N	N	N	Md	N	N
138	N	N	N	N	N	N	N	S	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
139	Md	N	N	Mt	Md	Md	N	Md	N	Md	Md	N	Md	Mt	Md	N	N	N	N	N	N	N	N	N	N	N	N	N	N
140	N	N	N	N	Mt	Mt	S	S	Mt	Mt	N	N	N	Md	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
141	N	N	N	N	Md	Mt	Mt	Mt	Mt	Mt	S	S	S	S	S	S	Md	Md	N	N	N	N	N	N	N	N	N	N	N
142	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
144	N	N	N	N	Mt	Md	N	Md	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Note: (N = Normal, Md = Mild, Mt = Moderate, S = Severe, NS = No Sample, M = Mucous)

### Vaccinated Calves (Days Post Challenge)

	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Animal #:	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9	10	10	11	11	12	12	13	13	14	14		
103	N	N	N	N	Mt	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
104	Md	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
106	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
110	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
111	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
114	Md	Md	N	N	N	N	NS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Md	N	N	N	N	N	N	
116	Md	N	N	N	N	N	N	N	N	N	Md	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
119	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Md	N	N	Md	N	N	Md	N	N	Md	N	N	N	N	N	
120	N	N	N	N	N	N	N	N	N	N	Md	N	N	N	Md	Md	N	N	N	Md	N	Md	N	Md	N	Md	N	Mt	Md	N
122	Md	N	Md	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
124	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Md	N	N	Md	N	N	Md	N	N	N	N	N	
126	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
127	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
128	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
129	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
130	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Md	N	N	N	N	N	N	N	N	N	N	N	N	N	
132	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	M	N	N	N	N	N	N	N
135	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
137	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	M	N	M	Md	N	N	N	N
143	N	N	N	N	N	N	N	N	N	N	Md	N	N	N	N	N	Md	N	N	N	N	N	N	Md	N	Md	N	Md	N	Md

Note: (N = Normal, Md = Mild, Mt = Moderate, S = Severe, NS = No Sample, M = Mucous)

## Dehydration

### Placebo-Treated Calves (Days Post Challenge)

	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Animal #:	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9	10	10	11	11	12	12	13	13	14	14
102	N	N	N	D	N	N	N	D	D	D	D	D	D	N	D	D	N	D	D	D	D	D	N	D	N	D	D	D
105	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
107	N	N	N	N	N	N	N	D	N	D	D	D	D	D	N	D	D	D	N	D	D	D	N	N	N	D	N	N
108	N	N	N	N	N	D	D	N	D	D	D	D	N	D	D	D	D	D	N	D	N	N	N	N	D	N	D	N
109	N	N	N	N	N	D	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	D	N	N	N	N	N	N
112	N	N	N	N	N	D	N	N	N	D	D	D	D	D	D	D	D	D	D	D	N	D	N	D	D	D	N	D
113	N	N	N	N	N	N	N	N	N	D	N	D	N	N	N	D	D	D	N	N	N	N	N	N	D	D	N	N
117	N	N	N	N	N	N	N	N	N	D	D	D	D	D	D	D	D	D	D	N	N	D	N	N	D	N	N	N
118	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
121	D	D	D	D	D	D	N	D	D	D	D	D	D	D	N	D	N	D	N	D	D	N	N	N	D	D	D	D
125	N	N	N	N	N	D	N	N	N	D	D	D	D	D	N	N	D	D	D	N	D	N	D	N	N	N	D	N
133	N	D	D	D	D	D	D	D	D	D	D	D	N	N	N	N	N	D	D	N	D	N	D	N	D	D	D	D
134	N	N	N	N	N	D	N	N	D	N	D	D	D	N	N	N	N	D	N	N	N	N	D	N	N	N	N	N
136	N	N	N	N	N	N	D	D	D	D	D	D	D	N	D	N	N	N	N	N	N	N	D	N	D	N	N	N
138	N	N	N	N	N	N	N	N	N	D	D	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
139	N	N	N	N	N	N	N	N	N	N	N	N	N	N	D	N	N	N	N	N	N	N	N	D	N	D	N	N
140	N	N	N	N	N	N	N	D	D	D	D	D	N	D	D	D	N	D	N	D	D	N	D	N	D	N	D	D
141	N	N	N	N	N	N	N	N	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
142	N	N	N	N	D	N	N	N	N	D	N	N	N	N	N	N	N	N	N	D	N	N	N	N	N	D	N	N
144	N	N	N	N	N	D	N	D	N	N	D	N	N	D	D	N	D	D	N	D	D	N	D	D	D	N	D	N

