



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Hygieia Biological Laboratories
USDA Vet Biologics Establishment Number	407
Product Code	2648.00
True Name	Escherichia Coli Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bovilis J-5 - Intervet, Inc. DUNPREBAC J-5 - Duncan Labs Animal Health
Date of Compilation Summary	August 23, 2021

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy																																													
Pertaining to	<i>Escherichia coli</i>																																													
Study Purpose	Efficacy against mastitis due to <i>Escherichia coli</i>																																													
Product Administration	1 dose subcutaneously, three times, at 30 and 72 day intervals after 1 st vaccination: 18 received product (vaccinate group) and 8 received a placebo (control group).																																													
Study Animals	Pregnant Holstein heifers aged 22-30 months less than 9 weeks fresh at the time of first vaccination																																													
Challenge Description	Challenged 23 days after last vaccination																																													
Interval observed after challenge	Milk samples were taken twice daily for six and-one-half days Palpation of the udder was performed within 15 minutes after milking.																																													
Results	<p>At each milking, the right front quadrant of the udder was observed for swelling (UQ1; 0 for normal, to 3 for severe, defined as > 50% larger than normal) and texture (UQ3; 0 for normal, to 4 for dry quarter due to blockage of teat canals with cheesy/chunky milk). Dry quarters were also marked as present/absent.</p> <p>Summary of peak severity score for RF udder swelling (UQ1) :</p> <table border="1"> <thead> <tr> <th>Group</th> <th>Min</th> <th>Q1*</th> <th>Median</th> <th>Q3</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>0</td> <td>1</td> <td>2</td> <td>3</td> <td>3</td> </tr> <tr> <td>Controls</td> <td>2</td> <td>--</td> <td>3</td> <td>--</td> <td>3</td> </tr> </tbody> </table> <p>Summary of peak severity score for RF udder texture (UQ3):</p> <table border="1"> <thead> <tr> <th>Group</th> <th>Min</th> <th>Q1*</th> <th>Median</th> <th>Q3</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>0</td> <td>1</td> <td>2</td> <td>2</td> <td>2</td> </tr> <tr> <td>Controls</td> <td>2</td> <td>--</td> <td>2</td> <td>--</td> <td>4</td> </tr> </tbody> </table> <p>*Q1 and Q3 not provided for the controls due to small sample sizes</p> <p>Summary of presence/absence of RF dry quarter observed at least once.</p> <table border="1"> <thead> <tr> <th>Group</th> <th>Positive</th> <th>Negative</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>0</td> <td>18</td> </tr> <tr> <td>Controls</td> <td>3</td> <td>5</td> </tr> </tbody> </table> <p>Raw data results are found on the following pages.</p>	Group	Min	Q1*	Median	Q3	Max	Vaccinates	0	1	2	3	3	Controls	2	--	3	--	3	Group	Min	Q1*	Median	Q3	Max	Vaccinates	0	1	2	2	2	Controls	2	--	2	--	4	Group	Positive	Negative	Vaccinates	0	18	Controls	3	5
Group	Min	Q1*	Median	Q3	Max																																									
Vaccinates	0	1	2	3	3																																									
Controls	2	--	3	--	3																																									
Group	Min	Q1*	Median	Q3	Max																																									
Vaccinates	0	1	2	2	2																																									
Controls	2	--	2	--	4																																									
Group	Positive	Negative																																												
Vaccinates	0	18																																												
Controls	3	5																																												
USDA Approval Date	April 12, 2012																																													

Control Group: Right Front Udder Quadrant Milk Color (MQ1), Milk Consistency (MQ2), California Mastitis Test (MQ3), Swelling (UQ1), Color (UQ2), and Texture Score (UQ3)

