



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1785.12
True Name	Newcastle-Bronchitis Vaccine, Mass & Ark Types, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Gallimune NC-BR - No distributor specified
Date of Compilation Summary	May 17, 2019

**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>	Infectious bronchitis virus, Arkansas type
<b>Study Purpose</b>	Demonstrate efficacy against infectious bronchitis virus, Arkansas type
<b>Product Administration</b>	Intramuscularly (IM)
<b>Study Animals</b>	Chickens
<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>	January 21, 2005

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious bronchitis virus, Massachusetts type
<b>Study Purpose</b>	Demonstrate efficacy against infectious bronchitis virus, Massachusetts type
<b>Product Administration</b>	Intramuscularly (IM)
<b>Study Animals</b>	Chickens
<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>	January 21, 2005

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious bronchitis virus, Massachusetts type
<b>Study Purpose</b>	Demonstrate efficacy against infectious bronchitis virus, Massachusetts type vaccine
<b>Product Administration</b>	One dose intramuscularly (IM) on study Day 21
<b>Study Animals</b>	<p>Twelve-week-old SPF chicks; 24-25 per group; Group 9 was primed at 9 weeks of age on study Day 0 with a live IBV Mass vaccine.</p> <p>Group 7: No priming; No vaccine; IBV Mass challenge  Group 9: Primed; Vaccinated; IBV Mass challenge  Group 13: No priming; No vaccine; no challenge</p>
<b>Challenge Description</b>	Infectious bronchitis, Mass type on study Day 42
<b>Interval observed after challenge</b>	Five days post challenge, the tracheas were harvested for tracheal ring evaluation and virus re-isolation of the strains used for the challenge.
<b>Results</b>	<p><b><u>Tracheal ring scores:</u></b> A bird was considered affected if less than 50% of a tracheal ring section had discernible ciliary activity in any of three samples (representing the upper third, middle third, and lower third of the trachea). Each bird received a score from 0-3 depending on how many sections were affected.</p> <p>Number of affected birds:  Group 7: 25/25 (unvaccinated control)  Group 9: 0/25  Group 13: 0/25 (non-challenged control)</p> <p><b><u>Virus Isolation:</u></b> A bird was considered affected if any embryos died after each tracheal swab was used to inoculate 5 embryonated eggs. Each bird received a score from 0-5 based on the number of embryos that died.</p> <p>Number of affected birds:  Group 7: 25/25 (unvaccinated control)  Group 9: 3/25  Group 13: 0/25 (non-challenged control)</p> <p>Raw data on attached page.</p>
<b>USDA Approval Date</b>	June 3, 2008

**Tracheal Ring Scores – Raw data**

Tracheal Score, individual Results

Three 2 mm wide tracheal rings representing the upper third, middle third and lower third of the trachea of each bird were examined for ciliary activity. Tracheal ring sections were considered positive if less than 50% of the ring had discernible ciliary activity. Each bird received a score of 0, 1, 2, or 3 depending on how many sections were positive. A score of zero indicated that all sections were negative. A score of three indicated that all sections were positive. A score  $\geq 1$  is considered affected.

Group	vaccine	challenge	Unit	ID	Score
7	None	MASS	7	381	3
				382	3
				383	3
				384	3
				385	3
				386	3
				387	3
				388	3
				389	3
				390	3
				391	3
				392	3
				393	3
			8	394	3
				395	3
				396	3
				397	3
				398	3
				399	3
				400	3
				401	3
9	Vaccine	MASS	3	331	0
				332	0
				333	0
				334	0
				335	0
				336	0
				337	0
				338	0
339	0				
				340	0

Group	vaccine	challenge	Unit	ID	Score
				341	0
				342	0
				343	0
			4	344	0
				345	0
				346	0
				347	0
				348	0
				349	0
				350	0
				351	0
				352	0
				353	0
				354	0
				355	0
13	None	N/A	1	306	0
				307	0
				308	0
				309	0
				310	0
				311	0
				312	0
				313	0
				314	0
				315	0
				316	0
				317	0
				318	0
			2	319	0
				320	0
				321	0
				322	0
				323	0
				324	0
				325	0
				326	0
				327	0
				328	0
				329	0
				330	0

