



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Addison Biological Laboratory, Inc.
USDA Vet Biologics Establishment Number	355
Product Code	2772.00
True Name	Moraxella Bovis Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	I-Site XP - Agri Laboratories, Ltd. Maxiguard - No distributor specified
Date of Compilation Summary	July 17, 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>Moraxella bovis</i> , Bovine
<b>Study Purpose</b>	To demonstrate efficacy against <i>Moraxella bovis</i>
<b>Product Administration</b>	
<b>Study Animals</b>	
<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>	July 15,1993

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Moraxella bovis</i> , Bovine
<b>Study Purpose</b>	To demonstrate efficacy against <i>Moraxella bovis</i>
<b>Product Administration</b>	Calves vaccinated at eight weeks of age.
<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>	July 20, 1994

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Moraxella bovis</i>
<b>Study Purpose</b>	To demonstrate duration of immunity for 120 days following a single dose administration.
<b>Product Administration</b>	
<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>	August 26, 2004

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety of vaccine under typical field use conditions
<b>Product Administration</b>	
<b>Study Animals</b>	
<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>	October 28, 1993

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety of vaccine under typical field use conditions
<b>Product Administration</b>	
<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>	September 10, 1997