Cow ID	Hours	MQ1RF	MQ2RF	MQ3RF	UQ1RF	UQ2RF	UQ3RF
63	24	1	2	3	2	0	1
63	36	1	3	3	1	0	4
63	48	1	3	3	1	0	1
63	60	1	3	2	1	0	1
63	72	0	3	3	0	0	1
63	84	0	3	1	1	0	1
63	96	0	0	1	0	0	0
63	108	0	0	1	0	0	0
63	120	0	0	1	0	0	1
63	132	0	0	0	1	0	1
63	144	0	0	0	0	0	0
63	156	0	0	0	0	0	0
78	24	0	3	3	3	0	2
78	36	1	3	3	3	0	2
78	48	1	3	3	2	0	2
78	60	1	3	3	2	0	2
78	72	1	3	3	2	0	2
78	84	1	2	2	3	0	2
78	96	0	2	2	2	0	1
78	108	0	0	2	2	0	2
78	120	0	0	1	0	0	0
78	132	0	0	2	2	0	1
78	144	0	0	1	1	0	1
78	156	0	0	1	1	0	1
89	24	1	3	3	2	2	2
89	36	1	3	3	2	0	4
89	48	1	3	3	0	0	0
89	60	1	3	3	0	0	0
89	72	1	3	3	1	0	1
89	84	1	0	2	1	0	1
89	96	0	0	2	2	0	2
89	108	0	0	1	2	0	1
89	120	0	0	1	1	0	1
89	132	0	0	1	1	0	1
89	144	0	0	0	1	0	1
89	156	0	0	1	0	0	0
93	24	1	3	3	3	0	2
93	36	1	3	3	2	0	2
93	48	1	2	3	2	1	1
93	60	1	3	2	2	0	2
93	72	0	0	1	2	0	4
93	84	1	2	2	2	0	4

93	96	1	0	2	0	0	4
93	108	1	0	1	2	0	4
93	120	0	0	4	2	0	4
93	132	1	0	1	2	0	4
93	144	1	3	2	2	0	4
93	156	1	1	1	2	0	4
105	24	1	0	2	2	0	2
105	36	1	3	3	3	0	2
105	48	1	3	3	2	0	1
105	60	1	3	2	2	0	2
105	72	1	3	3	3	0	2
105	84	1	3	2	3	0	2
105	96	1	1	2	3	0	2
105	108	1	3	2	3	0	2
105	120	1	0	2	2	0	2
105	132	1	3	2	2	0	2
105	144	1	3	2	2	0	2
105	156	1	3	2	1	0	1
109	24	1	3	3	1	0	2
109	36	1	3	3	3	0	2
109	48	1	3	3	2	0	1
109	60	1	3	2	2	0	2
109	72	1	3	3	2	0	2
109	84	1	3	2	3	0	2
109	96	1	3	2	3	0	2
109	108	1	3	2	2	0	2
109	120	1	3	2	2	0	1
109	132	0	2	2	2	0	1
109	144	0	0	2	1	0	1
109	156	0	0	2	0	0	0
122	24	1	0	3	3	0	2
122	36	1	3	3	2	2	2
122	48	1	3	3	3	0	2
122	60	1	3	3	2	0	2
122	72	1	3	2	2	0	2
122	84	1	3	2	3	0	2
122	96	1	3	2	3	0	2
122	108	0	2	2	2	0	2
122	120	0	2	2	2	0	1
122	132	0	0	1	1	0	1
122	144	0	0	2	2	0	2
122	156	0	2	2	2	0	1
152	24	1	3	3	0	0	0
152	36	1	3	3	2	0	2
152	48	1	3	3	2	1	1
152	60	1	3	3	1	0	1
152	72	0	3	2	1	0	1

152	84	1	3	3	1	0	1
152	96	0	2	2	2	0	1
152	108	0	0	1	1	0	1
152	120	0	0	1	0	0	0
152	132	0	0	1	0	0	0
152	144	0	0	0	0	0	0
152	156	0	0	1	0	0	0

Vaccinate Group: Right Front Udder Quadrant Milk Color (MQ1), Milk Consistency (MQ2), California Mastitis Test (MQ3), Swelling (UQ1), Color (UQ2), and Texture Score (UQ3)

