



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Brinton Laboratories Inc.
USDA Vet Biologics Establishment Number	343
Product Code	17E1.20
True Name	Hemorrhagic Enteritis Vaccine, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	PROTECT HE - No distributor specified
Date of Compilation Summary	December 08, 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	Hemorrhagic Enteritis Virus
Study Purpose	Demonstrate efficacy against Hemorrhagic Enteritis
Product Administration	Drinking Water
Study Animals	Turkey
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	May 02, 1991

Study Type	Safety
Pertaining to	Hemorrhagic Enteritis Virus Vaccine, Live Virus
Study Purpose	Safety under typical field conditions
Product Administration	Drinking Water
Study Animals	Turkey
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	May 12, 1992