MASS = Infectious bronchitis virus, Massachusetts type  
N/A = Not applicable

**Virus Isolation (VI) – Raw data**

VI Score, individual results

Each tracheal swab was used to inoculate 5 embryonated eggs. Each bird received a score of 0, 1, 2, 3, 4 or 5 depending on how many embryos died. A score of zero indicated that none of the embryos died and a score of 5 indicated that all five of the embryos died. A score  $\geq 1$  is considered affected.

Group	vaccine	challenge	Unit	ID	Score			
7	None	MASS	7	381	5			
				382	4			
				383	5			
				384	5			
				385	5			
				386	4			
				387	3			
				388	3			
				389	5			
				390	4			
				391	3			
				392	3			
				393	3			
			8				394	5
							395	5
							396	2
							397	5
							398	4
							399	4
							400	4
401	5							
402	4							
403	5							
404	5							
405	5							
9	Vaccine	MASS	3	331	4			
				332	0			
				333	0			
				334	2			
				335	0			
				336	0			
				337	0			
				338	0			
				339	0			
				340	0			
				341	0			

Group	vaccine	challenge	Unit	ID	Score
				342	0
				343	0
			4	344	0
				345	0
				346	0
				347	0
				348	0
				349	3
				350	0
				351	0
				352	0
				353	0
				354	0
				355	0
				507	0
				508	0
				509	0
				510	0
				511	0
				512	0
				513	0
				514	0
				515	0
				516	0
				518	0
			24	519	0
				520	0
				521	0
				522	0
				523	0
				524	0
				525	0
				526	0
				527	0
				528	0
				529	0
				530	0
13	None	N/A	1	306	0
				307	0
				308	0
				309	0
				310	0
				311	0
				312	0
				313	0
				314	0
				315	0
				316	0



Group	vaccine	challenge	Unit	ID	Score
				317	0
				318	0
			2	319	0
				320	0
				321	0
				322	0
				323	0
				324	0
				325	0
				326	0
				327	0
				328	0
				329	0
				330	0

MASS = Infectious bronchitis virus, Massachusetts type  
N/A = Not applicable

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious bronchitis virus, Arkansas type
<b>Study Purpose</b>	Demonstrate efficacy against infectious bronchitis virus, Arkansas type
<b>Product Administration</b>	One dose intramuscularly (IM) on study Day 21
<b>Study Animals</b>	<p>Twelve-week-old SPF chicks; 23-25 per group; Group 3 primed at 9 weeks of age on study Day 0 with a live IBV Ark vaccine,</p> <p>Group 1: No priming; No vaccine; IBV Ark challenge  Group 3: Primed; Vaccinated ; IBV Ark challenge  Group 13: No priming; No vaccine; no challenge</p>
<b>Challenge Description</b>	Infectious bronchitis, Ark type on study Day 42
<b>Interval observed after challenge</b>	Five days post challenge, the tracheas were harvested for tracheal ring evaluation and virus re-isolation of the strains used for the challenge.
<b>Results</b>	<p><b><u>Tracheal ring scores:</u></b> A bird was considered affected if less than 50% of a tracheal ring section had discernible ciliary activity in any of three samples (representing the upper third, middle third, and lower third of the trachea). Each bird received a score from 0-3 depending on how many sections were affected.</p> <p>Number of affected birds:  Group 1: 25/25 (unvaccinated control)  Group 3: 1/24  Group 13: 0/25 (non-challenged control)</p> <p><b><u>Virus Isolation:</u></b> A bird was considered affected if any embryos died after each tracheal swab was used to inoculate 5 embryonated eggs. Each bird received a score from 0-5 based on the number of embryos that died.</p> <p>Number of affected birds:  Group 1: 25/25 (unvaccinated control)  Group 3: 3/24  Group 13: 0/25 (non-challenged control)</p> <p>Raw data on attached page.</p>
<b>USDA Approval Date</b>	June 3, 2008