Cow ID	Hours	MQ1RF	MQ2RF	MQ3RF	UQ1RF	UQ2RF	UQ3RF
8	24	1	3	2	3	1	2
8	36	1	3	2	3	0	2
8	48	1	3	3	2	0	2
8	60	1	3	2	2	0	1
8	72	1	3	2	2	0	2
8	84	1	2	2	2	0	1
8	96	1	3	2	1	0	1
8	108	1	3	3	2	0	1
8	120	1	3	2	0	0	0
8	132	0	0	2	2	0	2
8	144	0	0	2	2	0	2
8	156	0	0	2	1	0	2
14	24	1	2	3	2	0	2
14	36	1	3	3	2	0	2
14	48	1	3	3	1	0	2
14	60	1	3	2	1	0	1
14	72	1	2	1	1	0	2
14	84	1	2	2	0	0	0
14	96	1	3	2	1	0	1
14	108	1	3	3	1	0	1
14	120	0	3	1	1	0	2
14	132	0	0	2	0	0	1
14	144	0	0	2	0	0	1
14	156	0	0	2	0	0	0
16	24	1	2	3	1	0	1
16	36	1	3	3	1	0	2
16	48	1	3	3	0	0	1
16	60	1	3	1	0	0	1
16	72	1	3	2	0	0	0
16	84	1	3	2	0	0	1
16	96	0	0	1	0	0	0
16	108	0	2	2	0	0	0
16	120	0	2	1	0	0	0
16	132	0	0	1	0	0	0

16	144	0	0	1	0	0	0
16	156	0	0	2	0	0	0
18	24	1	2	3	3	0	2
18	36	1	3	3	2	0	1
18	48	1	3	3	1	0	1
18	60	1	3	2	1	0	1
18	72	1	3	2	0	0	0
18	84	1	3	2	0	0	1
18	96	0	0	2	0	0	0
18	108	0	0	2	0	0	0
18	120	0	2	1	0	0	0
18	132	0	0	1	0	0	0
18	144	0	0	2	0	0	0
18	156	0	0	2	0	0	0
19	24	1	3	3	2	0	2
19	36	1	3	3	0	0	0
19	48	1	3	3	1	0	1
19	60	1	3	3	0	0	0
19	72	1	3	2	0	0	0
19	84	1	3	2	0	0	1
19	96	0	0	2	0	0	1
19	108	0	0	2	0	0	1
19	120	0	0	1	0	0	1
19	132	0	0	2	0	0	0
19	144	0	0	2	0	0	0
19	156	0	0	2	0	0	0
27	24	1	3	3	1	0	1
27	36	1	3	2	1	0	1
27	48	1	3	3	0	0	1
27	60	1	3	3	0	0	0
27	72	1	3	2	0	0	0
27	84	1	3	2	0	0	0
27	96	1	3	2	0	0	0
27	108	1	2	2	0	0	0
27	120	0	0	2	0	0	0
27	132	0	0	2	0	0	0
27	144	0	0	1	0	0	0
27	156	0	0	1	0	0	0
32	24	0	0	2	0	0	0
32	36	0	0	1	0	0	0
32	48	0	0	0	0	0	0
32	60	0	0	1	0	0	0
32	72	0	0	1	0	0	0
32	84	0	0	1	0	0	0
32	96	0	0	1	0	0	0
32	108	0	0	0	0	0	0
32	120	0	0	0	0	0	0

32	132	0	0	0	0	0	0
32	144	0	0	0	0	0	0
32	156	0	0	0	0	0	0
34	24	1	2	3	2	0	2
34	36	1	3	3	1	0	2
34	48	1	3	2	0	0	1
34	60	1	3	2	0	0	1
34	72	1	3	2	1	0	1
34	84	1	3	2	0	0	1
34	96	0	0	2	1	0	1
34	108	0	2	1	0	0	0
34	120	0	0	2	0	0	0
34	132	0	0	2	1	0	1
34	144	0	w	2	1	0	2
34	156	0	0	2	1	0	1
38	24	1	2	3	0	0	0
38	36	1	3	3	0	0	0
38	48	1	2	3	0	0	0
38	60	1	3	2	0	0	0
38	72	0	0	1	0	0	0
38	84	0	0	1	0	0	0
38	96	0	0	1	0	0	0
38	108	0	0	1	0	0	0
38	120	0	0	0	0	0	0
38	132	0	0	0	0	0	0
38	144	0	0	0	0	0	0
38	156	0	0	0	0	0	0
44	24	1	3	3	2	0	1
44	36	1	3	3	1	0	1
44	48	1	2	3	1	0	1
44	60	1	3	3	1	0	1
44	72	1	3	2	1	0	2
44	84	1	3	2	0	0	1
44	96	0	2	2	0	0	0
44	108	1	2	2	0	0	0
44	120	0	0	1	0	0	0
44	132	0	0	1	0	0	0
44	144	0	0	2	0	0	1
44	156	0	0	1	0	0	0
71	24	1	2	3	3	0	2
71	36	1	3	2	2	0	2
71	48	1	3	3	1	0	1
71	60	0	3	3	1	0	1
71	72	1	3	2	0	0	1
71	84	1	0	2	0	0	1
71	96	1	0	2	1	0	1
71	108	1	2	2	0	0	1

