

## **Certificate of Analysis for NR-453**

## Porcine Transmissible Gastroenteritis Virus (TGEV), Miller, Chemically Inactivated

Catalog No. NR-453

**Product Description:** Cell lysate and supernatant from swine testicular (ST) cells infected with the Miller strain of porcine TGEV. The suspension of cell lysate and supernatant was treated with binary ethyleneimine to inactivate the virus.

Lot: 4462789 Manufacturing Date: 07JAN2005

| TEST   | SPECIFICATIONS  | RESULTS   |
|--|---|---|
| Plaque Reduction Assay <sup>1</sup> on ST Cells  | Report results  | < 10 plaque forming units/mL  |
| Cell Culture Immunofluorescence Assay <sup>2</sup> on ST Cells   | Report results  | < 10 fluorescent focus units/mL   |
| Antigen-Capture ELISA <sup>3</sup>   | Report results  | 320   |
| Sterility (21-day incubation) Harpo's HTYE broth <sup>4</sup> , 37°C and 26°C, aerobic Trypticase soy broth, 37°C and 26°C, aerobic Sabouraud broth, 37°C and 26°C, aerobic Sheep blood agar, 37°C, aerobic Sheep blood agar, 37°C, anaerobic Thioglycollate broth, 37°C, anaerobic DMEM with 10% FBS, 37°C and 5% CO <sub>2</sub> | No growth | No growth |
| Mycoplasma Contamination  Agar and broth culture (14-day incubation at 37°C)  DNA Detection by PCR of Test Article nucleic acid  | None detected<br>None detected  | None detected<br>None detected  |

<sup>&</sup>lt;sup>1</sup>Bohl, E. H., R. K. P. Gupta, M. V. F. Olquin, and L. J. Saif. "Antibody Responses in Serum, Colostrum, and Milk of Swine after Infection or Vaccination with Transmissible Gastroenteritis Virus." <u>Infect. Immun.</u> 6 (1972): 289–301. PubMed: 4629259.

**Date:** 24 JUL 2006 **Signature:** Signature on File

**Title:** Technical Manager, BEI Authentication

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<sup>&</sup>lt;sup>2</sup>Welch, S. K. and L. J. Saif. "Monoclonal Antibodies to a Virulent Strain of Transmissible Gastroenteritis Virus: Comparison of Reactivity with Virulent and Attenuated Virus." <u>Arch. Virol.</u> 101 (1988): 221–235. PubMed: 2845894.

<sup>&</sup>lt;sup>3</sup>Titer is expressed as the reciprocal of the highest dilution that resulted in a mean absorbance greater than the mean absorbance of the mock-infected control plus three standard deviations. See, Sestak, K., Z. Zhou, D. I. Shoup, and L. J. Saif. "Evaluation of the Baculovirus-Expressed S Glycoprotein of Transmissible Gastroenteritis Virus (TGEV) as Antigen in a Competition ELISA to Differentiate Porcine Respiratory Coronavirus from TGEV Antibodies in Pigs." J. Vet. Diagn. Invest. 11 (1999): 205–214. PubMed: 10353350.

<sup>&</sup>lt;sup>4</sup>Atlas, Ronald M. <u>Handbook of Microbiological Media</u>. 3rd ed. Ed. Lawrence C. Parks. Boca Raton: CRC Press, 2004, p. 798.