Note: (N = Normal, D = Dehydrated)

### Vaccinated Calves (Days Post Challenge)

	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Animal #:	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9	10	10	11	11	12	12	13	13	14	14
103	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
104	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
106	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
110	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
111	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
114	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
116	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
119	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
120	N	N	N	D	D	N	N	N	N	N	D	N	N	N	N	N	N	N	D	N	N	N	N	N	N	D	N	N
122	N	N	N	N	N	N	N	N	N	N	N	N	N	N	D	N	N	N	N	N	N	N	N	N	N	N	D	N
124	N	N	D	N	D	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
126	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
127	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
128	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
129	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
130	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
132	N	N	N	N	N	N	N	N	N	N	D	N	N	N	N	N	N	N	N	N	N	N	D	N	D	N	N	D
135	N	N	N	N	N	N	N	N	N	N	N	N	N	N	D	N	N	N	N	N	N	N	N	N	N	N	N	N
137	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
143	N	N	N	D	N	N	N	N	N	N	N	N	N	N	D	N	N	N	N	N	N	N	N	N	N	N	N	N

Note: (N = Normal, D = Dehydrated)

## Depression

### Placebo-Treated Calves (Days Post Challenge)

Animal #:	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
102	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
105	A	A	A	A	A	A	A	A	Md	A	A	A	Md	A	A	A	A	A	A	A	A	Md	Md	A	A	A	A	A
107	A	A	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
108	A	A	A	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
109	A	A	A	A	Md	Md	A	A	A	Md	Md	A	A	A	A	Md	Md	A	A	A	Md	A	Md	A	A	Md	Md	Md
112	A	A	A	A	A	Md	A	Md	Md	Md	A	Md	Md	Md	A	Md	Md	Md	Md	Md	Md	Md	A	Md	A	Md	Md	Md
113	A	A	A	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
117	A	A	A	Md	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
118	A	A	A	Md	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
121	Mt	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
125	Md	A	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
133	Md	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
134	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
136	A	A	Md	Md	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
138	A	A	A	A	A	Md	A	Md	Md	Md	A	Md	A	Md	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
139	A	Md	A	A	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
140	A	A	A	Md	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
141	Md	A	A	A	Md	Md	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
142	A	A	A	A	Md	A	Md	A	Md	Md	A	Md	A	A	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md
144	Md	A	A	Md	A	Md	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md

Note: (A = Alert, Md = Mild, Mt = Moderate)

### Vaccinated Calves (Days Post Challenge)

Animal #:	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
103	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
104	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
106	A	A	A	A	A	Md	Md	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
110	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
111	A	A	A	A	Md	Md	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
114	A	A	A	Md	A	A	A	Md	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
116	A	A	A	Md	A	A	Md	A	A	A	A	A	A	A	A	A	A	A	A	A	A	Md	A	A	A	A	A	A
119	A	A	A	A	A	A	Md	Md	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
120	A	A	A	Md	Md	Md	Md	A	Md	Md	Md	A	A	Md	A	A	Md	A	A	Md	A	Md	A	A	A	A	A	A
122	A	A	A	Md	Md	A	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	Md	A	A	A	A	A	A	A
124	A	Md	Md	Md	Md	A	Md	Md	Md	Md	Md	A	Md	A	A	A	A	A	Md	A	A	A	A	Md	A	A	Md	A
126	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
127	A	A	A	Md	A	A	Md	A	Md	A	A	A	A	A	A	A	A	A	A	A	A	Md	A	A	A	A	A	A
128	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
129	A	A	Md	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
130	A	A	Md	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
132	Md	A	A	Md	A	A	Md	A	A	Md	Md	Md	A	Md	A	Md	A	A	Md	A	Md	A	Md	A	Md	A	Md	Md
135	Md	Md	Md	Md	A	A	A	A	A	A	A	A	A	Md	A	A	A	A	A	Md	A	A	A	A	A	A	A	A
137	Md	A	A	A	Md	A	Md	Md	A	A	Md	Md	A	A	Md	A	A	A	A	A	A	A	A	A	A	A	A	A
143	Md	A	A	Md	Md	Md	A	A	Md	Md	A	A	A	A	Md	A	A	A	A	A	A	A	A	A	A	A	A	A

Note: (A = Alert, Md = Mild, Mt = Moderate)

