

AVMA



American Veterinary Medical Association

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Dr. Richard E. Hill, Director  
USDA APHIS Center for Veterinary Biologics  
Animal and Plant Health Inspection Service  
510 South 17<sup>th</sup> Street, Suite 104  
Ames, IA 50010

**Re: Draft No. 352 - Conversion Formulas for S/P Ratio to Titer in  
Diagnostic Test Kit Inserts**

Dear Dr. Hill:

I am writing on behalf of the American Veterinary Medical Association (AVMA), established in 1863 and the largest veterinary medical association in the world. As a not-for-profit association established to advance the science and art of veterinary medicine, the AVMA is the recognized national voice for the veterinary profession. The association's more than 76,000 members comprise approximately 86% of U.S. veterinarians, all of whom are involved in a myriad of areas of veterinary medical practice including private, corporate, academic, industrial, governmental, military, and public health services.

I am responding to the draft Center for Veterinary Biologics guidance for relating the response obtained in an ELISA immunodiagnostic kit to a titer. The AVMA supports regulatory guidance that helps to establish a clear basis for the clinical and diagnostic interpretation of reported sample-to-positive (S/P) ratios. Such information would be useful to veterinarians.

We appreciate the opportunity to offer comments on this important initiative.

Sincerely,

Lyle Vogel, DVM, MPH  
Assistant Executive Vice President  
American Veterinary Medical Association