## Tracheal Ring Scores – Raw data

### Tracheal Score, individual Results

Three 2 mm wide tracheal rings representing the upper third, middle third and lower third of the trachea of each bird were examined for ciliary activity. Tracheal ring sections were considered positive if less than 50% of the ring had discernible ciliary activity. Each bird received a score of 0, 1, 2, or 3 depending on how many sections were positive. A score of zero indicated that all sections were negative. A score of three indicated that all sections were positive. A score  $\geq 1$  is considered affected.

Group	vaccine	challenge	Unit	ID	Score
1	None	Ark	11	431	3
				432	3
				433	3
				434	2
				435	3
				436	3
				437	2
				438	3
				439	3
				440	3
				441	2
			12	442	3
				443	3
				444	3
				445	3
				446	3
				447	2
				448	3
				449	3
				450	3
				451	3
				452	3
				453	3
				454	2
				455	3
3	Vaccine	Ark	5	356	0
				357	0
				358	0
				359	0
				360	0
				361	0
				362	0
				363	0
				365	0
				366	0
				367	0

Group	vaccine	challenge	Unit	ID	Score
			6	368	0
				369	0
				370	0
				371	1
				372	0
				373	0
				374	0
				375	0
				376	0
				377	0
				378	0
				379	0
				380	0
13	None	N/A	1	306	0
				307	0
				308	0
				309	0
				310	0
				311	0
				312	0
				313	0
				314	0
				315	0
			2	316	0
				317	0
				318	0
				319	0
				320	0
				321	0
				322	0
				323	0
				324	0
				325	0
326	0				
327	0				
328	0				
329	0				
330	0				

Ark = Infectious bronchitis virus, Arkansas type  
N/A = Not applicable

**Virus Isolation (VI) – Raw data**

VI Score, individual results

Each tracheal swab was used to inoculate 5 embryonated eggs. Each bird received a score of 0, 1, 2, 3, 4 or 5 depending on how many embryos died. A score of zero indicated that none of the embryos died and a score of 5 indicated that all five of the embryos died. A score  $\geq 1$  is considered affected.

Group	vaccine	challenge	Unit	ID	Score
1	None	Ark	11	431	5
				432	5
				433	5
				434	5
				435	5
				436	5
				437	5
				438	4
				439	5
				440	4
			441	5	
			442	5	
			443	5	
			12	444	5
				445	5
				446	5
				447	5
				448	5
				449	5
				450	5
451	5				
452	4				
453	5				
454	5				
455	4				
3	Vaccine	Ark	5	356	0
				357	0
				358	0
				359	0
				360	0
				361	0
				362	0
				363	0
				365	0
				366	0
			367	0	
			368	0	
			6	369	0
				370	0

Group	vaccine	challenge	Unit	ID	Score
				371	0
				372	1
				373	1
				374	1
				375	0
				376	0
				377	0
				378	0
				379	0
				380	0
13	None	N/A	1	306	0
				307	0
				308	0
				309	0
				310	0
				311	0
				312	0
				313	0
				314	0
				315	0
				316	0
				317	0
				318	0
			2	319	0
				320	0
				321	0
				322	0
				323	0
				324	0
				325	0
				326	0
				327	0
				328	0
				329	0
				330	0

Ark = Infectious bronchitis virus, Arkansas type  
N/A = Not applicable

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Newcastle disease
<b>Study Purpose</b>	Demonstrate efficacy against Newcastle disease
<b>Product Administration</b>	Intramuscularly (IM)
<b>Study Animals</b>	Chickens
<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>	January 21, 2005

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety under field conditions
<b>Product Administration</b>	Intramuscularly (IM)
<b>Study Animals</b>	Chickens
<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>	February 14, 2005