



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Epitopix, LLC
USDA Vet Biologics Establishment Number	365
Product Code	27A6.00
True Name	Escherichia Coli-Salmonella Enteritidis Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vaxxon SRP E.coli-SE - No distributor specified
Date of Compilation Summary	April 11, 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>	<i>Escherichia coli</i>																																																																																																																																																																																						
<b>Study Purpose</b>	To demonstrate effectiveness against <i>Escherichia coli</i> in chickens.																																																																																																																																																																																						
<b>Product Administration</b>	Two doses administered at an 8-week interval by subcutaneous injection.																																																																																																																																																																																						
<b>Study Animals</b>	Ten week old chickens were randomly assigned to one of two treatments, vaccinates (25 birds) or placebo (25 birds).																																																																																																																																																																																						
<b>Challenge Description</b>	All chickens were challenged with <i>Escherichia coli</i> 14 days following second vaccination.																																																																																																																																																																																						
<b>Interval observed after challenge</b>	The chickens were monitored for 7 days after challenge then tissues were examined.																																																																																																																																																																																						
<b>Results</b>	<p>A chicken was considered positive for <i>E. coli</i> if mortality occurred <b>and</b> <i>E. coli</i> colonization was detected in the liver, heart, spleen, air sac, oviduct, or ovary.</p> <p><b>Summary:</b></p> <table border="1"> <thead> <tr> <th></th> <th>Vaccinates</th> <th>Controls</th> </tr> </thead> <tbody> <tr> <td>Positive for <i>E.coli</i></td> <td>0/25</td> <td>19/25</td> </tr> </tbody> </table> <p><b>Raw Data (negative samples left blank)</b></p> <table border="1"> <thead> <tr> <th>Vaccinates ID #</th> <th>Mortality</th> <th>Liver</th> <th>Heart</th> <th>Spleen</th> <th>Air Sac</th> <th>Oviduct</th> <th>Ovary</th> </tr> </thead> <tbody> <tr><td>701</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>702</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>706</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>709</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>711</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>712</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>715</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>716</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>719</td><td></td><td></td><td></td><td>+</td><td>+</td><td>+</td><td>+</td></tr> <tr><td>720</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>721</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>722</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>723</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>728</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>731</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>733</td><td></td><td></td><td></td><td></td><td>+</td><td></td><td>+</td></tr> <tr><td>735</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>736</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>738</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>739</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>741</td><td></td><td></td><td></td><td></td><td>+</td><td></td><td></td></tr> </tbody> </table>		Vaccinates	Controls	Positive for <i>E.coli</i>	0/25	19/25	Vaccinates ID #	Mortality	Liver	Heart	Spleen	Air Sac	Oviduct	Ovary	701								702								706								709								711								712								715								716								719				+	+	+	+	720								721								722								723								728								731								733					+		+	735								736								738								739								741					+		
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	703							
	704	+	+	+	+	+	+	+
	705	+	+	+	+	+	+	+
	707	+	+	+	+	+	+	+
	708							
	710	+	+	+	+	+	+	+
	713	+	+	+	+	+	+	+
	714	+	+	+	+	+	+	+
	717	+	+	+	+	+	+	+
	718	+	+	+	+	+	+	+
	724	+	+	+	+	+	+	+
	725	+	+	+	+	+	+	+
	726						+	+
	727	+	+	+	+	+	+	+
	729	+	+	+	+	+	+	+
	730	+	+	+	+	+	+	+
	732	+	+	+	+	+	+	+
	734						+	+
	737	+	+	+	+	+	+	+
	740	+	+	+	+	+	+	+
	742/398							
	744	+	+	+	+	+	+	+
	747	+	+	+	+	+	+	+
	749	+	+	+	+	+	+	+
	750						+	
<b>USDA Approval Date</b>	August 31, 2018							