**Fecal Shedding– *Salmonella* Newport CFU/gram of feces log transformed**

**Placebo-Treated Calves (Days Post Challenge)**

Animal #:	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
102	0.0	2.5	3.8	5.7	5.8	5.5	6.3	6.6	7.3	7.5	7.5	7.3	6.9	7.0	6.7	7.3	6.6	7.2	6.8	6.5	6.4	6.8	6.5	5.8	5.5	5.3	4.1	3.0
105	0.0	1.0	0.0	0.0	0.0	1.0	1.0	1.0	1.0	1.7	1.0	3.5	0.0	0.0	1.0	1.0	0.0	3.5	1.0	1.7	1.0	1.0	1.0	1.0	1.0	1.0	1.7	1.0
107	1.0	2.0	2.0	5.9	5.5	5.4	4.9	5.9	6.6	6.7	7.1	7.0	6.7	7.1	6.7	6.4	5.1	5.2	5.4	4.9	4.8	4.4	4.8	4.6	5.0	4.6	4.9	4.7
108	2.9	3.8	3.8	3.1	5.0	5.9	6.5	6.8	7.0	7.1	7.3	6.5	6.8	6.9	6.0	6.3	5.8	5.5	5.2	5.3	5.5	5.0	5.1	4.8	4.0	4.2	5.2	4.1
109	0.0	1.0	1.0	1.0	2.4	1.0	0.0	3.6	2.2	3.9	3.5	3.7	2.8	1.0	1.0	3.2	1.0	1.7	1.0	3.3	1.0	1.0	0.0	1.0	2.3	3.0	1.0	1.0
112	0.0	1.0	7.4	7.1	6.2	5.2	6.0	7.0	7.1	7.1	6.6	6.8	5.9	6.1	5.8	7.1	8.0	7.3	5.2	7.1	6.9	6.7	7.4	7.3	7.3	7.1	7.0	6.8
113	1.0	1.0	5.7	6.0	4.8	4.7	5.0	5.6	7.9	7.9	6.3	7.0	5.9	6.1	5.9	6.6	5.7	5.5	5.4	5.4	5.9	6.2	6.4	6.4	6.6	6.7	6.5	6.4
117	1.0	1.0	1.0	4.9	7.3	7.2	7.4	7.5	7.5	6.9	6.7	6.7	6.7	7.0	6.7	6.3	5.7	5.8	5.7	7.1	6.0	5.7	6.3	6.6	6.7	6.6	6.5	6.5
118	0.0	1.0	1.0	3.4	3.3	3.5	4.0	4.8	4.9	5.0	5.1	5.3	5.5	5.7	5.4	5.7	5.0	4.5	4.2	3.9	6.0	6.1	5.5	4.9	5.2	4.3	5.2	4.3
121	0.0	0.0	1.0	1.0	1.0	1.0	1.0	2.4	0.0	1.0	1.0	3.1	1.0	1.0	2.0	1.0	1.0	0.0	5.1	0.0	1.0	1.0	1.0	1.7	1.7	1.0	2.5	1.0
125	0.0	0.0	1.0	0.0	1.0	1.0	1.0	1.0	1.0	1.7	1.0	1.0	1.0	1.0	1.0	1.0	1.7	4.3	2.0	1.0	1.0	1.0	0.0	1.0	1.0	1.0	1.0	1.0
133	0.0	1.0	5.7	5.1	5.8	6.0	6.9	7.0	7.0	8.0	7.3	5.0	7.0	6.6	6.7	5.2	5.2	7.1	7.2	6.8	6.5	5.8	6.4	5.2	5.2	5.7	5.2	5.2
134	2.0	1.7	1.0	1.0	1.7	1.7	2.0	2.3	2.0	1.7	1.0	3.7	1.0	2.0	1.0	1.0	1.0	0.0	1.0	0.0	1.0	1.0	0.0	1.0	1.0	0.0	1.0	1.0
136	0.0	0.0	6.5	6.2	6.6	6.4	6.1	6.2	6.4	6.1	5.7	6.0	6.2	6.1	6.3	6.8	5.8	6.3	6.8	6.9	6.8	6.6	6.7	6.9	6.7	6.6	6.5	5.9
138	0.0	1.0	0.0	1.0	1.0	2.0	1.7	1.7	3.2	3.1	2.5	1.7	1.0	1.0	1.0	1.0	1.7	1.0	1.7	1.0	3.3	1.0	1.0	1.7	1.0	0.0	1.0	1.0
139	0.0	1.0	5.8	6.0	5.4	5.2	5.3	5.7	5.5	6.1	7.1	7.2	6.7	6.1	5.2	4.7	4.6	4.5	3.2	3.0	3.4	2.4	2.0	2.0	1.0	2.0	1.0	1.7
140	0.0	1.0	5.5	5.8	6.0	6.4	6.0	6.7	6.3	5.9	6.2	6.2	6.5	6.4	5.9	5.9	5.8	4.5	3.0	2.0	1.0	2.5	1.7	1.0	1.7	1.0	1.0	1.0
141	1.0	0.0	4.9	6.5	8.1	8.4	8.2	8.4	7.7	7.3	7.8	8.0	7.2	8.0	7.1	7.6	5.7	5.6	6.7	6.9	6.9	6.9	6.8	7.0	6.4	6.8	6.8	6.5
142	1.0	0.0	0.0	1.7	4.0	3.5	5.5	1.0	4.0	2.8	1.0	1.0	1.0	4.9	2.8	1.0	1.0	2.4	1.7	1.7	1.0	0.0	0.0	1.7	0.0	1.0	2.3	1.0
144	0.0	0.0	1.0	1.0	6.3	6.5	6.7	5.6	5.2	5.1	5.0	5.0	7.5	5.4	5.5	5.4	7.1	7.3	6.9	6.8	7.0	6.9	6.7	6.2	6.8	6.8	6.5	7.1