71	120	1	3	2	1	0	1
71	132	1	3	2	2	0	1
71	144	1	3	2	2	0	2
71	156	0	0	2	0	0	0
73	24	1	3	3	3	0	2
73	36	1	3	3	2	0	2
73	48	1	0	3	1	0	2
73	60	1	3	2	1	0	2
73	72	1	3	2	0	0	1
73	84	1	2	2	1	0	1
73	96	1	3	2	0	0	1
73	108	1	3	2	0	0	0
73	120	1	2	2	0	0	0
73	132	1	3	2	0	0	0
73	144	1	3	2	0	0	0
73	156	1	3	2	0	0	0
81	24	0	3	3	2	0	1
81	36	1	3	3	0	0	0
81	48	1	3	3	0	0	0
81	60	1	3	2	0	0	0
81	72	0	3	2	0	0	0
81	84	0	0	2	1	0	1
81	96	0	0	1	0	0	0
81	108	0	0	1	0	0	0
81	120	0	0	1	0	0	1
81	132	0	0	0	0	0	0
81	144	0	0	1	0	0	0
81	156	0	0	1	0	0	0
82	24	1	0	3	3	0	2
82	36	1	3	3	2	0	1
82	48	1	3	3	2	0	1
82	60	1	3	2	0	0	0
82	72	1	3	3	0	0	0
82	84	1	3	2	0	0	0
82	96	1	0	2	0	0	1
82	108	1	3	2	0	0	0
82	120	1	2	2	0	0	1
82	132	0	0	1	0	0	0
82	144	0	0	2	0	0	0
82	156	0	0	2	0	0	0
85	24	0	0	2	0	0	0
85	36	0	3	1	0	0	0
85	48	0	0	2	0	0	0
85	60	0	0	1	0	0	0
85	72	0	0	1	0	0	0
85	84	0	0	1	0	0	0
85	96	0	0	1	0	0	0

85	108	0	0	0	0	0	0
85	120	0	0	0	0	0	0
85	132	0	0	0	0	0	0
85	144	0	0	1	0	0	0
85	156	0	0	2	0	0	0
99	24	1	3	3	0	0	0
99	36	1	3	3	1	0	1
99	48	1	3	2	0	0	0
99	60	1	2	2	0	0	0
99	72	0	3	2	0	0	0
99	84	0	2	1	0	0	0
99	96	0	2	1	0	0	0
99	108	0	0	1	0	0	0
99	120	0	0	0	0	0	0
99	132	0	0	0	0	0	0
99	144	0	0	0	0	0	0
99	156	0	0	1	0	0	0
157	24	1	0	2	0	0	0
157	36	0	3	1	2	0	2
157	48	0	3	2	0	0	0
157	60	0	3	2	0	0	0
157	72	0	0	1	0	0	0
157	84	0	0	1	1	0	1
157	96	0	0	2	0	0	0
157	108	0	0	1	0	0	0
157	120	0	0	1	0	0	0
157	132	0	0	0	0	0	0
157	144	0	0	1	0	0	0
157	156	0	0	1	0	0	0
160	24	1	3	3	2	0	2
160	36	1	3	3	1	0	1
160	48	1	0	3	1	0	1
160	60	1	3	2	1	0	1
160	72	1	0	2	0	0	1
160	84	1	0	2	3	0	2
160	96	1	3	2	2	0	2
160	108	1	3	2	2	0	2
160	120	1	3	2	0	0	1
160	132	1	3	2	2	0	1
160	144	1	3	2	0	0	1
160	156	1	3	2	0	0	0

Study Type	Safety
Pertaining to	Escherichia coli
Study Purpose	Demonstrate safety under field conditions
Product Administration	
Study Animals	Adult dairy cattle including pregnant cattle
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	September 13, 2001