<b>Study Type</b>	Efficacy																																																																																																																															
<b>Pertaining to</b>	<i>Salmonella</i> Enteritidis																																																																																																																															
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<b>Study Animals</b>	Ten week old chickens were randomly assigned to one of two treatments, vaccinates (37 birds) or placebo (36 birds).																																																																																																																															
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<b>Results</b>	<p>A chicken was considered affected if the tissue had a bacterial count of <i>Salmonella</i> Enteritidis &gt; 0.</p> <p><b>Summary</b></p> <table border="1"> <thead> <tr> <th>Samples</th> <th>Positive Vaccinates*</th> <th>Positive Controls</th> </tr> </thead> <tbody> <tr> <td>Oviduct/Ovary</td> <td>3/36</td> <td>10/35</td> </tr> <tr> <td>Liver/Spleen</td> <td>2/36</td> <td>4/36</td> </tr> <tr> <td>Cecal Junction</td> <td>7/36</td> <td>16/35</td> </tr> <tr> <td>Any Tissue</td> <td>9/36</td> <td>20/36</td> </tr> </tbody> </table> <p>*One bird died after vaccination and prior to challenge</p> <p><b>Raw Data</b></p> <p><i>Salmonella</i> Enteritidis Culture Data of Individual Tissues (negatives left blank)</p> <table border="1"> <thead> <tr> <th>Vaccinates</th> <th>Chicken ID #</th> <th>Liver</th> <th>Spleen</th> <th>Oviduct</th> <th>Ovary</th> <th>Cecal Junction</th> </tr> </thead> <tbody> <tr><td></td><td>501</td><td></td><td></td><td></td><td></td><td>+</td></tr> <tr><td></td><td>502</td><td></td><td></td><td></td><td></td><td>+</td></tr> <tr><td></td><td>503</td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td>505</td><td>+</td><td></td><td></td><td></td><td>+</td></tr> <tr><td></td><td>506</td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td>508</td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td>509</td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td>511</td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td>513</td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td>515</td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td>517</td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td>524</td><td></td><td></td><td></td><td></td><td>+</td></tr> <tr><td></td><td>530</td><td></td><td></td><td></td><td></td><td>+</td></tr> <tr><td></td><td>531</td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td>532</td><td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table>	Samples	Positive Vaccinates*	Positive Controls	Oviduct/Ovary	3/36	10/35	Liver/Spleen	2/36	4/36	Cecal Junction	7/36	16/35	Any Tissue	9/36	20/36	Vaccinates	Chicken ID #	Liver	Spleen	Oviduct	Ovary	Cecal Junction		501					+		502					+		503							505	+				+		506							508							509							511							513							515							517							524					+		530					+		531							532					
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		557					
		558					
		559					
		560					
		565					+
		566					
		567/568	+		+		+
		570					
	<b>Controls</b>	<b>Chicken ID #</b>	<b>Liver</b>	<b>Spleen</b>	<b>Oviduct</b>	<b>Ovary</b>	<b>Cecal Junction</b>
		504			+		+
		510					+
		512					
		514					
		516					
		518					+
		519					+
		520					
		521					
		522			+		+
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		525					+
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	544					+
	546			+		+
	547		+	+	+	
	549					
	550					
	553			+	+	+
	561					
	562			+	+	
	563					
	564					+
	569					
	571	+		+	+	+
	572					
	573					
	574					
<b>USDA Approval Date</b>	April 12, 2019					

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	To demonstrate safety of the product under field conditions.
<b>Product Administration</b>	Two doses administered at an 8 to 10-week interval by a subcutaneous route of injection.
<b>Study Animals</b>	A total of 103,404 chickens were enrolled in the study and housed at commercial egg or layer operations in three geographically distinct regions of the United States. The chickens were vaccinated with a test vaccine (Serial 1 or Serial 2) or left as non-vaccinated controls. Birds ranged in age from 9 weeks to 12 weeks at first vaccination.
<b>Challenge Description</b>	Not applicable
<b>Interval observed after challenge</b>	Chickens were observed for adverse events and mortality for 21 days after each of two vaccinations given 5 weeks apart.
<b>Results</b>	No adverse events were observed in any chickens after vaccination. See summary table by region below.
<b>USDA Approval Date</b>	February 22, 2021

**Tables show the number of mortality of chickens at each site after each vaccination.**

Region 1

Treatment	Starting Population	21-day Mortality	Mortality Rate (%)
<b>1<sup>st</sup> Vaccination</b>			
Control	15,287	16	0.10
Vaccine Serial 1	15,288	7	0.05
Vaccine Serial 2	15,288	6	0.04
<b>2<sup>nd</sup> Vaccination</b>			
Control	15,251	24	0.16
Vaccine Serial 1	15,251	22	0.14
Vaccine Serial 2	15,255	26	0.17

Region 2

Treatment	Starting Population	21-day Mortality	Mortality Rate (%)
<b>1<sup>st</sup> Vaccination</b>			
Control	19,365	47	0.24
Vaccine Serial 1	10,880	42	0.39
<b>2<sup>nd</sup> Vaccination</b>			
Control	19,280	63	0.33
Vaccine Serial 1	10,474	31	0.30

Region 3

Treatment	Starting Population	21-day Mortality	Mortality Rate (%)
<b>1<sup>st</sup> Vaccination</b>			
Control	13,648	14	0.10
Vaccine Serial 2	13,648	12	0.09
<b>2<sup>nd</sup> Vaccination</b>			
Control	13,627	3	0.02
Vaccine Serial 2	13,629	4	0.03