**Fecal Shedding– *Salmonella* Newport CFU/gram of feces log transformed**

**Vaccinated Calves (Days Post Challenge)**

Animal#:	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
103	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0	1.0	0.0	0.0	0.0	1.0	0.0	1.7	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0
104	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
106	0.0	0.0	0.0	1.0	0.0	1.0	0.0	2.2	2.9	1.0	1.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
110	1.0	1.0	1.0	1.0	0.0	1.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	1.0	1.0	1.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
111	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.4	1.0	0.0	1.0	1.0	1.7	1.0	0.0	0.0
114	0.0	0.0	1.7	3.7	5.6	5.6	2.8	6.7	5.9	5.0	2.3	1.0	1.0	1.0	1.0	1.0	1.0	1.7	2.0	1.0	0.0	1.0	1.0	1.7	0.0	1.0	0.0	
116	0.0	0.0	1.0	0.0	1.0	0.0	0.0	1.0	1.0	1.0	0.0	1.0	2.9	2.2	4.8	4.5	3.1	2.2	3.9	2.8	3.5	2.9	3.0	2.5	4.4	3.8	4.5	4.4
119	0.0	0.0	1.0	1.7	1.0	1.0	1.0	1.0	2.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	0.0	1.0	1.0	1.0
120	0.0	1.0	0.0	0.0	1.0	1.0	1.0	1.0	1.0	1.7	0.0	1.0	0.0	0.0	1.0	1.0	1.0	1.0	0.0	0.0	1.0	0.0	1.0	0.0	1.0	0.0	1.7	1.0
122	0.0	0.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	0.0	1.0	1.0	0.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	0.0	0.0
124	0.0	0.0	1.0	1.0	1.0	1.0	1.0	1.0	0.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	0.0	1.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
126	0.0	0.0	0.0	1.0	1.7	1.7	1.0	1.0	1.7	1.0	1.0	0.0	1.0	1.0	1.0	1.0	1.0	0.0	1.0	1.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0
127	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	2.7	1.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	1.0	1.0	0.0	1.0	0.0	1.0
128	0.0	0.0	0.0	1.0	1.0	0.0	0.0	0.0	2.6	1.0	1.0	1.7	0.0	0.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	1.7	0.0	1.0	1.0	0.0	0.0	0.0
129	0.0	0.0	0.0	1.0	1.0	1.0	1.0	1.7	1.0	1.0	1.0	0.0	0.0	0.0	2.5	1.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0
130	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	1.7	1.0	0.0	1.7	1.0	1.0	0.0	1.7	1.0	2.6	1.0	0.0	0.0	0.0	1.0	1.0	0.0	2.0	0.0	0.0
132	0.0	2.4	2.3	2.0	1.0	1.0	0.0	1.0	1.0	0.0	1.0	0.0	2.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0
135	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	1.0	0.0	1.0	0.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0	1.0
137	0.0	0.0	0.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	1.0	0.0
143	1.0	2.0	1.0	1.0	1.0	0.0	1.0	4.1	5.3	5.8	4.4	5.9	5.4	6.4	4.0	2.9	2.8	1.0	2.3	3.1	2.0	4.6	4.0	4.7	4.3	5.4	5.0	6.0

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety of the product under field conditions.
<b>Product Administration</b>	Two doses administered 3-4 weeks apart by subcutaneous route.
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	09/30/2004